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The Process of Scaling an Early Childhood Development Parenting Programme by Integrating into Primary Health Care Services in Bangladesh

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**The Process of Scaling an Early Childhood Development Parenting
Programme by Integrating into Primary Health Care Services in Bangladesh**

**A Thesis submitted in fulfilment of the requirement
for the Degree of Doctor of Philosophy
of the Bangor University, Wales, UK**

**By
Syeda Fardina Mehrin
2022**

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Author Contribution

I drafted the outline of the introduction and discussion chapter of the thesis and developed the theoretical framework with the help of my supervisor. I worked out almost all of the technical details of the thesis and compiled the individual chapters, tables, figures, and appendix. I performed the literature review. I developed the dissertation under the close guidance of my supervisor.

In all three projects, I contributed to the implementation of the research, adapting the curriculum according to the local context, coordinating field activities, imparting training and was involved in planning and supervising the research work. I was responsible for overall project administration. I was involved with data curation and analysis in the pilot paper. I drafted the original manuscripts under the guidance of the corresponding author. All authors reviewed and provided critical feedback and helped shape the research and manuscripts.

List of Acronyms

AHI	Assistant Health Inspector
ASQ	Ages and Stages Questionnaire
BMI	Body Mass Index
BRAC	Bangladesh Rural Advancement Committee
BSID III	Bayley Scales of Infant and Toddler Development III
CDA	Child Development agent
CES-D	Centre for Epidemiological Studies Depression
CC	Community Clinic
CDA	Child Development Agent
CDI	Communication Development Inventory
CI	Confidence Interval
CHN	Community Health Nurse
CHCP	Community Health Care Providers
CHP	Community Health Provider
CHW	Community Health Workers
CRCT	Cluster Randomized Controlled Trial
DDFP	Deputy Director of Family Planning
DGHS	Directorate General of Health Service
DGFP	Directorate of Health and Family Planning
DQ	Development Quotient
ES	Effect Size
ECCD	Early Childhood Care and Development
EN	Enhanced Nutrition
ECD	Early Childhood Development
FCI	Family Care Indicator
FGD	Focus Group Discussion
FHS	Family Health Strategy
FPC	Family Planning Commission
FPI	Family Planning Inspector

FWA	Family Welfare Assistant
ICDDR,B	International Centre for Diarrhoeal Disease Research, Bangladesh
ICDP	The International Child Development Program
IDA	Iron Deficient Anaemia
IQ	Intelligence Quotient
GCC	Grand Challenges Canada
GNP	Gross National Product
GDP	Gross Domestic Product
HA	Health Assistant
HAZ	Height for Age
HI	Health Inspector
HOME	Home Observation for Measurement of Environment
HAS	Health Surveillance Worker
HW	Health Worker
LBW	Low Birth Weight
MDI	Mental Development Index
MIS	Management Information System
MoHFA	Ministry of Health and Family Welfare
MoHWCA	Ministry of Women and Children Affair
MoPME	Ministry of Primary and Mass Education
MT	Mother Training
MUAC	Mid Upper Arm Circumference
NNS	National Nutrition Service
NANI	Neither Anaemic nor IDA
NCF	Nurturing Care Framework
NBW	Normal Birth Weight
NGO	Non-Government Organizations
PHC	Primary Health Care
NMT	No Mother Training
NNP	National Nutrition Programme

OR	Odds Ratio
PDI	Psychomotor Development Index
PL	Play Leader
PEM	Protein Energy Malnutrition
PPE	Pre-Primary Education
PS	Psychosocial Stimulation
RCT	Randomised Controlled Trial
RuL	Reach up & Learn
RS	Responsive Stimulation
SD	Standard Deviation
SDQ	Strengths and Difficulties Questionnaire
SDG	Sustainable Development Goal
SES	Socio-Economic Status
SWAP	Safe Water and Aids Project
UK	United Kingdom
USA	United States of America
UCT	Unconditional Cash Transfer
UH&FPO	Upazila Health and Family Planning Officer
UFPO	Upazila Family Planning Officer
UNICEF	United Nation's International Children Emergency Fund
WAZ	Weight for Age
WHO	World Health Organisation
WHZ	Weight for Height

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Abstract

Background

Globally, over 250 million children under five years of age do not reach their developmental potential with long-term negative consequences on children's educational and economic attainment, health and well-being. Efficacy trials, across many low- and middle-income countries, have shown that early childhood parenting interventions that support parents to provide a stimulating and responsive caregiving environment are effective in improving children's development. The challenge is to implement these parenting interventions on a larger scale by integrating into existing government services.

Methods

The body of work presented in this thesis includes three studies that report on the progress in scaling an early childhood parenting intervention through the government primary health care services in rural Bangladesh. The first study involved conducting formative research and feasibility studies to adapt an early childhood home-visiting programme, based on the Reach-Up and Learn Jamaican home-visiting intervention, to a group-based parenting programme suitable for integration into the primary health care services in rural Bangladesh with delivery by existing government health staff. This was followed by an effectiveness trial in forty community clinics (with 785 mother/child dyads) to test the effect of this integrated intervention on child development and behaviour and on mothers' child-rearing knowledge, home stimulation and depressive symptoms. In this effectiveness trial, the intervention was implemented by fifty-six government health staff working in community clinics with training and supervision provided by the research team. The third study was another randomised trial to investigate the feasibility and effectiveness of using government health inspectors to train and supervise the health staff. In this

study, sixteen health inspectors trained and supervised fifty-nine government health workers to implement the intervention over a six-month period to a total of 576 mother/child dyads.

Results

We developed a group-based early childhood parenting intervention that was acceptable and feasible for use by government health staff as part of their routine duties. In the effectiveness trial, health staff implemented the intervention for one year and mother/child dyads attended in groups of four on a fortnightly basis. We report significant benefits to child development using the Bayley scales including benefits to child cognition (Effect size = 0.85 SD), language (effect size = 0.69 SD), and motor development (effect size = 0.52 SD) and benefits to child behaviour during the test (with effect sizes ranging from 0.36 SD to 0.53SD). We also found significant benefits to mothers' child-rearing knowledge (effect size=1.27 SD), quality of stimulation in the home (effect size=0.77 SD) and maternal depressive symptoms (effect size = -0.18 SD). Benefits to mothers' child-rearing knowledge and home stimulation mediated the effect of intervention on child outcomes. In the second trial, we found that government health inspectors were willing and competent in training the clinic health staff, most health staff (34/59 (78%)) conducted the majority of the parenting sessions, sessions were conducted with adequate levels of quality, mothers' attendance was high with an attendance rate of 86%, and we found benefits to home stimulation (effect size = 0.53 SD). There were also some implementation challenges with the main challenge being the low levels of field supervision by government inspectors.

Conclusion

Integrating a group-based, early childhood parenting intervention into the government primary health care services in rural Bangladesh is a promising approach for extending the reach of evidence-based parenting programmes.

CHAPTER: ONE

1. Introduction

1.1: Early Childhood Development Program: Context and Impact Evaluation

The early years of life are the foundational period for future development, and in the first five years, the human brain is sensitive to exposure to negative environmental factors and poor nurturing care causing long-term negative effects on children's development (Britto et al., 2017). Over 250 million children from low and middle-income countries are not reaching their full developmental potential due to poverty, malnutrition, and lack of learning opportunities (Black et al., 2017). A meta-analysis including data from 99,223 children aged 3 to 4 years old in 35 low and middle-income countries over 10 years reported a global prevalence of low cognitive score of 32.9% (95% Confidence Interval (CI) 19.7% 46.3%) (McCoy et al., 2016). The highest prevalence of low score was in Sub-Saharan Africa (43.8%; 95% CI 30.5%, 57.2%) and South Asia (37.7%; 95% CI 24.3%, 51.1%). The lowest prevalence was in the Latin America /Caribbean region (18.7%; 95% CI 5.9%, 32.1%) and the North Africa/Middle East/Central Asia region (18.4%, 95% CI 6.3%, 31.8%). Early childhood development is a global priority area and is included in the UN sustainable goals (SDGs). These SDGs include a target for ensuring access to quality early childhood development with proper care and pre-primary education for all children aged 0-8 years old. Despite growing attention to promoting young children's development in low and-middle income countries, the progress is still limited. For example, more than 50% of the children aged 3-6 years around the world are still not enrolled in pre-primary education (Shawar et al., 2017).

Intervention in the first few years of a child's life can bring about a substantial, positive impact over the entire life course and may transform livelihood trajectories in adulthood (Chan et al., 2017). The Lancet series on Early Childhood Development: from 'Science to Scale' emphasizes the importance of generating evidence in support of early childhood development programs in order to draw policy makers' attention to scaling up and establishing a sustainable infrastructure to reach all children living in poverty or low resource settings (Black et al., 2017; Britto et al., 2017; Richter et al., 2017).

Parents and caregivers play a vital role in ensuring a nurturing environment with proper nutrition, health care, and responsive parenting. Positive parenting practice and responsive parent-child interaction are crucial to promote a child's full developmental potential (Britto et al., 2017). Supporting parents to provide nurturing care requires a model that is feasible, accessible, low-cost, and may be replicable in different socio-cultural contexts (Daelmans et al., 2017).

Many early childhood intervention studies have been conducted in different low and middle-income countries. Most studies report the significant benefits of parenting interventions on children's development outcomes for children below 5 years of age (Zhang, et al, 2021); in some studies, the intervention also benefitted the child behaviour (Jeong et al., 2021). In addition, parenting interventions have a beneficial effect on parental outcomes, including improved quality of stimulation at home, increased maternal knowledge of child-rearing practice, and increased quality of mother-child interaction (Jeong et al., 2021).

1.2: Longer-Term Effects of Early Childhood Parenting Interventions:

A systematic review by Jeong et al. (2021)) reported on follow-up studies from early childhood parenting interventions. These were defined as short-term (1-3 years after intervention), medium-

term (4-9 years) and long term (10+ years) follow-up; and assessed children's intelligence, academic functioning, behaviour, and mental wellbeing (Jeong et al., 2021). Four trials assessed short term effects. All short-term studies found short-term effects on at least one of child development domains (that is, cognition, language, motor skills, socio-emotional skills); however, there were fewer benefits to parental outcomes including mother-child interaction, home stimulation and maternal knowledge (Jeong et al., 2021). Only one study showed sustained effect in mother-child interaction and parenting knowledge two years after the intervention. The medium term follow-up studies reported sustained program benefits on intelligence, executive functioning and behaviour (Jeong et al., 2021). The long-term effect of the intervention in adolescents and adulthood had only been assessed in Jamaica and the studies found sustained benefit in intelligence, educational attainment, behaviour and mental health (Jeong et al., 2021).

In addition, the long-term follow-up of the Jamaican study reported a 25% increase in earnings of intervened children in adulthood (at 22 years of age) compared to the control group (Gertler et al., 2014). The participants were again followed up at the age of 31 years, and the study found 43% higher hourly wages and 37% higher in earning compared to the control group. This is a substantial increase than 22 years of age (Gertler et al., 2021). The systematic review of follow up studies highlighted that, the sustainable impact of intervention depends on the magnitude of the benefit immediately after the intervention. The longer-term return of the intervention is stronger when the immediate effect is higher (Jeong et al., 2021).

1.3: Importance of Assessing Intervention Effect Over Time:

Early stimulation is proven to be influential in improving the development of children and high quality programmes have the potential for persistent impacts on intelligence, behaviour and,

academic attainment in later years of life (Walker et al., 2011). Therefore, it is worth investing in early childhood development programs to promote better livelihood over the entire life course (Richter et al., 2017). The burden of poor development of children has a detrimental effect on a country's economic growth, increasing inequality in accessing human rights and basic facilities. The effect may persist in subsequent generations and cumulatively increases loss in human capital resulting from the poverty cycle, poor health and malnutrition that exists over the generations (Lo et al., 2016). Therefore, investing in designing a pragmatic and functional early intervention model is crucial in saving human capital and productivity by promoting the well-being of the children during the entire life course.

1.4: Implementation Aspects of ECD Intervention:

An effective early childhood development intervention model requires an appropriate delivery strategy, including appropriate intervention content and duration, skilled delivery agents, effective training methodology and a structured monitoring system are needed to be considered to implement a successful ECD program.

Type of intervention:

Four types of intervention delivery strategies have predominantly been reported in the literature:

- Home visits
- Community group sessions
- Combined approach of home visiting and group sessions
- Sessions in clinic settings

Home visiting session:

Among the existing literature, most of the studies report on interventions delivered through home visiting. Home visiting programs focus on providing face-to-face learning during home visiting sessions to promote mothers' responsive parenting and increase the quality of stimulation in the home. Most of the studies found benefits of home visiting intervention on the children's cognitive and language development (Jeong et al., 2021).

Group session

A growing number of studies report on interventions that delivered sessions to groups of mothers and children. Group sessions may be more feasible at scale may be more cost-effective, and less labour-intensive. Group sessions may also promote community acceptance of the intervention, promote peer learning opportunities and provide opportunities for social support. Group sessions have also been found to be effective in improving the developmental outcome of young children and parental outcomes (Jeong et al., 2021; Yousafzai & Aboud, 2014).

The combined approach of home visiting and group sessions:

Other studies used a combined method of home visiting and group sessions. The combined approach combines the benefits of individual support through home visiting with the group support through group sessions with other parents. Studies used the combined delivery model (individual and group) found positive effect on all developmental outcomes (Jeong et al., 2021; Yousafzai & Aboud, 2014).

Clinic studies

A few studies have used clinic-based intervention delivery strategies where psychosocial stimulation is integrated into the existing health infrastructure. In this delivery model, the health professionals deliver ECD sessions as part of their health service. Studies investigating this approach have also have beneficial impact of the intervention on children's some of the developmental domain or parental outcomes (Chang et al., 2015; Yousafzai & Aboud, 2014).

Intervention Content:

The key principle of ECD intervention is encouraging parental involvement in promoting child health, nutrition, cognitive, language, motor, and socio-emotional development and behaviour. Mother- child interaction and responsive parenting are given priority in ECD interventions and the content is delivered using behaviour change techniques. In general, the ECD interventions include introducing caregivers to developmentally appropriate activities using low-cost materials and/or materials that are available in the home. Different curricula are used with the most common being Reach up & Learn and Care for Child Development. The Jamaican home visiting intervention now called Reach up & Learn is a widely used evidence-based intervention that has been proven to be effective in improving child cognitive, language and motor development of children across different countries and contexts (Grantham-McGregor & Smith, 2016). The curriculum was developed by Prof. Sally Grantham-McGregor (Grantham-McGregor & Desai, 1975) and has been adapted for different socio-cultural contexts including countries in the Caribbean and Latin America, South Asia, East Asia and Africa. Care for Child Development curriculum is another widely used intervention (Yousafzai & Aboud, 2014) and focuses on responsive interaction during feeding and playing. A few studies have used the Learning

Through Play curriculum. All ECD interventions promote learning through play, and increasing positive caregiver-child interaction (Yousafzai & Aboud, 2014).

Delivery agent

Most studies used either locally recruited community volunteers (paraprofessionals) or existing government staff to deliver the parenting session. In the integrated programs, where the intervention is integrated into existing systems, government staff delivered the intervention. However, the government staff was usually trained and supervised by the study team. The average duration of the training were one to two weeks and almost all intervention trials included ongoing supervision by the research team (Yousafzai & Aboud, 2014). Utilising government staff to conduct early childhood parenting programme is a promising approach to going to scale. Still there is a lack of evidence on the effectiveness of using government infrastructure; hence, more evidence is required to determine the feasibility of taking to scale with maintaining quality.

1.5: Evidence of Integrated program:

Several countries have stepped forward to scale up integrating ECD parenting intervention into any existing services such as health, nutrition, conditional cash transfer, and sanitation to achieve expected success. This approach has been shown to be effective at improving child development; however, there are implementation challenges related to staffing, providing adequate supervision, maintaining quality implementation, and managing of logistics and proper delivery. Nutrition is the most widely used platform for integration; several studies reported significant improvement of ECD parenting interventions integrated into nutrition services on the developmental outcomes of the children under 5 years of age, although most have found no significant benefits to child growth (Dulal et al., 2021). A review by Dulal et al. (2021) reported

the effect of the integrated intervention is stronger in undernourished children. Combined interventions of stimulation and micronutrient supplementation (with or without nutrition education) had moderate beneficial effect on cognition and language development but not on motor skills (Dulal et al., 2021; Yousafzai & Aboud, 2014). Yousafzai & Aboud (2014) reported the beneficial effect of psychosocial stimulation is larger for child cognitive and language development than the nutritional supplementation alone. Although there is little evidence on that nutritional supplementation alone benefits child development, a combined nutritional supplementation and psychosocial stimulation are recommended, especially for undernourished children, and nutritional supplementation is required to improve children's growth, especially for children below two years of age (Grantham-McGregor et al., 2014).

Another potential infrastructure is cash transfer programmes. Cash transfer programs provide cash to ultra-poor families and may present the opportunity to promote acceptance of the ECD service within the community. In Colombia and Bangladesh, ECD parenting interventions had been integrated with the government cash transfer program, and benefits were found for child development and parental knowledge of the child-rearing practices. (Hossain et al., 2021, Attanasio et al., 2014). In Mexico, a combined cash transfer and early childhood parenting programme led to significant benefits to child development when the programmes were integrated together within the community but not when they operated in tandem in the same community (Fernald et al., 2016). The health service is another promising platform for expanding ECD programs with the provision of health facilities at the community level, an appropriate workforce, and a structured monitoring system. Several countries have attempted to integrate ECD programmes with primary health care services. In Pakistan, an ECD intervention was integrated with the Government health program and the sessions were provided by

Government frontline health workers (Yousafzai et al.,2014). The study showed benefits to children's developmental outcomes and behaviour (Yousafzai et al., 2014). The children were followed up two years after the intervention and sustained benefits were found for children's cognitive development and for mothers' child rearing knowledge and the quality of home stimulation (Yousafzai et al., 2016). In the follow-up study, the effect sizes of child outcome were small comparing to the main study. Factor's like the child's level of risk, type of continued parenting practice, amount of health and education services child receives were needed to understand. In Jamaica, Antigua and St. Lucia, an early childhood parenting intervention was incorporated into immunization and routine health check-up services in primary health care centres. In the health centre, mothers received five sessions in the waiting areas and counselling during their routine health check-ups when the child was 3, 6, 9, 12, and 18 months of age. This light-touch intervention led to benefits for the child's cognitive development at post-test (Chang et al., 2015). However, benefits were not sustained when children were followed-up at age of 6 years (Smith et al., 2021). less intense intervention containing small number of sessions and less duration is less beneficial on child outcome at post-test and reduce the potential for sustained benefits (Smith et al., 2021).

These studies suggest that although the health service is a potential delivery platform for moving to scale, attention does need to be given to the intensity and dosage of the intervention for sustained benefits to be achieved.

1.6: Key Factors of Integrating ECD Program: Some important factors for the success of ECD parenting programs that are integrated into existing services are the quality of training, supervision, and monitoring of quality implementation. The following are some elements needed while planning an integrated model.

Training:

Designing an effective training program for government health workers plays a vital role in strengthening the health workers' capacity to deliver the program appropriately. Hence, it is necessary to take account of training duration, mode of training, and assuring quality. The inclusion of role play, practical demonstration, video and live modelling, and guidelines on how to provide positive feedback in the training program has been shown to enhance health worker's skill in implementing the interventions (Yousafzai et al., 2014).

Curriculum:

Though different studies used different curriculum, the underlying theme of all the curriculums is the same: to promote children's development through enhancing mother-child interaction and positive parenting practice. The curriculum should be precise and easy to use by government health workers.

Cost benefit analysis:

Integrating childhood development intervention with other programs may be a cost-effective way of scaling-up. The advantage of integrating with any existing platform is that it may not require additional infrastructure and workforce to deliver the program at the community level.

Monitoring:

Intervention fidelity is a crucial factor for scaling up an evidence-based program. It is a significant challenge ensuring quality of the program when integrating with any national service. Developing an effective monitoring strategy with rigorous monitoring system is essential for implementing quality program.

Conclusion

In the last three decades, significant progress has been made in generating evidence in support of early childhood development programs globally. However, a large number of disadvantaged children are still not reached through effective programmes. Hence, selecting an appropriate and viable delivery platform is essential to scale up the program in different settings. The most common method of scaling up ECD interventions is through health and nutrition services, the challenges of integrating with health and nutrition services need to be addressed. The successful implementation of an ECD program depends on the availability of resources and skilled delivery personnel. In Bangladesh, several small-scale studies of early childhood parenting interventions have been carried out over the last two decades and have found consistent benefit on the developmental outcomes of the young children. Based on the success of these studies, now the country is stepping forward to scale. A snapshot of the previous Bangladeshi trials is illustrated in the subsequent section.

CHAPTER: TWO

Literature Review

Section: 1

2.1.1: Early Childhood Development Research Project in Bangladesh:

Bangladesh is a densely populated country with high prevalence of malnutrition, low GDP rate, unemployment and illiteracy. In Bangladesh, poverty, inequality in education, inadequate nutrition, underdeveloped rural infrastructure, lack of parental awareness of the importance of early childhood and poor child rearing practice are factors predicting poor developmental outcomes of children and poor performance in school (Hamadani et al., 2014). It is estimated that in Bangladesh, 32% of the population live below the international poverty line and 42% of the children under 5 years of age suffer from stunting and 32% are underweight. There is large disparity in child cognitive and language development according to socio-economic and parental educational status. Child cognitive and language skills decline over time and only 21% of children aged 36 to 59 months achieve literacy and numeracy milestones on time (Nomura & Matsuda, 2017). Children of less-educated parents and from poorer families have increased risk of developmental delay and poor nurturing care leads to adverse developmental outcomes over the entire life course (Nomura & Matsuda, 2017). To address the gaps, over the past few years, the Bangladesh Government has developed strategies to improve the early development of young children. The Ministry of Primary and Mass Education (MPoME) initiated an action plan with a long term vision of “all children, 3-5 years of age, are attending pre-school programs of some

kind and have access to programs of health, nutrition, social, physical and intellectual development, and being initiated into formal education” (Bangladesh country report, 2013). As part of the National Education Policy 2010, preschool education has been integrated into primary education by introducing a minimum of one year of preschool education for children aged 3-5 years. The government primary schools are running the pre-primary education program (PPE). With the support of different NGOs, Bangladesh Shishu Academy and UNICEF, the MoPME and the Ministry of Women and Children Affairs (MoWCA) have initiated several attempts to ensure access to Pre-primary education (PPE) for all children below 6 years of age across the country. In addition, a Comprehensive Early Childhood Care and Development (ECCD) Policy has been developed to provide an operational framework for developing a comprehensive ECCD program for children from conception to age eight and an action plan has been approved by the cabinet in 2016 (Bhatta et al., 2020). The Ministries of Primary and Mass Education (MPoME) and Ministry of Women and Children Affairs (MoWCA) and several non-Government organizations are running nutrition program countrywide and they are providing health and nutritional services to young children free of cost. The Early Childhood Care and Development (ECCD) program is incorporated into some of these services. However, most of the ECD programs are focusing on preschool children and very few target children below 3 years old. In addition, the existing ECD program coverage is still limited to specific regions and the program implementation is at the primary stage. In addition, few rigorous research studies have been conducted to evaluate the effectiveness of this approach (Aboud et al., 2013).

2.1.2: ECD intervention trials in Bangladesh:

Several ECD evaluation projects have been conducted in Bangladesh. The studies were carried out to assess the effect of psychosocial stimulation intervention on the development and behaviour of children below 5 years old. The studies aimed to improve young children's development through an intensive stimulation intervention of nurturing care and responsive parenting. Here we reported eight randomized controlled trials and one quasi-experimental study (**Table 2.1.1**). The studies have been carried out over the period of last 15 years. Out of the nine studies, eight were conducted in rural areas, and one in urban slum. All studies used an intervention focusing on improving positive parenting practice to improve children's developmental outcome. The summary information of the studies is given below:

Sample characteristics

The children's enrolment age was from 3 to 48 months. Out of the nine studies, two were conducted with malnourished children, six with underprivileged children and one study included children with iron deficiency anaemia.

Intervention details:

Duration of intervention

The duration of intervention ranged from six to twelve months. The intervention lasted one year in four studies and six months in two studies. Two studies reported about nine months of intervention. One study used ten months of intervention.

Type and number of sessions

Studies reported different session delivery strategies. Four studies (38%) reported on interventions delivered through individual sessions either through home-visiting or in a clinic setting. Group sessions (group size ranging from 6 to 18 mother-child dyads) were conducted in three studies and two studies used a combination of individual and group sessions. The session schedule varied from weekly (n=3) to fortnightly (n=3). Three studies (38%) used a combination of session delivery schedule (e.g. weekly then fortnightly, fortnightly then monthly).

Intervention content:

The majority (N=5, 55%) of the trials used an adaption of the Jamaican Reach up & Learn curriculum. The curriculum was adapted according to local context; locally available toys and local rhymes were replaced while keeping the underlying theme the same. The intervention in all studies focuses on responsive parenting and improving caregiver child interaction and included age appropriate play activities using low cost toys and picture books. The ECD programs were integrated with other components (nutrition supplementation in two studies, iron syrup in one study, one study integrated ECD with the government primary health care service, one with a cash transfer program and one into sanitation programme).

Intervention process:

Five studies used Reach up & Learn intervention and used toys made by locally available low-cost materials. During the session, mothers were supported to play and interact with their children to promote their cognitive, language, motor and social-emotional development. The facilitator demonstrated the activities and let the mothers' practice with their children. The toy materials are given to the mothers to practice at home in exchange of a new set of toys in the subsequent session. The remaining four studies used messages emphasizes on enhancing mother-

child interaction and encouraging mothers to play with children to promote their child's development. Among these studies only one provided picture books. The shortest duration of the session was 10 minutes. The other studies varied in duration with group sessions lasting from 40-90 minutes and individual sessions, 10-60 minutes.

Delivery agent

Out of the nine studies, two involved government frontline health workers and seven used locally recruited staff. The lowest tier of the primary health care service is community clinic, which is run by the frontline health workers. They are involved in providing basic health service in the rural areas and their average educational qualification varies from higher secondary level for one cadre of staff to much higher graduate qualifications for other staff. In studies that recruited locally-available staff, these were local woman with educational qualifications ranging from 9th to 12th grade.

Training and supervision

The session providers received extensive training on the psychosocial stimulation curriculum in all studies. The duration of the training ranged from four-to-twenty-one days. The training mostly combined with theory and practice. The guidelines used in training focused on learning through play and enhancing caregiver skills to provide developmentally appropriate activities to their children. Seven studies included supervision. The supervisors observed live parenting sessions and rated the session quality using a checklist and used the checklist to give feedback to the facilitators. The intensity of supervision varied from fortnightly to monthly.

2.1.3: Findings of The Studies

Primary outcomes: Eight studies assessed at least one child development outcome, for example, cognition, language or motor skill of the children using the Bayley Scale of Infant and Toddler Development II or III. Seven studies measured cognitive skill and six found significant benefit of intervention on the children's cognitive score with effect size ranging from 0.25 to 1.60 SD. Six studies assessed language development and five found significant improvement in language scores of intervened children with the effect size ranging from 0.14 to 0.89 SD. Five studies assessed motor development and three found improvement with the effect size ranging from 0.22 to 0.38. Three studies assessed the children's behaviour using Wolke's behaviour Rating Scale. The scale includes a rating of five behaviours: responsiveness to the examiner, emotional tone, activity or movement, cooperation with the examiner and vocalization. Different studies reported treatment effect on different behaviours: response to examiner (n=3, range of effect sizes: 0.13 to 0.45 SD), emotional tone (n=2, effect size: 0.11 & 0.28 SD), cooperation (n=2, range of effect size: 0.41 and 0.44 SD), activity (n=1, effect size: 0.13) and vocalization (n=1, effect size: 0.27). Growth of the children was measured in seven (70%) studies and only three found improvement in weight-for-age Z score of intervention group with the effect size ranged from 0.11 to 0.38 SD. Out of these three studies, two provided food or micronutrient supplementation. Studies that have found no benefit in infant nutrition have not used any nutritional supplementations.

Secondary outcomes

Quality of home stimulation had been assessed in Seven studies using either the Home Observation & Measurement of Environment (HOME) or the Family Care Indicator Questionnaire. Home stimulation of the intervention group was significantly improved in six

studies and five found benefits in home stimulation (range of effect sizes: 0.26 to 1.08 SD). Four studies measured maternal knowledge on child caring practice and three found benefits with the effect size ranging from 0.31 to 1.0 SD. Three studies measured maternal depression symptoms and one reported reduced depressive symptoms of the mothers of intervened children with the effect size -0.23 SD.

Summary of the findings

In summary, the findings across the studies show that early childhood parenting interventions were beneficial in improving early childhood development. Most of the studies followed a randomized controlled design; using developmentally appropriate curriculum, intensive training, and ongoing supervision. In those studies, where intervention was given to malnourished children in rural and urban areas, beneficial effects were found on their development (Hamadani et al, 2006). Severely malnourished children also significantly benefitted from the program. (Nahar et al., 2012). Stimulation benefitted the Mental Development Index (MDI) for children with and without iron-deficiency anaemia in one study; however, no benefits to motor development were found for children with iron-deficiency anaemia. Children with iron-deficiency anaemia overall benefitted less from the intervention than non-anaemic (Tofail et al., 2013). An integrated ECD and cash transfer programme was more effective in improving the developmental outcome of young children than using the cash transfer platform alone (Hossain et al., 2021). Similarly, the integrated studies reported significant program impact on young children's development when the intervention was provided by the government frontline health workers under Primary Health Care (PHC) service (Aboud et al., 2013). Trials on responsive feeding also showed significant intervention benefits on children's cognition and one trial found

a significant benefit on language skill (Aboud et al., 2013). Both studies reported an increase of home stimulation (Aboud et al., 2013 & Aboud et al., 2011).

In summary, combining the stimulation intervention with nutrition, sanitation or unconditional cash transfer has been shown to be effective in improving children development. Adding nutritional supplementation with psychosocial stimulation had beneficial effect on the development of the severely malnourished children's development (Nahar et al., 2012). All studies significantly benefitted child development of the children although in one study, where the intervention was delivered by the government health workers, benefits were small (only $ES=0.08$ on child cognition) and there was no significant impact on parental knowledge (Chinen et al., 2016). The intervention implementation fidelity was low in this study and almost 50% of the households of the intervention did not receive any intervention materials or messages. Time and resource constrain were identified as key challenges by the service providers to implement the program successfully. However, despite delivering the low intensity intervention the program was successful in integrating with national nutrition service with minimal cost (Chinen et al., 2016).

Table: 2.1.1: Summary of Bangladeshi Studies

Author Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Bangladesh Hossain et al., 2021	Cluster- randomized controlled trial 11 Unions randomly selected and 3 clusters of each union were randomly assigned into 3 arms: 1.Psychosocial stimulation + Unconditional cash transfer (PS+UCT: n=197) 2.Uncondition al cash transfer (UCT: n=188) 3. Comparison (n=209)	Mother and children aged 6-16 months old Duration: 12 months	locally recrui ted Village Health Worker (VHW)	Training: 10 days basic training, The training includes didactic sessions, in- class practice and field practice. Supervision: One supervisor visited the field everyday to track the session, ensure availability of toys, to check session conduction forms and troubleshooti ng of field related issues.	Session: 24 home- based fortnightly sessions	ECD intervention: Adapted version of Jamaican Reach up & Learn Home visiting curriculum The content of the curriculum focused on: i. Caregiver and child interaction ii. Age specific play activities iii. Messages on personal hygiene and nutrition Unconditional cash transfer (UCT): Mothers received monthly 500 tk.	Home visiting session Session duration: 40-60 minutes Each session comprised with 6 activities: 1. Feedback of the previous session 2. Song/rhymes 2. Picture book activity 3. Toy activity and 4. General and nutritional messages on nutrition Each VHW conducted 3 to 4 sessions in 6 days in a week The toys were used in the session made by recycled materials. VHW encouraged mothers to play with their child using the toys and exchanged with new sets of toys in the following session.	Primary Outcome <i>Bayley Scale of Infant and Toddler Development III:</i> - Cognition, - Language and - Motor development <i>Wolke's Behaviour Rating Scale:</i> - Response to examiner - Emotional tone - Cooperativeness to examiner -Activity and -Vocalization <i>Anthropometric Measurement:</i> - Weight for age - Length for age Secondary outcomes <i>Rosenberg Self Esteem Scale:</i> Maternal self esteem <i>Maternal Depression Home Observation and Measurement of Environment (HOME):</i> Home stimulation	Primary Outcome <i>Bayley Scale of Infant and Toddler Development III:</i> PS+UCT vs UCT group: Cognition: ES=0.24, P=0.021 Language: ES=0.21, P=0.022 PS+UCT vs comparison group: Cognition: ES=0.32, P=0.003 Language: ES=0.24, P=0.016 Motor: ES=0.22, P=0.031 <i>Wolke's Behaviour Rating Scale:</i> Responsive to examiner: PS+UCT vs UCT group: ES=0.30 (95% CI: 0.06, 0.52) PS+UCT vs comparison group: ES=0.30 (95%CI: 0.08, 0.52) <i>Anthropometric Measurement:</i> No intervention effect on children growth Secondary outcomes <i>Rosenberg Self-esteem scale:</i> Maternal self-esteem: PS+UCT vs comparison group: ES =0.48, P=0.002 <i>Home Observation and Measurement of Environment (HOME):</i> PS + UCT vs UCT: ES=0.81, P<0.001 PS + UCT vs comparison: ES=1.04, P<0.001 No effect was found in maternal depression among the groups

Author Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Bangladesh Pitchik. et al., 2021	Cluster randomized controlled trial 31 villages were randomly allocated to 3 arms: 1. Group session (n=160) 2. Combined (alternating) group and home visits (n=160) 3. Passive control arm (n=301 pregnant woman)	Pregnant women and children < 15 months on enrolment Duration: 9 months	Specially employed CHWs Age: 18-38 years Education: completed higher secondary education	Training - 8 days basic training, Refresher training: - 4 days refresher training prior to start of intervention - Nine additional 2-3 day trainings The training includes didactic sessions, in-class practice and field practice. Supervision: Each CHW was supervised every 2 weeks.	Group sessions: 18 fortnightly sessions Combined group and home visits: 18 fortnightly sessions – alternating between group sessions and home visits	Intervention included: Play activities adapted from Reach-UP Provision of appropriate play materials (including a toy and a picture book) was included in all sessions. Emphasis on responsive caregiving. Other components: -Nutritional supplements - Sanitation education - Information on lead - Adapted Thinking Healthy Program (for maternal mental health) - Help in providing sanitation and assistance for children born LBW - Toys and books	Group sessions: Group size: 3-6 pregnant women and mother-child dyads. Duration: Group sessions were 40-60 minutes long. Sessions were delivered in nearby homestead. Home visits: Duration: 20-25 minutes Inclusion of other caregivers in some sessions. Attendance: Mean attendance 14.2 in group arm and 15.2 in combined arm. Fathers attended two sessions (father only)	Primary Outcome <i>Family Care Indicators (FCI):</i> parent report on home stimulation Secondary outcomes <i>Ages and Stages Questionnaire (ASQ):</i> primarily parent report <i>Bayley Scale of Infant & Toddler Development III:</i> Subset of children (134 control, 120 intervention) <i>Communicative Development Inventory (CDI): language Center for Epidemiological Studies Depression Questionnaire (CES-D):</i> Maternal depression <i>Other (not recorded here)</i> Dietary diversity, knowledge about lead, household sanitation.	Primary Outcome <i>Family Care Indicators (FCI):</i> Group vs control: ES=0.66 (95% CI: 0.45, 0.87) Combined vs control: ES=1.08 (95% CI: 0.87-1.29) Secondary outcomes <i>Ages and Stages Questionnaire (ASQ)</i> Group vs control: ES=0.39 (95% CI: 0.16, 0.64) Combined vs control: ES=0.25 (95% CI:- 0.07, 0.54) <i>Bayley Scale of Infant & Toddler Development III:</i> Group and combined vs control: Expressive language: ES=0.33(95% CI: 0.02, 0.64) Bayley III score: ES=0.38 (95% CI: 0.06, 0.74) <i>CDI:</i> <i>Group VS control:</i> <i>Receptive score:</i> 0.25 (−0.04 to 0.55) <i>Expressive score:</i> 0.29 (0.06 to 0.50) <i>Combined vs control:</i> <i>Receptive score:</i> 0.19 (−0.15 to 0.52) <i>Expressive score:</i> 0.17 (−0.17 to 0.53) <i>Center for Epidemiological Studies Depression Questionnaire (CES-D):</i> Group vs control: ES=-0.23 (95% CI: -0.36, -0.066) Combined vs control: ES=-0.15 (95% CI: -3.12, -0.41) There was no difference in maternal and child diet diversity between the groups. Knowledge of lead was significantly higher in intervention 0.10 (0.00 to 0.21) and combined group was higher 0.13 (−0.02 to 0.28) than control group.

Authors/co untry	Study design & Sample size	Child age & duration	Staffing	Training & Supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Bangladesh Chinen et al., 2019	Cluster Randomized controlled trial 78 Community Clinics (CC) randomized into 2 groups: i. Intervention: National Nutrition Service+ Early Childhood Stimulation (n=1287 children) ii. Control: only NNS (n=1287 children)	3-18 months Duration : 12 months	- Community Health Care Providers (CHCP) - Health Assistants (HA) - Family Welfare Assistants (FWA) Gender: Female: 74% Male: 26% Educational qualification : Secondary education: 64% Mean age: 35 years Working experience: on average 13 years	Training: 4 days training on stimulation Refresher training: 2 times throughout the intervention period Supervision: The Health Inspectors, Assistant Health Inspectors and Family Planning Inspectors monitored the stimulation activities during their routine monitoring visits of household visits.	Pregnant mothers received 15 counselling visits. Mothers of older children received 3 visits.	The ECD curriculum comprised with 8 contents: i. Care during pregnancy, ii. Love and affection iii. Play and games iv. Talk and communication v. Positive discipline vi. Responsive feeding vii. Health and hygiene viii. Share messages	Home Visiting session: Each household received a child development card, two picture books and a booklet with one key message. Child development card divided into 5 sections: i. Pregnancy ii. Birth to six months, iii. 7 to 12 months, iv. 1 to 2 years, v. 2 to 3 years. Community service providers delivered stimulation session during their routine household visits, EPI or sick child visit at community clinic. Quantity of household visits: - At least 1 visit: 44% households - Two visits: 41% - Three visits: 11.7% - four to six visits: 3% Cost: \$6.84 USD per child	Primary outcomes: <i>Bayley Scale of Toddler & Infant Development (III):</i> Cognition Language <i>Wolke's Behaviour Rating Scale:</i> Response to Examiner Emotional tone Cooperation Activity and Vocalization <i>Anthropometric measurement:</i> Weight for age, Height for age Head circumference Secondary outcomes: <i>Parenting Stimulation Knowledge</i> <i>Home Observation for Measurement of the Environment (HOME)</i> <i>Centre for</i>	Primary Outcomes: Intervention vs control: <i>Bayley Scale of Infant & Toddler Development III:</i> Cognition: ES=0.076, P<0.004 Language: ES=0.137, P<0.001 <i>Wolke's Behaviour Rating Scale:</i> Intervention vs control: Responsive to the examiner: ES=0.13, P=0.007, Happier emotional tone: ES=0.11 P=0.037 Activity: ES=0.13, P=0.019 No difference had been found in cooperativeness and vocalization <i>Anthropometric measurement:</i> Weight for age: ES=0.108, P<0.001 Secondary outcome: Intervention vs control: No difference had been found in parental stimulation knowledge and total home inventory score <i>Home subscales:</i> Varieties of play materials and variety of learning activities when combined significant effect had been found in variety of learning activities: ES=0.09, P<0.05. Number of children book at home: ES=0.10, P<0.05

Authors/ country	Study design	Child age & duration	Staffing	Training & Supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
<p>Bangladesh</p> <p>Tofail et al, 2013</p>	<p>Cluster randomized Controlled Trial</p> <p>30 villages with 434 children having Iron Deficiency Anemia(IDA) and non-anemic children randomized into 4 groups:</p> <p>1. Intervention group 1: Stimulation +iron syrup group= 117 NANI children)</p> <p>2. Intervention group 2: Stimulation + iron syrup group=106 IDA children)</p> <p>3.Control group 1: (no stimulation +iron syrup=108 NANI children</p> <p>4. Control group 2: No stimulation + no iron syrup=103 children</p>	<p>6-24 months</p> <p>Duration: 9 months</p>	<p>Locally recruited play leaders</p> <p>Educatio n: 9-12 years education</p>	<p>Training: 3 weeks</p> <p>Supervision : Each Play leader was supervised every 2 weeks by the supervisor and a checklist was used to assess the quality of the session</p>	<p>36 weekly home visiting session</p>	<p>Psychosocial stimulation: The curriculum was adapted from Jamaican home visiting curriculum. Developmental age appropriate play activities focusing cognition, language and motor development. The play activities were organized into easy to difficulty level. The toy materials were made by locally available recycled and low cost materials.</p> <p>Iron supplementation : Weekly 35 ml iron syrup</p>	<p>Home visits: The PLs demonstrated the scheduled activities following the curriculum.</p> <p>During the visit they showed to mothers how to play and interact with children. Toys and picture book materials are given to the mothers to practise for 1 week and exchanged with new toys and book in the next week</p>	<p>Primary outcome:</p> <p><i>Bayley Scale of Infant Development (BSID II):</i></p> <p>- Mental developmental index (MDI)</p> <p>- Psychomotor developmental index (PDI)</p> <p><i>Wolke's Behaviour Rating scale:</i></p> <p>Nine-point ratings of 5 behaviour scale:</p> <p>- Responsiveness to the examiner</p> <p>- Activity</p> <p>- Emotional tone</p> <p>- Cooperation &</p> <p>- Vocalization</p> <p><i>Anthropometric Measurement:</i></p> <p>Weight for Age</p> <p>Height for Age, Mid-upper arm circumference (MUAC), Head circumference (OFC)</p> <p>Secondary outcomes:</p> <p><i>Family Care Indicator:</i></p> <p>quality of stimulation at home.</p>	<p>Primary Outcome variables:</p> <p><i>Bayley Scale of Infant Development (BSID II):</i></p> <p>NANI Stimulation VS stimulation IDA group MDI score: ES=0.37, (95% CI: 0.13, 0.62)</p> <p>PDI: ES=0.13 (95% CI: 0.12, 0.38) is not significant</p> <p>IDA stimulation vs IDA no stimulation group: MDI score: P=0.02</p> <p><i>Wolke's Behaviour Rating scale:</i></p> <p>IDA stimulation VS IDA no stimulation: Cooperation: ES=0.44, P=0.04</p> <p>There is no stimulation benefit has been found in PDI scores and other behaviour ratings in IDA group.</p> <p><i>Anthropometry measurement:</i></p> <p>Height for Age was significantly improved in Both IDA and NANI group (P<0.001). No effect was found in Weight for Age, MUAC and OFC.</p> <p>Secondary Outcome variables:</p> <p><i>Family care Indicator</i></p> <p>NANI Stimulation VS stimulation IDA group</p> <p><i>Home stimulation:</i></p> <p>ES=0.48 (95% CI:0.15, 0.52)</p> <p>Stimulation significantly improved MDI (P=0.003), and the interaction between IDA/NANI and the stimulated group approached significance (P = 0.10).</p> <p>Differential effect: Benefit of intervention in the intervened group had been found by maternal education (P < 0.001), HAZ (P = 0.001), and female sex (P = 0.006)</p>

Authors/co untry	Study design & Sample size	Child age & duration	Staffing	Training & Supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Bangladesh Aboud et al. 2013	Randomize d cluster trail 25 villages as randomly allocated into: i. Intervention (n=<12mon s =115, n≥ 12 months =111) ii. Control (n=<12mon s 12=115, n≥ 12 months = 122)	6-18 month Duration : 10 months	i. Group session: Session provider with 10 th grade educational qualification ii. Home- based session: Govt. Family welfare Assistant (FWA) with minimum 12 th grade education	Training: Group Session: 4 days main training Refresher training: 3 bi-weekly 1 day Individual session: Main training: 2-days main training & Refresher training: 1-day refresher training in the mid of the program. Supervision: Supervisor initially observed several sessions of each facilitator. Supervisor observed 10-15 household visits of each FWA over 1 st 4 months. Fidelity checklist included: - Demonstration of appropriate activities - Following steps of demonstration. Fidelity checklist for 10-min counselling includes demonstration and problem solving.	Fortnightly : 14 fortnightly sessions for 4 months Monthly: 6 monthly sessions 10-mintues home-based counselling session	Intervention includes: messages on - Health - Nutrition -Communication -Play messages -Showing love - Avoiding harsh discipline, - Responsive self-feeding and - Providing a diverse diet, - Hand-washing before feeding and after defecation, -Talking and singing with the child, and - Providing Interesting play materials and playmates.	Group session: A card containing key practice message for 6-12 months and 12-24 months old children were given to mothers to remind to practice at home. Group size: 18 mothers Attendance: 85% of the session attended Home visit: 10-minuts counselling session mothers at their home and community clinic Cost: Group session: per child USD 6.17 Home visits: USD 1.34	Primary outcomes: - <i>Bayley Scales of Infant and Toddler Development III:</i> Cognition, Language and Motor Secondary outcome: <i>Home Observation and Measurement of Environment:</i> Home stimulation <i>Maternal knowledge on developmental milestones.</i> <i>Centre for Epidemiological Studies- Depression (CES-D):</i> Maternal depressive symptoms	Primary outcome: <i>Bayley Scales of Infant and Toddler Development III:</i> Intervention vs control: Cognition: Younger children: ES=1.60, P<.0001 and Older children: ES=1.30, P<.0001 Receptive language: Younger children: ES=0.89, P<0.0001 and Older children: ES=0.77, P<0.0001 Expressive language: Younger children: ES=1.13, P<.0001 and Older children: ES=0.84, P<.0001 Secondary outcomes: <i>Home Observation and Measurement of Environment:</i> Home stimulation Intervention vs control: ES=0.40 knowledge on developmental milestone: ES=0.68 <i>Centre for Epidemiological Studies- Depression (CES-D):</i> Cognition: Younger children: ES=-0.06, P=0.73 Older children: ES=0.01, P=0.73 Maternal depression was reduced among the mothers of group session than home visiting group (P=0.004))

Authors/ country	Study design	Child age & duration	Staffing	Training and Supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
<p>Bangladesh</p> <p>Nahar et al., 2012</p>	<p><i>Randomized Controlled trial</i></p> <p>507 severely malnourished admitted into hospital randomly allocated into 5 groups;</p> <p>i. Psychosocial group (PS, n=102)</p> <p>ii. Food Supplementation (FS, n=101)</p> <p>iii. PS +FS (n=103)</p> <p>iv. Clinic-control (n=99)</p> <p>v. Hospital-Control (102)</p>	<p>6-24 months</p> <p>Duration: 6 months</p>	<p>Female health workers (FHW)</p> <p>Education: 8-10 years of schooling</p>	<p>No information on training</p> <p>Supervision:</p> <p>Each FHW was supervised in the monthly visits. The supervisors monitored the tracking of the sessions and progress of the child.</p>	<p>Weekly centre based individual session</p>	<p>Psychosocial stimulation:</p> <p>The curriculum was prepared based on Jamaican Home Visiting curriculum. The session includes play activities of toy and book. Messages on child development, praising, importance of play, chatting.</p> <p>Food supplementation : Children received food packet for 3 months.</p>	<p>Centre based individual session:</p> <p>Duration: 1 hour</p> <ul style="list-style-type: none"> Demonstration by the health worker and practice by the mothers with their children. The toy and book materials were given to them at the end of the session to practice at home and mothers return back the toy materials in next sessions in exchange with new sets of materials. 	<p>Primary outcome:</p> <p><i>Bayley Scale of Infant Development II:</i></p> <p>i. Mental Developmental Index and</p> <p>ii. Psychomotor developmental Index</p> <p><i>Anthropometric Measurement:</i></p> <p>Children's weight, length and head circumference were measured</p> <p>Secondary outcome:</p> <p><i>Home Observation and Measurement of Environment:</i> Home stimulation</p>	<p>Primary outcome:</p> <p><i>Bayley Scale of Infant Development II: Mental developmental index (MDI):</i></p> <p>PS+FS VS CH group: ES=0.33, P=0.022</p> <p>The PS+FS VS CC group: ES=0.24, P=0.092</p> <p>Combined stimulation VS no stimulation group: ES=0.37, P=0.017</p> <p><i>Psychomotor index (PDI):</i></p> <p>PS+FS VS CH group: ES=0.29, P=0.031</p> <p>PS+FS VS CC group: ES=0.28, P=0.047</p> <p>PS+FS VS FS group: ES=0.38, P=0.003</p> <p><i>Anthropometric:</i></p> <p>Combined stimulation VS no stimulation group</p> <p>Weight for age: ES=0.26, P=0.078</p> <p>Secondary outcome variables</p> <p><i>Home Observation and Measurement of Environment:</i></p> <p>Combined stimulation group vs no stimulation group:</p> <p>Home stimulation: Ranges of effect size: 0.66 to 0.33 SD, P=0.012</p>

Authors/ country	Study design	Child age & duration	Staffing	Training and Supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Bangladesh Aboud et al., 2007	Intervention-control design i. Intervention : (n=170) who attended a year-long educational program iii. Control group : (n=159)	30-48 months Duration : 12 months	Education: Facilitators with secondary level education.	Training: 17 days basic training on 40 topics of the manual. Refresher Training: Monthly Supervision : 4 days a month	Weekly: Educational session	The intervention topic includes common diseases and oral rehydration solutions, hygiene, sanitation, breastfeeding, weaning foods, micronutrient deficiencies, stages of cognitive and language development, how parents can help children learn, how to encourage language development, positive discipline, gender equality, and child rights.	Group session: Size: 9-25 mothers Duration: 90 minutes	Primary Outcome: <i>Home stimulation: Home Observation and measurement of Environment (HOME):</i> Home stimulation <i>Parental knowledge:</i> through a structured questionnaire <i>Mother-child interaction:</i> through picture talk Child outcome: <i>Wechsler Pre Primary Scale of Intelligence:</i> Receptive Vocabulary <i>Anthropometric measurement:</i> Weight for Age Z score	Primary outcome: Intervention vs control <i>Home stimulation: Home Observation and measurement of Environment (HOME):</i> ES=0.21 <i>Parenting knowledge:</i> knowledge on good practice for childhood development was significantly higher in the intervention group (ES=0.31) <i>Mother-child interaction:</i> No difference in mother child interaction had been found between the groups. <i>Primary Scale of Intelligence:</i> Receptive Vocabulary: No difference was found in receptive vocabulary between the groups <i>Anthropometric measurement:</i> No effect on Weight for Age Z score between the groups Differential effect: in parenting group session, boys had higher receptive vocabulary than girls with the effect size η^2 0.013.

Authors/ Country	Study design	Child age & duration	Staffing	Training & Supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Bangladesh Hamadani et al., 2006	Randomized Controlled Trial Twenty Community Nutrition Centers (CNC) were randomly selected as intervention and control: i. Intervention group (malnourished children with <-2 Z score, n=107) ii. Control (malnourished children with Weight for age Z score <-2,n=107) iii. Better- nourished/compar ison group (malnourished children with Weight for age Z score WAZ ≤2, n=107)	6-24 months Duration : 12 months	One Play Leader (PL) was recruited from each village	Training: 2 weeks training Supervision : Two supervisors attended session regularly.	Group session: Weekly: Center based sessions for 10 months Fortnightly : 2 months Home- based session: Weekly: 4 months Fortnightly : 8 months	Psychosocial intervention: Curriculum is developed based on Jamaica curriculum. Curriculum includes: Developmental ly appropriate play activities - local song - General messages on parenting practice- like as, praising children, giving positive feedback, chatting with them, labelling things in the environment and discouraging punishment.	- Demonstration of play activities - Practice with child - Let mothers practice with child - left the toys at home and exchanged the toys in the subsequent session with new sets of toys.	Primary outcome: <i>Bayley scale of Infant Development II:</i> Mental Developmental Index (MDI) Psychomotor developmental index (PDI) <i>Wolke's behaviour rating scale: 9 points</i> 5 behaviour rating: i. Response to examiner ii. Emotional tone iii. Activity/movement iv. Cooperation with examiner v. Vocalization <i>Anthropometric measurement:</i> - Weight for age Z score - Height for age Z score Secondary outcome: Maternal knowledge on health, hygiene, nutrition, child development and child caring practice	Primary outcomes: <i>Bayley scale of Infant Development II:</i> Intervention vs control group: Mental development Index: ES=0.2, P<0.05 <i>Wolke's behaviour rating scale:</i> Response to examiner: ES= 0.45, P<0.001 Emotional tone: ES=0.28, P<0.05 Cooperation: ES=0.41, P<0.005 Vocalisation: ES=0.27. P<0.05 <i>Bayley scale of Infant Development II:</i> Undernourished control vs better-nourished group: Mental development: ES=0.20, P<0.05 Motor development: ES=0.38, P<0.01 <i>Wolke's behaviour rating scale:</i> Response to examiner: ES=-0.32, P<0.05 Emotional tone: ES=-0.48, P< 0.001 Cooperation: ES=-0.44, P<0.01 Vocalisation: ES=-0.42, P<0.01 Undernourished intervention vs better-nourished group: Psychomotor development (PDI): ES=-0.38, P<0.05 <i>Anthropometric measurement:</i> No group difference in Weight for Age and Height for Age Z score Secondary outcome: Intervention vs control group: Maternal knowledge: ES=1.0, P< 0.001 Intervention vs better-nourished groups: ES=0.90, P< 0.001 No significant improvement in growth had been found in both undernourished groups. No treatment effect was found on the maternal knowledge on health and hygiene

Conclusion

In Bangladesh, there has been some success from combined early stimulation and nutrition programmes though benefits to child growth are likely to require nutritional supplementation. The health sector has the potential for population-level reach and is a potential entry point for delivering ECD interventions, given that they provide universal services to pregnant women and mothers with young children and have an existing national infrastructure and appropriate human resources. Therefore, the enablers and challenges of integrating ECD interventions into the health services need exploration. The majority of evidence in Bangladesh is from individual home-visiting, although there is some evidence for the effectiveness of a group-based parenting programmes. Group-based interventions may be a feasible way of reaching a larger number of children. In the following section, I discuss group intervention studies conducted in different contexts across low- and middle-income countries.

Section: 2

2.2.1: Group Intervention and Early Child Development:

There is strong evidence that early childhood development parent programs are effective in improving children's development. However, how to deliver these programs at scale while maintaining their effectiveness still requires investigation. Initially, most ECD interventions mainly focused on individual home-visiting programmes and showed benefits to cognitive, language, motor development and the behaviour of children below five years of age (Dulal et al., 2021). Many studies also reported increased maternal knowledge and improved home stimulation with mixed results for maternal depressive symptoms (Dulal et al., 2021). In recent years, increased focus has been placed on group-based ECD interventions with a view to increasing the coverage, scalability, and cost- effectiveness. Group sessions also allow for participatory methods that have been shown to be effective in learning new skills and widens the scope for peer learning (Yousafzai & Aboud, 2014).

2.2.2: Group based Parenting Intervention to Promote Young Children's Development:

In this section, I report on studies that report on ECD interventions that use a group-based delivery method, either alone, or in combination with home visiting. The aim was to understand the delivery strategies used in group interventions, the curricula used and to learn about the challenges that may arise in a group session and how to mitigate them. Our other interest was to know understand the group curriculum used in these studies. Here I report on fourteen trials conducted to assess the effect of group-based and mixed-delivery ECD parenting intervention on children's cognitive, language and motor development. The studies are randomized controlled

trials conducted in low and middle-income countries of Asia, Africa and Latin America. The detail information of the studies is presented in **Table no 2.2.1**.

Sample characteristics:

The age range of the children across the studies was from birth to 48 months. Enrolment age starting from six months in seven studies and three studies included children below 6 months of age.

Intervention details

Duration and types of the intervention:

The shortest duration of the intervention was 4.5 months, consisting of 17 sessions. The maximum duration was two years and comprised of 24 monthly sessions. Half of the studies used a weekly session format (n=6), four studies delivered sessions fortnightly and one study used monthly sessions. A combination of weekly plus monthly sessions was used in one study. One delivered intervention consisting five sessions spread over 15 months. The range of session duration ranged from sixteen to ninety minutes.

Intervention content

Out of the fourteen studies, three used an adapted version of the Jamaican Reach up & learn curriculum (Attanasio et al., 2018; Grantham-McGregor et al., 2020; Pitchik et al., 2021). The UNICEF and WHO Care for Child Development package was used in one study (Yousafzai et al., 2014). One study used short films developed based on nine

topics of parenting practice. The films were shown in the waiting area of the health centre's and followed by a demonstration of the activities shown in the films by Community Health Workers that shown in the films (Chang et al., 2015). The ECD intervention was combined nutritional supplementation in three studies, and one study integrated the group-based ECD parenting intervention into a sanitation programme.

Intervention Process

Community workers provided support to the caregivers to promote responsive care and parental stimulation skills through guidance, demonstration, practice and feedback and encouraging caregivers to continue the activities with their child at home. Peer learning was also emphasised in the sessions. The group sessions were delivered to the group of mother-child dyads with group size ranging from three to twenty-five participants. Two studies included fathers' sessions in addition to sessions with mothers.

Delivery agent

Nine studies recruited local women to deliver the intervention. Five studies involved integrating into the government health service with the program run by government staff. Out of these five studies, four used existing government health workers who are involved with delivering health at community level. One study, in Kenya, used existing community volunteers and paid a monthly stipend. The community volunteers are involved with improving community health and linking with people with primary health facilities (Luoto et al., 2021).

Training

The shortest duration of training for facilitators was three days and was used in two studies. (Abimpaye et al., 2020; Chang et al., 2015) and the highest duration was more than three weeks (Attanasio et al., 2018). Two studies delivered training in two tranches; with the first training focusing on the first part of the curriculum and a second tranche of training focusing on the latter sessions (Attanasio et al., 2022; Luoto et al., 2021). The majority of studies (n=7) also included refresher training.

The training generally comprised practical sessions and field practice and in addition to understanding the activities and principles underpinning the intervention, additional emphasis is given to delivering activities according to child age, maintaining harmony in the groups, paying attention to all participants equally, and encouraging peer support.

Supervision

All studies reported ongoing supervision during the intervention period. Two studies included weekly supervision (Grantham-McGregor et al., 2020; Singla et al., 2015), and two reported bi-weekly supervision (Abimpaye et al., 2020; Pitchik et al., 2021). Supervisors use a structured monitoring form in most studies to record information related to the facilitators' competence in implementing the session.

2.2.3: Findings of the studies:

Primary outcomes

All studies measured child development as the primary outcome. The Bayley Scales of Infant and Toddler Development were used most. The Ages and Stages Questionnaire was used in

some of studies and one study used the Griffith Mental Development Scale. Twelve studies measured cognitive development and reported post intervention benefit in cognition with the effect size ranging 0.11 to 1.60 SD. Thirteen studies assessed language skills of the children and ten found benefits with the effect sizes ranging from 0.15 to 0.89 SD. Ten studies assessed motor development and benefits were found in 50% of the studies (n=5) with the effect sizes ranging from 0.11 to 1.0 SD. Five studies assessed socio-emotional development and four found benefits with the effect sizes ranging from 0.21 to 0.84 SD.

Nine (60%) studies measured weight and length of the children. Three studies found improvement in weight for age with the effect sizes ranging from 0.12 to 0.60 and length for age was improved in one study with an effect size 0.15. Out of the three studies two studies used micronutrient supplementation (Aboud et al., 2013; Yousafzai et al., 2014) and one used food supplementation (Helmizar et al., 2017).

Secondary outcome

Ten studies assessed home stimulation and nine found significant benefits of the intervention, with effect sizes ranging from 0.21 to 1.11SD. Maternal knowledge was assessed in seven studies and only four found benefits with the effect sizes ranging from 0.22 and 0.68 SD. In addition, one study found benefits to mother-child interaction during book reading: Odds Ratio (OR)=3.58, singing songs: OR=3.38 and playing with child: OR=2.59. Six studies measured maternal depressive symptoms and three reported significant reductions in maternal depressive symptoms in the intervention group at end line, with the effect size ranging from -0.13 to -0.39 SD.

2.2.4: Comparison of Group Session Vs Home Visiting Session:

Benefits to child cognition and language development were found consistently. One study, conducted in India, compared a group-based parenting intervention with a home visiting intervention and found similar benefits of both intervention on child development, home stimulation and parental knowledge on child caring practice (Grantham-McGregor et al., 2020).

A systematic review by Zhang et al. (2021) reported the finding of nine home visiting and twelve group (with or without home visits) intervention studies. The benefits in child cognitive (pooled effect size = 0.53 vs. 0.28, $Q = 4.99$, $P = 0.03$) and motor (pooled effect size = 0.31 vs. 0.08, $Q = 7.59$, $P = 0.006$) skills are larger for group-based intervention than the home visiting programmes (Zhang et al., 2021). In a pilot feasibility study in Malawi, an ECD intervention was integrated into the health system with government staff (Health Surveillance Assistants (HSA) delivering the intervention. HSAs are responsible for routine health care service in the community with each HSA assigned to approximately 1000 people. HSAs delivered the ECD intervention through group and individual sessions. The rate of attendance in group sessions was higher than the individual session. On average, 86% (62 out of 72) of the group sessions and 30% (3.6 out of 12) of the individual sessions were completed over six months (Gladstone et al., 2018). The Health Workers reported that other work assignments like vaccination, HIV campaign, and not getting incentive for extra work were the main barriers to conducting the session regularly. They also showed found it difficult to conduct home visits within their existing work schedule. Mothers reported a positive attitude towards both home visits and group sessions. They reported that individual sessions were more helpful in maintaining privacy and created the opportunity to build an open and amicable relationship with the health workers. Group sessions were reported to be effective in highlighting the importance of participating in the program to the husband and

family members and helped to boost their feelings of empowerment in the community. However, they also stated that sometimes they faced difficulties in joining group sessions due to economic activities (Gladstone et al., 2018). In a study in Colombia, mothers reported that the main advantage of the home visits was the participation of the family members, and in that they could pay more attention in the session if it is held at home. They reported that the group sessions were more fun than home visits, and they valued the opportunity to interact and learn from other mothers. The facilitators liked the home visits and group session equally (Gomez et al., 2021).

In a Caribbean study, ECD sessions were delivered at the primary health care centre with groups of mothers and children and through individual home-visiting. In the health centre, mothers were shown short films on ECD content followed by a demonstration of the session activities by the Community Health Worker (CHW). In one arm of the trial, participants also received follow-up home visits. In the qualitative interviews, most mothers and Community Health Workers expressed a preference for home visits over the sessions in the health centres as there was more space and less noise at home. Mothers felt their children benefited more from the home visiting session as the CHW only focused on one child (Walker et al., 2017). The health centre environment was noisy and crowded and mothers watched films in the waiting areas with other patients waiting for health “check-ups”. Mothers found it difficult to pay attention to the films and activities in this context. Due to the limited space, the CHWs faced challenges in interacting with mothers and the children properly. Despite these challenges, benefits were found to child cognition from the clinic-based intervention although these benefits were not sustained at six years (Chang et al., 2015, Smith et al., 2021).

Cost and benefit ratio related to home visits vs group session

There is limited information on the costs of ECD programmes in LMIC. However, two studies have found similar benefits to child development from group-based and home-visiting programmes with lower costs for the group-based sessions indicating that group sessions may be a more cost-effective approach in some settings (Grantham-McGregor et al., 2020; Walker et al., 2015). In Kenya, the benefit of the group “intervention-only” group was larger for children’s cognition and socioemotional development than the benefits of mixed delivery (individual plus group session) group (Luoto et al., 2021).

The summary information of the above studies is presented in **Table 2.2.1**.

Table :2.2.1: Summary of group intervention studies

Author/ Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Bangladesh Pitchik et al., 2021	Cluster Randomised Controlled Trial 31 villages were randomly allocated into 3 arms: 1. Group session (n=160) 2. Combined group + home visits (n=160) 3. Passive control arm (n=301 pregnant woman)	Pregnant women and children <15 months on enrolment Duration: 9 months	Specially recruited CHWs Age: 18-38 years Education: Higher secondary education	Training: 8 days basic training Refresher Training: - 4 days refresher training prior to start of intervention - 9 additional 2- 3 days trainings The training includes didactic sessions, in- class practice and field practice. Supervision : Bi weekly visit	- 18 fortnightly group session -18 fortnightly sessions home visits -Home visiting session and group session delivered every week alternative ly.	Intervention included: Play activities adapted from Reach- UP Provision of appropriate play materials (including a toy and a picture book) was included in all sessions. Emphasis on responsive caregiving. Other components: -Nutritional supplements - Sanitation education - information on lead - Adapted Thinking Healthy Program (for maternal mental health) - Help in providing sanitation and assistance for children born LBW - Toys and books	Group sessions+ Home visits: Group size: 3-6 pregnant women and mother-child dyads. Duration: Group sessions were 40-60 minutes long. Sessions were delivered in nearby homestead. Home visits: Duration: Home visits 20-25 minutes Inclusion of other caregivers in some sessions. Fathers attended two sessions (father only)	Primary Outcome <i>Family Care Indicators (FCI):</i> Parenting stimulation Secondary outcomes <i>Child Development Ages and Stages questionnaire (ASQ):</i> primarily parent report <i>Bayley Scale of infant and Toddler Development III:</i> A subset of children (134 control, 120 intervention) <i>Communicative Development Inventory (CDI):</i> language <i>Centre for Epidemiological Studies (CES-D) :</i> Maternal depressive symptoms <i>Other (not recorded here).</i> Dietary diversity, knowledge about lead, household sanitation.	Primary Outcome <i>Family Care Indicators (FCI):</i> Parenting stimulation (Reading book, playing and sing song to children): Group vs control: ES=0.66 (95% CI:0.45, 0.87) Combined (group + home visit) vs control: ES=1.08 (95% CI: 0.87, 1.29) Secondary outcomes <i>Ages and Stages questionnaire (ASQ) Score:</i> Group vs control: ES=0.39 (95% CI:0.16, 0.64) Combined vs control: ES=0.25 (95% CI: -0.07, 0.54) <i>Bayley Scale of Infant and Toddler Development III:</i> Combined vs control: ES= 0.38 (95% CI: 0.06, 0.74) <i>CDI:</i> <i>Group VS control:</i> <i>Receptive score:</i> 0.25 (-0.04 to 0.55) <i>Expressive score:</i> 0.29 (0.06 to 0.50) <i>Combined vs control:</i> <i>Receptive score:</i> 0.19 (-0.15 to 0.52) <i>Expressive score:</i> 0.17 (-0.17 to 0.53) <i>Maternal depression:</i> <i>Centre for Epidemiological Studies (CES-D):</i> Group vs control: ES= -0.23 (95% CI: -0.36, -0.066) Combined vs control: ES=-0.15 CI: -3.12, -0.41 There was no difference in maternal and child diet diversity between the groups. Knowledge of lead was significantly higher in intervention 0.10 (95% CI: -0.00, 0.21) and combined group 0.13 (95% CI:-0.02, 0.28) than control group.

Authors/ country	Study design	Child age and duration	Staffing	Training	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
India McGregor et al., 2020	Cluster Randomised Controlled Trial In Odisha, 192 villages randomly allocated into 4 arms 1. Nutritional Education (n=361) 2. Home visiting and nutritional education (n=369) 3. Group sessions and nutritional education (n=363) 4. Control (n=356)	7-16 months Duration : 2 years	141 local female facilitators were recruited. Mean age: 25 years Educatio n: - Bachelor degree: 40% - Higher Secondary degree: 55% - Secondary degree: 5%.	Training: 3 weeks initial training Refresher Training: 3 refresher trainings across the intervention period Supervision: Weekly	Weekly Group sessions or home visits	Psychosocial stimulation intervention: Adapted version of Reach-up and learn curriculum includes age specific activities to promote the development of children. Toys used in the session were made by locally available recycled materials. Nutrition Education: Quality of children's diet and hygiene practice	Group session + Home visit: Group size: 7-8 mother child dyads Duration: Home visiting session lasted 90 minutes and group session lasted for 60 minutes. Demonstration of play activities. Intervention includes toy and book materials. Session attendance: At home visits =75% At group sessions = 51% Cost: Per child was \$135 and group session cost per child includes \$38 personal salaries, training materials and home visiting cost	Primary outcome: Measured at midline (1 year) and end line (2 years) <i>Bayley Scale of Infant and Toddler Development III:</i> - Cognitive - Language and - Motor development <i>Anthropometric Measurement:</i> - Weight for age and - Length for age Z score Measured at end line only <i>Socio-emotional development: SDQ:</i> Externalising Internalising Pro-social. Secondary outcome: Parenting outcomes Measured at midline (1year) and end line (1 year) <i>Home stimulation Family Care Indicators:</i> play materials and play activities) <i>HOME scale:</i> Responsivity and involvement <i>Parenting knowledge.</i>	Primary outcomes: <i>Bayley Scale of Infant and Toddler Development III:</i> Cognition: Group vs control: ES=0.30, P<0.018 at midline ES=0.281, P<0.006 at end line Home visiting vs control: ES=0.31, P<0.006 at midline ES=0.324, P<0.001 at end line Language: Group vs control: ES=0.31, P=0.006 at midline ES=0.309, P=0.001 at end line Home visiting vs control: ES=0.16, P=0.36 at midline ES=0.239, P=0.009 at end line No significant group difference was found in motor development Socio-emotional development (SDQ): No benefits to externalizing, internalizing or prosocial at any time point. Only one outcome approaching significance: Home Visiting at end line: ES=0.215, P=0.054 No benefits to nutritional status or morbidity. <i>Anthropometric Measurement:</i> No benefit on growth Secondary outcomes <i>FCI play activities;</i> Home visiting vs control: ES=0.383, P<0.001 Group vs control: ES=0.331, P<0.001 <i>HOME Subscale:</i> Only one significant finding: Group vs control: Home involvement scale: ES=0.221, P=0.034 No benefits to Parenting knowledge No benefits to FCI variety of materials

Author/ Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Kenya Luoto et al., 2020	Cluster Randomised Community Effectiveness Trial 60 villages were randomly assigned into 3 arms: i. Only group sessions (n=376) ii. Mixed session (n=400) iii. Comparison group (n=376)	6-24 months old children Duration: 8 months	Forty Community Health Volunteer (CHV) of primary health service Gender: Male=10 & female=30 Age: Mean age 44 years Education: 11 years Experience : 9-11 years	Training: - 8 days initial training for session number 1-8 - 8 days training on session number 9-16 after 6 mothers Refresher Training: 1 day refresher training: in every months Supervision: Skills rated during supervisory visit: discussions, coaching parents, answering questions and engagement. Supervisory visits: Group session: 496 (89%) Of 560 mothers were monitored by a SWAP supervisor Home visits: 122 (9%) of 1411 home visits were supervised.	16 fortnightly sessions	ECD curriculum: Focused on 5 key messages; i. Responsive play ii. Responsive communication iii. Hygiene, iv. Love and v. Respect in the family.	Group session: Group size: Median= 13 (range: 10-15) Duration: median is 90 minutes Both fathers and mothers attended together in 12 sessions and separately in 4 sessions. Emphasis in father's session: i. Practicing respectful communication, ii. Father involvement in child-care, and iii. Emotional support Session attendance: Average attendance 13% Mixed delivery arm is 74% (n=11.9) Group only is 64.3% (n=10.3)	Primary Outcomes: <i>Bayley scale of infant and toddler development:</i> - Cognitive -Language and - Socio emotional development Secondary outcome: <i>Home Observation and measurement of Environment (HOME)</i> <i>Parenting Knowledge:</i> <i>Depressive symptoms</i>	Primary outcomes: <i>Bayley scale of infant and toddler development:</i> Only group intervention vs comparison group: Cognition: ES=0.52, P<0.0013 Receptive language: ES=0.42, P=0.017 Socio-emotional development: ES=0.23, P=0.024 Mixed intervention vs comparison group: Cognition: ES =0.34, P<0.021 Socio-emotional development: ES=0.22 (95% CI: 0.05 to 0.38) Receptive Language and expressive language score was not differed among the groups (ES=0.20, P=0.20) and (ES= -0.09, P=0.45) respectively Secondary outcomes: <i>Home Observation and measurement of Environment (HOME):</i> Only group intervention vs comparison group: ES=0.80, P<0.0001 Mixed intervention vs comparison group: ES=0.77, P<0.0001 <i>Parenting Knowledge:</i> Only group intervention vs comparison group: ES=0.22, P=0.0006 Mixed intervention vs comparison group: ES=0.16, P=0.032 No effect on depression symptoms

Author/ Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Rwanda Abimpaye et al., 2019	Randomised Controlled Trial 1447 families randomly allocated into 3 groups: i. Light touch (n=482), ii. Full intervention (n=482) iii. Control (n=483)	6-36 months Duration: 4.5 months	Locally recruited Community Family Volunteer (CFV) Education: 9 th grade Each local volunteer was responsible for 20 families.	Training: Light touch group: 3 days training Supervision: Bi Weekly: Each Community Family Facilitator was responsible for 3 local volunteers to monitor. Monthly: CFFs met Umuhuza staff to share feedback and status of the program. Monitoring data was discussed on a monthly basis and this informed program correction measures. .	17 weekly sessions	ECD intervention i. Step-by-step session guide/manual, ii. Flip charts with key messages, iii. 15–20 min Radio segment that included a drama and a key message for the specific day. Emphasis on responsive care and playful learning	Group session: Group size: 20 families attended group session. Duration: Both light touch and full touch group received 1.5 hour long group session. Full touch group received take home materials and book bank consisting 70 children book as loan share with other groups. Session attendance: Average attendance at session was 70% (n=12)	Primary Outcomes: <i>Ages and Stages Questionnaire:</i> - Problem solving skill - Personal social - Communication - Fine motor - Gross motor Secondary Outcomes: <i>Home Observation o and Measurement of environment (HOME):</i> Home stimulation	Primary outcomes: <i>Ages and Stages Questionnaire:</i> Light touch vs Control Communication: ES=0.38, P <0.001 Gross motor: ES=0.58, P<0.001 Fine motor: ES=0.32, P <0.001 Problem solving: ES=0.38, P <0.001 Personal-social: ES=0.35, P <0.001 & ES=0.46, P <0.01 <i>Ages and Stages Questionnaire:</i> Full touch intervention vs control: Communication: ES=0.53, P<0.001 Gross motor: ES=0.24, P <0.05 Fine motor: ES=0.36, P <0.01 Problem solving: ES=0.50, P <0.001 Personal-social: ES=0.46, P <0.01 Secondary Outcomes: <i>Home Observation and Measurement of environment (HOME):</i> Mothers in the light touch and full intervention groups had More learning and nurturing behaviours group (P <0.001) and providing more positive discipline (P <0.001) with their children and less harsh discipline behaviours with their children (P <0 .05) and (P <0.01) respectively No difference had been found in father's parenting behaviour among the groups.

Author/ Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Colombia Attanasio et al., 2018	Randomised Control Trial. Government FAMI programmes running: 87 towns were randomly allocated into 2 arms i. Intervention: 46 towns (n=702) ii. Control: 41 towns (n=758)	0-24 months Duration: 15 months	171 govt. FAMI mothers involved in the treatment arm. Mean age: 42 years Education: 13 years of education (high school degree) Experience: 12 years of working experience in the Govt. FAMI program.	Training: FAMI mothers received 3.5 weeks training sequentially by town. Refresher training: In every 6 months in throughout the intervention period. The refresher training includes feedback session. Supervision: Nine tutors supervised the FAMI mothers. Each tutor was responsible for 5 towns and 19 FAMI mothers. Each FAMI mothers was observed once in every 6 months by the tutor. The tutor observed 1 home visiting and 1 group session and provided feedback to the FAMI mothers. Each tutor was supervised by the study team once in every 2 months.	Home visiting session: Monthly 24 sessions Group session: Weekly 20 group sessions Additional 4 group session for 0-5 months old children.	ECD intervention: The curriculum is adapted based on Jamaican Reach up & learn. Age appropriate activities using age appropriate books, puzzles, homemade toys. Emphasis on improving cognition, language and motor development, maternal knowledge and responsive parenting. Nutritional supplementation : Monthly nutritional supplement with 35% daily calorie and 54% daily protein intake.	Group session: Group size: 5 mother child dyads Duration: 1.10 hours Group session comprised with 6 components; - Feedback from the previous group session (10 minutes) - Song (5 minutes) - Demonstration and practice of age appropriate play activity and language activity for the week with material (30minutes); - Discussion on parenting theme or activity (15minutes) - Review of the session (10 minutes) Mothers were split into 3 groups: pregnant to mother having 6 months old children, 6-11 months old children and 12 to 24 months. Cost: per child cost 320\$ per year which include 28\$ for toy and print material, \$82 for supervision, \$212 for additional nutritional supplements)	Primary outcomes: <i>Bayley Scale of Infant and Toddler development III:</i> - Cognition, - Language and - Motor development Ages and Stages <i>Questionnaire;</i> Socio-Emotional (ASQ:SE) <i>Anthropometric Measurement:</i> - Weight for age and - Length for age Z score Secondary outcomes: i. <i>Home Observation and measurement of Environment (HOME):</i> Home Stimulation iii. <i>Maternal knowledge on child development and child rearing practice</i> iv. <i>Maternal self- efficacy</i> v. <i>Food insecurity</i>	Primary outcomes: <i>Bayley Scale of Infant and Toddler development III:</i> Intervention vs control: Bayley factor score: ES=0.163, P=0.015 Expressive language: ES=0.151, P=0.016 Cognition: ES=0.142, P=0.069 Receptive vocabulary: ES=0.105, P=0.066 Motor skill and ASQ social emotional score was not differed between the groups. No effect on child growth. Secondary outcomes: Intervention vs control: <i>Home Observation and measurement of Environment (HOME):</i> Home stimulation: ES=0.34, P<0.001 Maternal knowledge on child development, self-efficacy and food insecurity did not differ between the groups. The differential treatment effect had been found between the group by maternal education and sex. The effect of family wealth on the outcomes had been found in the intervened group with effect size 0.22SD, P=0.029. Children from poorer families scored higher in cognition comparing to the children from affluent families.

Author/ Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Uganda Muheezi et al., 2018	Cluster Randomised Controlled Trial 511 mother & child dyads randomly allocated into 2 groups: i. Intervention (n=263) and ii. Control (n=248)	6-8 months Duration: 6 months	Education team comprised with 4 trainers (2 male and 2 female) Education: graduation degree in nutrition. Village Health Team: Locally recruited to conduct group sessions	Training: The Education team delivered group session and they trained mother leader or Village health team (VHT) leader to assist in delivering intervention Supervision: sessions were monitored by the supervisor	26 weekly group session	The stimulation intervention was developed based on social learning theory. <ul style="list-style-type: none"> • Role of play on the activities of cognition, language and motor development of children. • Messages on use, name and identifying body parts, hiding child's favourite item/toys and child has to find, • Screwing and unscrewing bottle lids imaginary • Songs, music, • Calling children by their name, responding to children by talking and using gestures • Holding objects by finger, throwing ball games, scribbling, kicking ball games for motor development • Messages on nutrition, health and hygiene practice were also included into the intervention. 	Group session Group size: unknown Duration: 6-8 hours long <ul style="list-style-type: none"> • The VHT leader or Mother leader organized monthly meeting to discuss on nutrition aspects with the mothers and conduct monthly follow up home visits to encourage the mothers to practice the intervention activities with the children. • The VHTs or Mother leaders together set the toy activities that are used for the development of the children. • They also identify the barriers and challenge 	Primary Outcome: <i>Bayley Scale of Infant and Toddler Development Scale III</i> - Cognition and - Language <i>Ages & Stages Questionnaire (ASQ):</i> - Problem solving, - Personal-social, -Communication, - Fine and - Gross motor <i>Anthropometric Measurement:</i> Length-for-age z score, -Weight for age, - Mid upper arm circumference (MUAC) and -Head circumference (OFC)	Primary Outcome: Findings at endline (20 months): Intervened children scored significantly higher in all developmental outcomes of both measurements. <i>Bayley Scale of Infant and Toddler Development Scale III</i> Intervention vs control: Cognition: ES=1.0, P <0.0001, Language: ES=0.73, P <0 .0001 Motor: ES=1.0, P < 0.0001 <i>ASQ sub-scales score:</i> Communication: ES=0.44, P<0.00001, Gross motor: ES =0.37, P< 0.0009, Fine motor: ES=0.4, P =<0.0005, Problem solving: ES= 1.4, P <0.0001 Personal-social: ES=0.84, P = 0.034. <i>Anthropometric Measurement</i> No difference had been found in the length-for-age, weight for age Z score, MUAC and OFC score between the groups at the age of 20 months

Author/ Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Indonesia Helmizar et al., 2017	Community based Randomised Controlled Trial 40 clusters of 5 villages were randomized into 4 arms i. Food supplementatio n (n=81), ii. Psychosocial stimulation (n=81) iii. Food + psychosocial stimulation (n=81) iv. Control group (n=81)	6-9 months Duration: 6 months	Locally recruited Community Health worker	Training: 2- days Supervision: -- A supervisor visited session with CHW to monitor and assess the quality of the session. -- Two assistant researchers observed mothers or caregivers who had practiced the psychosocial stimulation module in the parenting class. They also recoded compliance.	24 weekly centre- based parenting session	ECD intervention: A hand book developed containing play sessions standardized according to cognition, language, social and emotional development and comprised with traditional song and play activities. Nutrition intervention: Food supplementation: packet of formula food with adjusted with 200 to 250 kcal energy and 6-8-gram protein	Group session: Group size: unknown Duration: 1 hour Demonstration of play activities Focus on improving mother-child interaction. Toys and books were given to mothers to practice at home	Primary outcome: <i>Bayley Scale of Infant and Toddler Development (BSID III):</i> - Cognitive - Language and - Motor development <i>Anthropometric Measurement:</i> - Weight for age and - Length for age Z score	Primary outcome: <i>Bayley Scale of Infant and Toddler Development (BSID III):</i> PS+FS vs control group: Cognition: ES=0.56, P <0.001 Motor: ES=0.50, P<0.001 No significant difference was found in language development among the groups. <i>Anthropometric Measurement:</i> PS+FS VS Control: Weight for age Z score: ES=0.6

Author/ Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Caribbea Chang et al., 2015	Randomised Controlled Trial Fifteen Public Health Centres were randomly allocated to: i. Intervention (n=251 mother- child pairs) ii. Control (n=250 mother- child pairs) Integrated with Government Health Center	3-18 months Duration : 15 months	Community Health Workers. Government staff. Education: minimum 3 years of secondary education Government nurse of the health centres	Training: 3 days training. Training contains viewing of films and role play. Supervision: A supervisor visited the clinic, reviewed topics and provided feedback in discussion and practice. Supervisor conducted monitoring visit in every 6 weeks and used a 3-point checklist. The checklist consists ratings on how well the CHW demonstrated and involved with mothers and praised them.	Five sessions Each session consists of 5 visits at 3, 6, 9, 12 and 18 months of age.	Five 3 minutes short films on parental stimulation were developed to promote development of children. The film consists of 9 modules: i. Love, responding and comforting ii. Talking to children iii. Praise\ iv. Using bath time to play and learn v. Looking at books vi. Simple toys to make vii. Drawing viii. Games ix. Puzzle Nurses provided message cards to the mothers. Cards include information on the topic of the films. Book reading encouraged to increase mother-child interaction. Concepts such as in/out and big/little and the shapes circle and square were taught to mothers.	Group session Group size: Median=37 Range: 26 to 50 Duration: Median duration was 16 minutes Range: 14 to 20 minutes Nurses give 2-3 minutes per mother. The CHW discussed the topics and demonstrated with mothers in the waiting area. The CHWs were given manual before each health visits containing step of the session. Nurses discussed session. They gave picture books at 9 and 12 months of age and puzzle at 18 months of age. Mother attendance: At 3 months visits: 97.9% At 18 months visit: 89.4% All sessions: 83.1% Cost: yearly 100.9 USD per child	Primary outcomes: <i>Griffith Mental Development scales:</i> - Cognition - Language - Motor - Eye-Hand coordination <i>MacArthur-Bates Short Form of the Communicative Development Inventory (CDI)</i> <i>Anthropometric measurement:</i> - Weight for Age - Length for Age Secondary outcomes: <i>Home Observation and Measurement of Environment (HOME):</i> Subscales: -Involvement -Responsivity - Acceptance - Learning materials - Practice <i>Centre for Epidemiological Studies- Depression Scale (CES-D):</i> Maternal depression	Primary outcomes: <i>Griffith Mental Development scales:</i> Intervention vs control group: Cognition: ES=0.3 (95% CI:1.31, 4.87) No treatment effect was found in language, motor and eye-hand coordination and CDI scores between the groups. Secondary outcomes: Parental knowledge: ES=0.4 (95% CI: 1.01, 2.17) <i>Anthropometric measurement:</i> No group difference was found in children's growth No difference had been found in home stimulation and maternal depressive symptoms between the groups.

Author/ Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Zambia Rockers et al., 2016	Randomised Controlled Trial 30 villages were randomized into 2 arms: i. Intervention (n=268)) ii. Control (n=258)	6-12 months Duration: 1 year	10 local women as Community Development Agent (CDA) Education: 9 th grade education Experience: Previous working experience in community- based health service.	Training: 5 days Training included how to support and facilitate group session and screening of children. Supervision: CDAs filled up forms during home visits which includes information on tracking of implementation of the intervention. They also tracked the attendance of the caregivers during visits.	20 fortnightly group session	ECD intervention: - Parenting skill - Child nutrition - Cooking demonstration - Play activities on cognitive and language development	Group session: Group size: unknown Each group meetings led by a local ‘head mother’ selected by the community. CDA met the head mother prior to each group meeting and they provided training and materials of the respective session to them. Each CDA was responsible for 25 households. Session attendance: 89% mothers attended 10 or more sessions Caregivers attended average 14 session	Primary outcome: <i>Savings Brains Early Child Development Scale.</i> Parental report on child cognition and motor function were collected by using <i>INTERGROWTH-21st NDA tool:</i> Cognitive and Socio-emotional development <i>Anthropometric Measurement:</i> Weight for age and Height for age Z score Secondary outcome: Mother-child interaction <i>Self-Reporting Questionnaire (SRQ):</i> Maternal depressive symptoms	Primary outcomes: <i>Savings Brains Early Child Development Scale</i> Intervention vs control group Cognition: ES=0.11 (95% CI: -0.09, 0.32) Motor: ES=0.11 (95% CI: -0.11, 0.33) No significant difference in NDA score: ES=-0.10 (95% CI: -0.35, 0.15) <i>Anthropometric Measurement:</i> Intervention vs control group Weight-for-age: ES=0.12 (95% CI: -0.14, 0.38) Height-for-age: ES=0.15 (95% CI: -0.18, 0.48) Secondary outcomes: <i>Mother-child interaction:</i> Intervention VS Control group: Reading books: OR=3.58 (95% CI: 2.32, 5.52) Singing song with child: OR=3.38 (95% CI: 1.85, 6.18) Playing with child: OR=2.59 (95% CI: 1.64, 4.07) Maternal depressive symptoms: ES=-0.13(95% CI: -0.38, 0.11)

Author/ Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Uganda Singla et al., 2015	Community- based cluster- Randomised Control Trial 12 selected Parishes (Sub- districts) were randomly assigned into two arms: i. Intervention (n=194) ii. Control (n=154).	12-36 months Duration: 6 months	13 Community volunteers Gender: Female=6 Male=7 Education: 8 th grade education	Training: 2 weeks training at the beginning Refresher Training: 2 weeks refresher training in the middle of the intervention. Topic covered: program content, effective communication skill and motivational interviewing skill Supervision: Weekly Supervision includes the assistance of Community Volunteers to prepare their session, discussion of problems and feedback through a structured monitoring form. Each supervisor attended 6 sessions, and all supervisors attended first 3 sessions of the program.	12 fortnightly session	5 messages: i. Child care and maternal well being ii. Play with children using home-based materials, iii. Two-way talk with the child using story and picture, iv. Diverse diet and hand washing v. Discipline- teaching on how to show love and respect to others.	Group session + Home visit: Group size: Mother +fathers: Mean=28.6 (range: 21- 37) Mothers: Mean=18.1 (SD=4.74) Fathers: Mean=10.5 (SD:1.8) Duration: 60- 90 minutes. - Role play games - parent-child interactions and group- based problem solving. Families received their own activity booklet to practice at home. Home visit: Volunteers visited homes to follow up the 5 messages. Home visit lasted for 40- 50 minutes and a checklist was filled up by the volunteers	Primary outcomes: <i>Bayley Scale of Infant and Toddler Development:</i> - Cognition - Language and - Motor. Secondary outcome: <i>Home Observation and Measurement of Environment:</i> Home stimulation <i>Centre for Epidemiological Studies CES-D questionnaire:</i> Maternal depressive symptoms	Primary outcome: <i>Bayley Scale of Infant and Toddler Development:</i> Intervention VS Control: Cognition: ES=0.36 (95% CI: 0.12, 0.59) Receptive language: ES=0.27 (95% CI: 0.30, 0.50) No difference was found in motor skill. Secondary outcomes: <i>Home stimulation: Home Observation and Measurement of Environment:</i> Intervention VS Control: Home stimulation: ES=1.11, (95% CI: 0.85, 1.35) <i>Maternal knowledge:</i> ES= 0.36, (95% CI: 0.13, 0.59) <i>Centre for Epidemiological Studies CES-D questionnaire:</i> Intervention VS Control: Maternal depressive symptoms: ES= -0.39 (95% CI: -0.62, -0.16) P=0.010)

Author/ Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Pakistan Yousafzai et al., 2014	Community- based Cluster- Randomized Effectiveness Trial 1489 Children randomly allocated into 4 groups: i. Enhanced Nutrition (n=364) ii. Responsive Stimulation (n=383) iii. EN+RS (n= 374) iv. Control (n=368)	6 - 24 months Duration: 2 years	Government Lady Health Worker Education: 8 years education	Training of LHW EN group: 2 days training RS group: 3 days training on responsive stimulation curriculum For combined group: 5 days training Refresher training: 1 day refresher training in every 6 months. 15 days were allocated for refresher training in each year. Supervision: 6 supervisors supervised intervention sessions. Each supervisor supervised 25 LHWs and used a checklist to evaluate the quality of the session. The checklist includes information on: • Frequency, of LHW visits • Information about the last LHW visit; e.g. duration and purpose • Recall about advice provided pertaining to basic curriculum and enriched interventions	Monthly home visit & group session.	ECD curriculum: Adapted curriculum of UNICEF and WHO Care for Child Development package was used to promote sensitivity and responsively of the mothers using developmentally appropriate toys. The curriculum includes messages on care for development and problem solving. Nutritional supplementation: Sprinkles (multiple micronutrient powder)	Group session + Home visit: Group size: unknown Duration: 1.20 hours. The curriculum provided through monthly group meeting Home visit: The Care for development package was integrated regular routine home visits, lasted for 30 minutes.	Primary outcomes: At 12 and 24 months <i>Bayley Scale of Infant and Toddler Development III:</i> - Cognitive, - Language and - Motor <u>At 12 months of age:</u> Social-emotional scores <i>Anthropometric Measurement:</i> - Weight for age and - Length for age Z score	Primary outcomes: At 24 months age <i>Bayley Scale of Infant and Toddler Development III:</i> <u>RS VS Control group:</u> Cognition: ES=0.6 (95% CI: 0.5, 0.8) Language: ES=0.7 (95% CI: 0.5, 0.8) Motor: ES=0.5 (95% CI: 0.4, 0.7) RS+EN VS control group: Cognition: ES=0.5 (95% CI:0.3, 0.6) Language: ES=0.6 (95% CI:0.4, 0.7) Motor: ES=0.4 (95% CI: 0.2, 0.6) EN VS control group: Cognition: ES=0.2 (95% CI: 0.0, 0.4) Language: ES=0.4 (95% CI:0.3, 0.6) Motor: ES=0.2 (95% CI: 0.0, 0.4) Combined intervention group (RS & RS+EN) VS Control group: Cognition: ES=0.36 (95% CI:0.12, – 0.59) Receptive language: ES=0.27 (95% CI:0.03, 0.50) <i>Anthropometric Measurement:</i> EN group had significantly better height for age Z score than other 3 groups –2.4 [1.1] P=0.02. Weight for age not differed among the groups

Authors/ Country	Study design & Sample size	Child age & duration	Staffing	Training & Supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
<p>Bangladesh</p> <p>About et al. 2013</p>	<p>Randomized cluster trail</p> <p>25 villages as randomly allocated into:</p> <p>i. Intervention (n=<12mons =115, n≥ 12 months =111)</p> <p>ii. Control (n=<12mons =115, n≥ 12 months = 122)</p>	<p>6-18 month</p> <p>Duration: 10 months</p>	<p>i. Group session: Session provider with 10th grade educational qualification</p> <p>ii. Home-based session: Govt. Family welfare Assistant (FWA) with minimum 12th grade education</p>	<p>Training: Group Session: 4 days main training</p> <p>-3 bi-weekly 1 day refresher training</p> <p>Individual session: 2-days main training &1-day refresher training in the mid of the program.</p> <p>Supervision: Supervisor initially observed several sessions of each facilitator. Supervisor observed 10-15 household visits of each FWA over 1st 4 months.</p> <p>Fidelity checklist included: - Demonstration of appropriate activities - Following steps of demonstration.</p> <p>Fidelity checklist for 10-min counselling includes demonstration and problem solving.</p>	<p>Fortnightly : 14 fortnightly sessions for 4 months</p> <p>Monthly: 6 monthly sessions</p> <p>10-mintues home-based counselling session</p>	<p>Intervention includes: messages on</p> <ul style="list-style-type: none"> - Health - Nutrition -Communication -Play messages -Showing love - Avoiding harsh discipline - Responsive self-feeding and - Providing a diverse diet - Hand-washing before feeding and after defecation, -Talking and singing with the child, and - Providing Interesting play materials and playmates. 	<p>Group session: A card containing key practice message for 6-12 months and 12-24 months old children were given to mothers to remind to practice at home.</p> <p>Group size: 18 mothers</p> <p>Attendance: 85%</p> <p>Home visit: 10-minuts counselling session mothers at their home and community clinic</p> <p>Cost: Group session: per child USD 6.17 Home visits: USD 1.34</p>	<p>Primary outcomes: -</p> <p><i>Bayley Scales of Infant and Toddler Development III:</i> Cognition, Language and Motor</p> <p>Secondary outcome:</p> <p><i>Home Observation and Measurement of Environment:</i> Home stimulation</p> <p><i>Maternal knowledge on developmental milestones.</i></p> <p><i>Centre for Epidemiological Studies-Depression (CES-D):</i> Maternal depressive symptoms</p>	<p>Primary outcome: <i>Bayley Scales of Infant and Toddler</i></p> <p>Intervention vs control: Cognition: Younger children: ES=1.60, P<.0001 and Older children: ES=1.30, P<.0001</p> <p>Receptive language: Younger children: ES=0.89, P<0.0001 and Older children: ES=0.77, P<0.0001</p> <p>Expressive language: Younger children: ES=1.13, P<.0001 and Older children: ES=0.84, P<.0001</p> <p>No difference found in motor skill</p> <p>Secondary outcomes: Intervention vs control: <i>Home Observation and Measurement of Environment:</i> Home stimulation: ES=0.40</p> <p><i>Maternal knowledge on developmental milestones</i> Maternal knowledge: ES=0.68</p> <p><i>Centre for Epidemiological Studies-Depression (CES-D):</i> Younger children: ES=-0.06, P=0.73 Older children: ES=0.01, P=0.73 Maternal depression was reduced among the mothers of group session than home visiting group (P=0.004))</p>

Authors/ Country	Study design	Child age & duration	Staffing	Training & Supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Bangladesh Aboud et al., 2011	Cluster-Randomized Controlled Trial 45 villages randomized into 3 groups: i. Intervention : responsive feeding & stimulation (RFS): n=92 ii. Responsive feeding & stimulation+ sprinkles (RFS+S): n=100 iii. Control group: (n=110)	8-20 months Duration: 6 months	Locally recruited Peer educators Education: minimum 9 th grade	Training: 4 days Supervision: No information	Weekly: 5 Booster session Monthly: 3 sessions for 3 months Both intervention group received total 6 sessions. Control: 12 monthly sessions on basic health messages	Responsive feeding & Stimulation intervention: i. Hand-washing ii. Self-feeding iii. Maternal verbal responsivity iv. Solutions to child refusals v. Dietary diversity, and vi. Responsive stimulation during play. General messages on: i. Emphasis on behaviour strategy using practice ii. Problem solving and peer support Nutritional Supplementation: RFS+S group received sachet of sprinkle containing contained 12.5 mg of iron, 300_g of vitamin A, 150_gof folic acid, 50 mg of vitamin C, and 5 mg of zinc.	Group session: - Coaching to mothers, - Practice with children. - Mothers were asked to bring a play bag fill with household materials (cloth, spoons, sticks, pictures). Group size: 6 mother-child dyads	Primary outcome: <i>Bayley Scale of Infant Development BSID II</i> Language Skill: 11 language items were used. <i>Mother-child interaction:</i> Mother-child picture activity was measured using coding system. The frequency of each utterances of mothers during showing were recorded. <i>Anthropometric measurement:</i> Weight for Age Z score Secondary Outcome: <i>Home stimulation: Home Observation and measurement of Environment (HOME):</i> Home stimulation	Primary outcome: <i>Bayley Scale of Infant Development BSID II:</i> Combined intervention vs control: Language skill: ES=0.35, P<.0001 <i>Mother-child interaction:</i> Responsive talk: Combined intervention vs control: ES=0.40, P<.0001 <i>Anthropometric measurement:</i> Weight-for-age Z score: RFS+S VS RFS: ES=0.38, P=0.02. Secondary outcome: <i>Home stimulation:</i> Combined intervention vs control: ES=0.38, P<.0001 <i>Responsive feeding:</i> Combined intervention VS control: Number of mouthfuls: ES=0.35, P <.0001 No group difference in behaviour and length-for-age

Authors/ Country	Study design	Child age & duration	Staffing	Training & Supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Bangladesh Aboud et al., 2007	Intervention-control design i. Intervention: (n=170) who attended a year long educational program iii. Control group : (n=159)	30-48 months Duration: 12 months	Education: Facilitators with secondary level education.	Training: 17 days basic training on 40 topics of the manual. Refresher Training: Monthly Supervision: 4 days a month of supervision	Weekly: Educational session	The intervention topic includes common diseases and oral rehydration solutions, hygiene, sanitation, breastfeeding, weaning foods, micronutrient deficiencies, stages of cognitive and language development, how parents can help children learn, how to encourage language development, positive discipline, gender equality, and child rights.	Group session: Size: 9-25 mothers Duration: 90 minutes	Primary Outcome: <i>Home stimulation: Home Observation and measurement of Environment (HOME):</i> Home stimulation <i>Parental knowledge:</i> through a structured questionnaire <i>Mother-child interaction:</i> through picture talk <i>Child outcome:</i> <i>Wechsler Pre Primary Scale of Intelligence:</i> Receptive Vocabulary <i>Anthropometric measurement:</i> Weight for Age Z score	Primary outcome: Intervention vs control <i>Home stimulation: Home Observation and measurement of Environment (HOME):</i> ES=0.21 <i>Parenting knowledge:</i> knowledge on good practice for childhood development was significantly higher in the intervention group (ES=0.31) No effect on weight for age was found No difference in mother child interaction had been found between the groups. <i>Wechsler Pre Primary Scale of Intelligence:</i> Receptive Vocabulary No difference was found in receptive vocabulary between the groups Differential effect: in parenting group session, boys had higher receptive vocabulary than girls with the effect size η^2 0.013

Conclusion

The success of an integrated ECD program depends on the selection of an appropriate delivery platform with adequate resources and infrastructure to deliver the program at the community level. Effective delivery strategies are required to extend the reach of these programmes. One-to-one parenting sessions have been shown to be effective but are time intensive and may be difficult to scale in many contexts. Integrating programmes into the existing duties of the workforce without overburdening the existing staff is essential to maintain motivation and compliance. Using group parenting interventions may be an effective strategy for incorporating ECD interventions into existing staff's routine duties without imposing an extra work burden for them. The size of the group varies according to the local context, space, content of the curriculum and availability of resources. In the following section, I report on studies that have integrated ECD parenting interventions into existing government services, using a range of delivery methods: home visiting, group-sessions, and combined delivery models (**section:3**).

Section: 3

2.3.1: An overview of integrated studies: Evaluation and Challenges:

Substantial amounts of literature have showed the concurrent benefits effect of psychosocial stimulation intervention on the development of children in early years of life (Jeong et al., 2021). The recent Lancet series depicted the need for integrating early childhood development programs into existing services and the importance of generating new evidence in support of such integrated models (Shonkoff et al., 2017).

Several systematic reviews illustrated that the integrating ECD programs into existing service delivery platforms such as nutrition or health services can be effective in improving young children's development (Yousafzai & Aboud, 2014). Here I present the implementation process of selected integrated programs and the findings of eleven ECD intervention trials from different low and middle-income countries.

2.3.2: Study Review

Study 1: The Brazil integrated home visiting program with Family Health Strategy:

Brazil has launched a policy related to home-based Primary Care for child survival and nutrition in 2001. Currently the program covers 64% of the populations in Brazil and involves Community Health Workers (CHW) to promote health and health education in the community and to build linkages between the community and the health sector. In this study, an ECD program was integrated with Government Family Health Strategy (FHS) and carried out in the FHS and non FHS catchment areas enrolling 826 children aged 9-15 months old, half of whom received bi-weekly ECD session and half were control. In the FHS area, the existing CHWs delivered

parenting sessions for one year and were given a stipend of 30% of their salary. In non-FHS areas, a separate cadre of staff Child Development Agent (CDA) was recruited by the research team to run the ECD program.

The study used an adapted version of the Jamaican Reach up & Learn curriculum. The study found significant program benefits on child cognition (Effect size=0.22, P=0.05) and language (Effect size=0.22, P=0.05) skills of the intervention group in non-FHS area, that is when specially recruited staff were responsible for program implementation. In FHS areas, the CHAs perceived the home visiting as extra workload for them due to distance and travelling time. Only 9% of mothers received home visiting session by the CHW. Therefore, in this context, utilizing existing staff was not feasible and alternative approaches are required (Brentani et al., 2021).

Study 2: Integrated early childhood program with Primary Health Care platform in Lesotho:

In this study, the early childhood development program was integrated into a government health center located in a rural area of south western region in Lesotho. The catchment population of the health centre is 15000 persons. The centre consists of two types of Village Health Workers who are involved with two types of health service in the community: 1. TB and HIV and 2. Maternal and child health care. This study used a prospective case control study design. The intervention groups consisted of 130 caregiver-infant dyads and 125 were in the control group and did not receive any intervention. The age range of the children was 7-11 months. Mothers received total of 7 Caregiver education sessions: four group sessions (with a group size of 4-5 participants) were held at the health centre and three home visiting sessions (group size= 4/5). The sessions were spread to week 6, 8, 10, 12, 14, 16 and 18. Session of 6, 10, 14 & 18 were conducted by a trained ECD nurse in the health centre, these dates were corresponded to national

immunisation schedule. The remaining three sessions took place in the households, were conducted by maternal health Community Health Volunteers (CHV) without any extra incentive. The ECD intervention package used in the study was adapted from a Peruvian program focusing on 4 key elements: 1) knowledge sharing about child development and child observation; (2) demonstration and initiation of social interaction activities tailored to the child's development; (3) caregiver encouragement on caregiving behaviour, development and interactions; and (4) caregiver social support and reassurance. The intervened group scored significantly higher in communication, personal-social, motor development skill and total ASQ score ($P < 0.05$ for all) than the control group. The mothers of intervened group also reported doing more stimulation activities with their children including book reading, story-telling, singing songs and naming & counting objects ($P < 0.05$). The findings highlighted that integrating an ECD program into the rural primary health care platform was feasible and has the potential to take into scale (Ndayizigiye et al., 2022).

Study 3: China home visiting parenting intervention using Family Planning Service:

The study evaluated the impact of home visiting parenting intervention, delivered by staff of the Family Planning Commission (FPC) on the development of children using a randomised trial. After the termination of 'One Child Policy', the FPC started to include early childhood education and care. The commission formerly operated the family planning service in the community. The FPC has the appropriate infrastructure at the community level to implement the parenting program. In this study, The FPC recruited additional parenting trainers to deliver the parenting program. The programme was evaluated in 131 villages (intervention=65, control=66). A total of 592 children aged 18-30 months old living in 131 villages were enrolled in the study. The curriculum used in the study was adapted from Jamaican Reach up & Learn curriculum. Mothers

received weekly home visit for 6 months from the parenting trainers. The intervened group had better mental development Index with an effect size of 0.29. Mothers of the intervened group had improved parenting skill (ES=0.32). The family planning infrastructure in China has potential for delivering the home visiting program to young children successfully (Sylvia et al., 2021).

Study 4: A Cluster Randomized Community Effectiveness Trial on group-based parenting intervention Kenya

The study was a cluster randomized trial integrated with Kenyan non-government organization, Safe Water and Aids Project (SWAP). The study was implemented in 60 villages with a high prevalence of child mortality and stunting in the SWAP catchment area and the villages were randomly allocated into three groups: 1) only group intervention consisting of sixteen fortnightly session (n=376 children) 2) mixed delivery with twelve group session and four home visits (n=400 children) and 3) comparison group (n=376 children). Children's age range was 6-24 months. Existing Community Health Volunteers (CHV) delivered group sessions and they received a monthly stipend from the project. The intervention ran for 8 months. The average group size was ten to fifteen participants and each group lasted for 90 minutes. The group only intervention arm scored higher in cognition (ES=0.52), receptive language (ES=0.42) and social-emotional development (ES=0.23) than the comparison group. The mixed delivery group had better cognition (ES=0.34) and socio-emotional skill (ES=0.22) than the comparison group although no benefit was found for receptive language scores. Parental stimulation was also significantly improved in the group only and mixed delivery group with the effect size 0.80 and 0.77 respectively. The findings indicate the potentiality of scaling up the ECD program using community volunteers in the primary health service in Kenya (Luoto et al., 2021).

Study 5: Peruvian Integrated ECD program with Wawa IIIari project to enhance ECD outcome of children

The study is integrated with the Wawa IIIari project under the Ministry of Health and it runs three programmes in urban settings of Peru: (1) creation of community and home gardens, (2) workshops in conscious nutrition and meal preparation, and (3) improvement of the caregiver-child interaction. The International Child Development Program (ICDP) program was used and combined with the home/community garden workshop. The government Community Health Providers (CHP) delivered the programme and each CHP was assigned to 7-11 families. The communities under the programme were randomised into intervention communities (sample size: n=113 children) and control communities (n=127 children). The ICDP consists of home visits and it focuses on eight guidelines: i). Show love and positive feelings to your child ii) Follow and adjust to your child's initiatives, iii) Establish close communication, with or without words, iv) Praise and appreciate on child's efforts and achievements v) Establish shared focus and attention with your child, vi) Provide meaning by naming and describing things and actions, and vii) Expand on meaning by connecting, comparing and using creativity (songs, stories, painting etc.). The findings showed reduced risk of language and motor delay of the children in the intervened group. The intervened mothers had better interaction with their children and increased stimulation activities ($P<0.0001$). There were some challenges in involving the CHPs. Initially, 15 CHPs were trained as part time workers, However, seven left the job. In addition, some of the CHPs found the messages are difficult to understand and recall. To mitigate this challenge, weekly sensitization meetings were organized for the CHPs to increase their confidence. Other challenges involved selecting suitable locations in the communities and gathering all mothers at a specific time. This challenge was addressed by CHPs delivering ICDP

guidelines at participant's home. Significant benefits were found for children's language development but not for motor or cognitive skills. (González-Fernández et al., 2020).

Study 6: An evaluation of home visiting program on children's development in China

This study involved integrating an early childhood development program integrated with the Government health service; 91 home visitors were recruited by the local government to deliver the intervention. The study is a randomized controlled trial; 111 villages were randomly allocated to intervention villages (n=56) with 715 children and control villages (n=55) with 820 children aged 0-24 months old. The China Reach Curriculum was used in the study, adapted from Jamaican Reach up & Learn curriculum. The intervention involved weekly home visiting for twenty-one months. Benefits were found for cognition (effect size (ES)=0.75), language (ES=0.75), motor (ES=0.73) and socio-emotional skill (ES=0.40) (Heckman et al., 2020). This study showed that it is possible to integrate ECD into a government health programme although an additional cadre of staff were recruited to implement the intervention.

Study 7: An integrated parenting program in rural China:

The study was integrated with Health Promotion program in rural China and integrated stimulation with child health promotion. The program was delivered by the local Community Health workers (CHW) who conducted home visits as part of the Nutrition Health Care service. They also provided nutrition and health education during home visits. Forty-three villages were randomly allocated to intervention (n=222 children) or control (n=227 children). The adapted version of Jamaican Reach up & Learn curriculum was used. The intervention lasted for one year and children were age 6-18 months at baseline. The intervention benefited child cognition (Effect Size=0.24) and increased home stimulation (Effect Size=0.35). The authors conclude that

the integrated program of health promotion and psychosocial stimulation was beneficial in improving developmental outcomes of the children and feasible to scale (Luo et al., 2019).

Study 8: Community based integrated nurturing care intervention in rural China and early development of children

The study evaluated the effect of an Integrated Early Childhood Development (IECD) Programme using a nurturing care framework-based intervention package through a quasi-experimental design. The Integrated Early Childhood Development (IECD) Program was launched in 2014 by the government, and delivers a cross-sectoral package of nurturing care to children below 3 years of age in forty poverty prone rural areas. There was an ECD centre in each village under the IECD program, and this was equipped with toys, story books, and touch screens. The study aimed to assess the effectiveness of the intervention in decreasing the prevalence of development delay in children below 3 years of age. The IECD program was running in 40 counties and each county consists of 10 villages. 83 villages randomly selected from the selected counties and were again randomly allocated into intervention (n=40) and control (n=43). All children aged below 3 years old residing in the respective villages were enrolled in the programme. The caregivers and children received group intervention at the center. The intervention includes content on child health, nutrition, responsive care, protection and early learning. The content is designed according to age of the children and emphasis was placed on promoting mother-child interaction. The activities include mother-child play activities and reading to children. The key findings are: i) Overall Suspected Developmental Delay (SDD) decreased from 37% to 19% ii).SDD decreased in communication (OR= 0.69, P=0.049) iii) SDD decreased in gross motor (Odds ratio (OR)=0.65, P=0.035) iii) SDD decreased in fine motor (OR=0.40, P<0.001) iv) SDD decreased in Problem solving (OR=0.50, P<0.001 v) SDD

decreased in personal-social (OR=0.58, P=0.017). The community based integrated intervention could be an effective measure to reduce the risk of developmental delay of young children (Zhou et al., 2019).

Study 9: Effect of Integrated program of nutritional supplementation and home visiting on growth and development of children in Madagascar:

In this study, the early childhood development programme is integrated with the Government community-based nutrition programme named Standard of Care. The programme provides growth monitoring, nutrition education and health referrals to children and to pregnant and lactating mothers by the existing Community Health Workers (CHWs). 125 sites that were running the Standard of Care program were randomly allocated to five intervention groups: i). Standard-of-care programme with monthly growth monitoring and nutrition education (T0, n=497 children) ii). T1=T0+Home visit for nutrition counselling (T1, n=500), iii) T2=T1+ lipid-based nutritional supplementation (LNS) for 6-18 months old children (T2, n=494) iv) T3= T2+LNS for pregnant or lactating mothers (T3, n=499) v. T4= T1+Home visiting programme (T4,n= 500) on early childhood development. The micronutrient supplementation (LNS) was provided during pregnancy and infancy by the government. The intervention includes 48 fortnightly sessions and ran over 2 years. The existing Community Health Workers were involved with delivering the monthly Standard-to-Care programme. They were responsible for growth monitoring activities of infants and children, cooking demonstrations, community mobilization and nutrition and hygiene education. An additional number of CHWs were recruited by the government for conducting the home visiting sessions to provide nutrition counselling and child stimulation activities. Their home visiting session schedule was: one visit during pregnancy, monthly visits for the first eight months of age, bi-monthly visits from 9 to 12

months of age and quarterly visits from 12 to 24 months of age. The CHWs received extra theoretical and practical training on ECD messages. The curriculum used in the study was adapted from Jamaican Reach up & Learn home visiting programme. No difference was found in any of the developmental domains between the groups. The study reported challenges in providing toys to children due to cost constraints and difficulties in conducting home visiting sessions due to geographical diversity. The toy materials are a core component of Reach up & Learn and so it is not surprising that no benefits were found when toys were not provided to mothers to use at home. In addition, the communities in rural Madagascar are spread over large areas with low density and households were scattered and this caused logical challenges to CHWs and required additional time for traveling long distance. Another reason for the lack of significant benefits may be the low levels of supervision which was due to lack of resources (Galasso et al., 2019).

Study 10: A scalable intervention on early stimulation integrated with Government program in Colombia:

Attanasio et al. (2022) evaluated the effects of enhancing an existing government parenting programme in Colombia. The program is run by FAMI mothers under the Government Family Welfare Agency and delivers services to disadvantaged pregnant women and mothers with children up to two years of age. In this project, the FAMI mothers delivered weekly group sessions and monthly home visits with mothers and their children (aged 0-24 months). In the study, 87 towns were randomly allocated to intervention (n=46 towns with 702 children in the evaluation sample) or control (n=41 towns with 758 children). The enhancements involved training FAMI mothers to use adapted versions of Jamaican Reach up & Learn curriculum in both the group sessions and the home visits. The intervention benefitted child cognition (effect

size=0.16) and home stimulation (effect size=0.34) (Attanasio et al., 2018). The study showed that it was possible to integrate an evidence-based curriculum into the existing FAMI program. However, FAMI mothers initially found it difficult to adjust activities according to child's developmental level and needed time to become competent at delivering the curricula. Furthermore supervision levels were low (approximately once every six weeks) and play materials were not always lent to the mothers for use at home (Attanasio et al., 2022; Gomez et al., 2021).

Study 11: Health centre based integrated parenting intervention in Caribbean:

The study is a cluster randomized controlled trial of integrating an early child development intervention into the existing maternal and child health care service. In each centre, a Public Health Nurse with support from Community Health workers runs the routine health services. The ECD intervention was incorporated into this routine health care service, and mothers received parenting information during the routine immunization and health check-up when their child was age 3, 6, 9, 12 and 18 months. Fifteen public health centres were randomly allocated to intervention (n=250 mother-child dyads) and control (n=250 mother-child dyads in the evaluation sample). Five short films consisting of nine modules on early child development messages were shown in the health centre waiting area followed by a practical session led by the community health workers. In addition, when the mother saw the nurse, she reinforced the topic and encouraged the mothers to use the strategies at home. Mothers were given a picture book at nine and twelve months of age and a puzzle at eighteen months of age. They were also given a take-home card after each clinic visit with key points from the sessions. Significant benefits were found for child cognition (effect size=0.3) and the mothers' parenting knowledge also increased

(effect size 0.4). No significant benefit was found on children language score or quality of home stimulation. Despite some limitations such as- the crowded and noisy environment in the clinic, difficulties in interacting with mothers during session demonstration, and staff turnover, the clinic-based intervention could be an effective platform for improving the children's cognitive development without involving additional staff or requiring extra time of the caregivers (Chang et al., 2015). However, the benefits to child development were not sustained at the age of six years (Smith et al., 2021). The initial study was successfully integrated with health service; however, the program effect on the children was not sufficient for long-term benefits to child development (Chang et al., 2015).

Study 12: Integration of responsive stimulation within the Pakistan Lady Health Worker programme—A cluster randomised factorial design

The Lady Health Worker (LHW) programme in Pakistan is part of the Government Family Planning and Primary Health Care service in which the Lady Health Workers provide health service to families in rural areas. In this study, an early child development programme was integrated into the duties of LHW. LHWs delivered a responsive stimulation intervention to mothers with children aged from birth to 24 months of age. Eight LHW catchment areas were randomly selected and again randomly allocated to 4 groups: 1) Responsive stimulation and enhanced nutrition (n=374 children), 2) Responsive stimulation alone (n=383 children), 3) Enhanced nutrition alone (n=364 children) and 4) control (n=368 children). The intervention consisted of monthly home visits and group sessions and lasted for 2 years. The adapted curriculum of UNICEF and WHO Care for Child Development package was used. The duration of group session was about 70 minutes and home visits 30 minutes. At the end of the intervention, children in the responsive stimulation group scored significantly higher in cognition

(Effect Size=0.6), language (Effect Size=0.7) and motor (Effect Size=0.5) development. The responsive stimulation plus enhanced nutrition group had better cognition (Effect Size=0.5), language (Effect Size=0.6) and motor skill (Effect Size=0.4) development than the control group. The intervention also benefitted the language (Effect Size=0.4) of children in the nutrition only group. These children were followed up at the age of 4 years. At follow up, the combined group of responsive stimulation plus enhanced nutrition and the responsive stimulation only group had higher intelligence quotient (Effect Size=0.1), executive functioning skill (Effect Size=0.3), pre-academic skills (Effect Size=0.2) and pro-social behaviour (Effect Size=0.2) compared to the no stimulation group. The program faced some challenges initially. For example, some LHW's took time to develop skills for effective implementation and there was community scepticism towards the program. These challenges were mitigated through supportive supervision, and community sensitization by the LHWs. Overall, it was feasible to integrate the programme into the community-based health care service (Yousafzai et al., 2014).

The studies are more or less successful in integrating with any existing service platform and most of the programs showed beneficial effect in improving early development of the children.

However, there is always a scope for learning new experiences when any program is being integrated with another program, especially with government services. The above studies faced different types of challenges according to their respective local context and some studies reported mitigation strategies. Some implementation challenges involved service providers' workload, session delivery strategy and community acceptance.

In the following section some of these issues are discussed in more detail.

2.3.3: Key indicators of successful implementation of integrated program

Adjustment of ECD activities with work schedules of the service providers

The studies used either existing staff or hired new staff by government. In Brazil, the Health workers were paid extra salaries (30% of the wages) for conducting home visiting sessions in their catchment areas (Brentani et al., 2021), whereas in Madagascar additional health workers were recruited to conduct home visits (Galasso et al., 2019). Despite the attempt to add extra incentives or workforce, children in both studies showed little improvement in their developmental outcomes. In Brazil, home visiting required an extra effort, time and traveling that demoralized the health workers in spite of the extra salary. Moreover, some trained health workers refused to conduct home visits; they perceived this as merely an extra workload for them. In addition, difficulties in completing home visits in a single attempt and rescheduling by the parents caused additional work burdens for the health workers (Brentani et al., 2021). In Madagascar, the travelling distance was a barrier to conducting the home visits.

In contrast, health workers in Colombia and Pakistan more easily adjusted the home visiting sessions into their routine work and significant benefits were found for children's cognitive and language development without receiving any extra incentive (Attanasio et al., 2018 ;Yousafzai et al., 2014). In both of these contexts, the health staff were already conducting home-visits and child development content was added to these existing visits. In the Caribbean clinic study, the intervention was delivered by the Community Health Workers (CHW) and nurses in the health centres. Each health centre was staffed by two nurses and six CHWs. The CHWs were overloaded, especially where there was a shortage of staff and where they faced difficulties

managing time for home visits (Smith et al., 2018). Lack of adequate numbers of staff is a major problem as it creates an additional work load for the existing staff.

Supportive supervision can play a key role in mitigating these challenges by enhancing the facilitators' skills and sustaining motivation to deliver sessions more effectively. In Colombia, the FAMI mothers stated that they lacked confidence to use the new curriculum at first; however, over time, they improved their skill with the help of the tutors (Gomez et al., 2021).

In the Pakistani Lady Health Worker Program, at the early stages of the intervention, the LHWs did not always deliver the parenting sessions efficiently. However, with ongoing supervision, they acquired the required knowledge and skills related to the intervention content and also became more competent at adjusting the session schedule into their routine work. For example, in the early stages of implementation, only 69% of the LHWs praised the efforts of mothers, but this increased to 91% of LHWs after 1 year of intervention (Yousafzai et al., 2018). These are the key elements of nurturing CHWs' capacity to deliver the program more effectively (Yousafzai et al., 2018). Creating a collaborative relationship between the health workers and the supervisors is key to enhancing HWs self-confidence, increasing their acceptance of the programme and increasing their problem-solving abilities.

Session Delivery point

Another key factor is the location of the session. For example, in the Caribbean clinic study, delivering group sessions in the health centre was difficult due to the noisy, hot and crowded clinic environment that prevented mothers from paying full attention towards the session (Smith et al., 2018). Home visits were perceived as an extra work burden by CHWs in Brazil due to the travel time and the fact that mothers were not always home at the allotted time. In Colombia, FAMI mothers conducted group sessions and home visits and both were valued as they were

perceived to have specific advantages. For example, home visits were more personalized and there was less distraction, while groups sessions facilitated peer learning (Gomez et al., 2021). Therefore, it is important to consider the local context and staff workload and preferences when designing a scalable program.

Community sensitization

Community sensitization is another important factor to engage families and communities in ECD programmes. In Pakistan, the Lady Health Workers (LHW) provided door-to-door service with health counselling and treatment for minor ailments. Initially, the programme was less acceptable in the community, and community people were sceptical about the importance of the program (Yousafzai et al., 2018). The beneficiary mothers played an active role in increasing community interest towards the program; they informed other mothers and the neighbours and the community people about the importance of the program in the development of their children (Yousafzai et al., 2018).

The negative perceptions of people in the community and neighbourhoods can have a salient impact on a family's engagement in the programme and can result in mothers' low attendance or withdrawing from sessions. Community mobilization meetings have been shown to be effective in raising awareness and sensitizing families to participate the program (Akter et al., 2020).

Relationship between the service providers and the participants

Rapport building and maintaining positive relationships with the participants is an important factor for motivating mothers to attend the sessions regularly. In China, the authors found that where the home visitors had better relations with the mothers, the children scored higher than children in families with poor relationships between mothers and home visitor (Heckman et al.,

2020). Hence, relationship-building techniques needs to be a key component in training and supervision.

Conclusion

Supportive supervision, intensive training, community mobilization, attention to the workload of the existing staff, and effective partnership between stakeholders are some of the key requirements for successful integration of ECD services into existing programs. More studies on feasibility assessment are required to generate evidence to identify the key enablers and challenges of integrating ECD program with different existing service platforms. The summary of the studies is presented in **Appendix 8.2**.

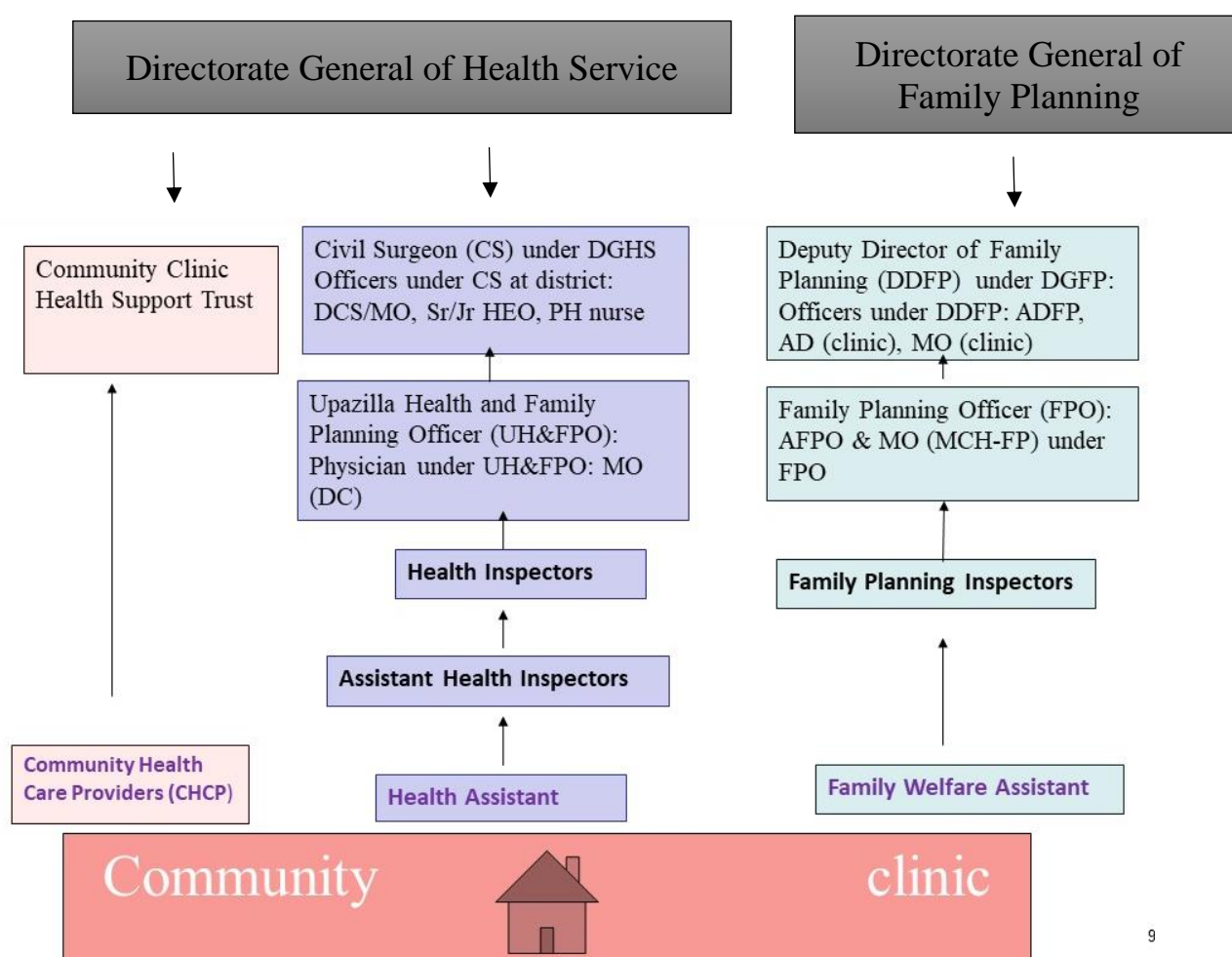
Section: 4

2.4.1: Summary of Bangladeshi studies integrated with primary health service:

In the light of the previous sections, establishing delivery models that involve integrating ECD activities into an existing service delivery platform is important for scaling up an ECD programme. In Bangladesh, considering the required resource, infrastructure and coverage, the Primary Health Care Service is a potential delivery platform as this is where pregnant women and children below 5 years of age receive health care at the community level. In addition, the PHC service already has a suitable organizational structure with a large number of accessible community clinics and suitable staff and supervisors in place. Therefore, if the child development program can be integrated with the Primary Health Care Service, large numbers of mothers and children will benefit. With the long-term aim of building a sustainable infrastructure for early childhood development service countywide, we conducted a pilot study followed by three cluster-randomised trials testing the effectiveness of integrating ECD into the Primary Health Care Service and utilising existing staff.

The Ministry of Health and Family Welfare (MoHFA) conduct the health service and family planning programs in Bangladesh. MoHFA consists of two divisions: Directorate General of Health Service (DGHS) and Directorate General of Family Planning (DGFP). Both DGHS and DGFP have district, sub-district and community level health services and have a separate infrastructure (**Figure 2.1**). DGHS run the program through Upazila Health Complex. Community Clinic (CC) is the lowest tier of DGHS providing health care service in rural areas

Figure: 2.1: District level infrastructure of the PHC health system



9

Description of the Community Clinic

Community clinics are the lowest tier of health facilities which are established in rural areas in Bangladesh including in remote and hard to reach areas. Community clinics (CC) provide a one stop service of primary health, family planning and nutrition at the community level. The CC provide free treatment, free drugs, need-based health services and immunisation services. The community clinic programme was revitalized in 2009 and at present 13,136 CCs are actively functioning, soon two hundred more CCs will be added to this number. Community clinics are a unique example of public-private partnership, all the CCs have been constructed on the land donated by village elites. The Government supplies medicines, contraceptives, logistical support

and other necessary goods to CC and recruit community clinic health care provider (CHCP) to run the CC. CHCPs are trained on how to provide basic health services within the community. They also receive refresher training at different time intervals. Health Assistants (HA) and Family Welfare Assistants (FWA) also support CHCPs at the CC. CHCP work six days a week in the CC and HAs and FWAs assist CHCP 3 days a week. The CHCPs are involved with delivering basic health care and treatment. The HA mainly conduct immunization activities and FWAs perform door-to-door visits, maintaining birth registries providing family planning counselling and contraceptives and birth control materials. The CHCPs and HAs mostly have Masters degrees. FWAs have mostly completed higher secondary education. The service hour of the CC is 9 am to 3.00 pm. Generally, patients come to clinic at morning and the clinic is relatively quiet in the late morning and early afternoon. The CC activities are managed by both Government recruited staff and community leaders to carry on the improvement of CC service. The catchment area under each CC is around 1200-1500 households with a population coverage of approximately 6000-10,000 persons.

With the long-term aim of scaling up the ECD program, we conducted four studies between the 2014 to 2019 using the infrastructure of Primary Health Care Service. We collaborated with the Ministry of Health and Family Planning and signed a memorandum of understanding (MOU) to use the community clinic and to train the service providers to deliver the intervention. The summary information of the respective studies is given below:

2.4.2. Paper: 1

Title: Integrating an early childhood development programme into Bangladeshi primary health-care services: an open-label, cluster-randomised controlled trial:

Authors: Jena D Hamadani, Syeda Fardina Mehrin, Mohammed Imrul Hasan, Fahmida Tofail, Najmul Huda Deborah Ridout, Helen Baker-Henningham, Sally Grantham-McGregor,

Hamadani, J. D., Mehrin, S. F., Tofail, F., Hasan, M. I., Huda, S. N., Baker-Henningham, H., Grantham-McGregor, S. (2019). Integrating an early childhood development programme into Bangladeshi primary health-care services: an open-label, cluster-randomised controlled trial. *The Lancet Global Health*, 7(3), e366-e375. [https://doi.org/10.1016/S2214-109X\(18\)30535-7](https://doi.org/10.1016/S2214-109X(18)30535-7).

This study is a cluster randomised controlled trial the study was integrated Primary Health Service, under the Ministry of Health and Family Welfare (MoHFW). Ninety Community Clinics were randomly and randomised into intervention and control. Children aged 6-24 months under each CC catchment area were screened for malnutrition and children having mild to moderated malnutrition defined as a weight-for-age Z score of -2 SDs of the Weight-for-Age Z scores of -2 SD of the WHO standard were enrolled into the study; intervention (n=878) and control (n=859). The frontline health workers conducted the session with two dyads of mother and child together twice a month; the sessions lasted 30-40 minutes. The intervention ran for 1 year. The adapted version of the Jamaican Reach up & Learn curriculum was used in the study using low-cost play materials covering the activities of 6-36 months. A subsample of 658 children (eight children from each CC) cognition, language, motor and behaviour were assessed at pre and post and we found significant benefit in all developmental domains. Home stimulation and maternal knowledge of the intervened group also improved significantly. We found reduced depressive symptoms in the mothers of the intervened children (see **Appendix 8.2**).

This study is associated with the other three studies and had been carried out along with the group intervention study. However, this study is not part of my thesis, I presented the paper in Appendix 8.2 of my thesis.

2.4.2: Paper 2

Title: Adapting an Evidence-Based, Early Childhood Parenting Programme for Integration into Government Primary Health Care Services in Rural Bangladesh

Syeda Fardina Mehrin, Jena Derakhshani Hamadani, Nur-E-Salveen, Mohammed Imrul Hasan, Sheikh Jamal Hossain, Helen Baker-Henningham

Mehrin, S. F., Hamadani, J. D., Salveen, N.-E., Hasan, M. I., Hossain, S. J., & Baker-Henningham, H. (2021). Adapting an evidence-based, early childhood parenting programme for integration into government primary health care services in rural Bangladesh. *Frontiers in Public Health*, 8, 1052. <https://doi.org/10.3389/fpubh.2020.608173>

In this pilot study, we adapted the Reach-Up and Learn curriculum for group delivery and tested the feasibility, challenges and process of integrating the programme into the primary health care infrastructure in rural Bangladesh. The study included (1) adapting the Jamaican Reach up & Learn curriculum for the use in the local context by government health staff (2) testing the delivery of the intervention to pairs and to small groups of mothers and children, (3) documenting the perspectives of government health staff and utilizing these inputs to revise the intervention. We developed two versions of the parenting programme, one for use with pairs and one for use with small groups of mothers and children aged 6-36 months. The final outputs of this study were two versions of an early childhood parenting programme, suitable for use within government primary health care services in rural Bangladesh, to be tested in randomised trials (**Chapter 3**).

2.4.3: Paper 3:

Title: Integrating a Group-Based, Early Childhood Parenting Intervention into Primary Health Care Services in Rural Bangladesh: A Cluster-Randomized Controlled Trial

Authors: Syeda Fardina Mehrin, Mohammed Imrul Hasan, Fahmida Tofail, Shamima Shiraji, Deborah Ridout, Sally Grantham-McGregor, Jena D Hamadani, Helen Baker-Henningham

Mehrin, S. F., Hasan, M. I., Tofail, F., Shiraji, S., Ridout, D., Grantham-McGregor, S., Hamadani, J. D., & Baker-Henningham, H. (2022). Integrating a Group-Based, Early Childhood Parenting Intervention into Primary Health Care Services in Rural Bangladesh: A Cluster-Randomised Controlled Trial. *Frontiers in Pediatrics*. <https://doi.org/10.21203/rs.3.rs-1393282/v1>.

Based on the finding from the pilot study, we conducted a cluster randomized controlled trial involving integrating an early childhood parenting program into the government primary health care system with the intervention delivered by existing staff as part of their routine duties. We evaluated the effect of the programme on child development, growth, and behaviour. We randomly selected 40 Community Clinics (CC) out of 74 eligible from the Kishorganj district and randomized into intervention (n=20) or control (n=20). We enrolled the children aged 6-24 months with weight for age $<-1.5sd$ living under the CC catchment area. Government health workers conducted fortnightly parenting session with small groups of 4-5 mother-child dyads at the CC as a part of their routine work. The intervention ran for 1 year. All children were measured at the beginning and the end of the intervention to assess intervention effect. We found significant benefits to child development and behaviour and to home stimulation, parenting knowledge and maternal depression (**Chapter 4**).

2.4.4: Paper: 4

Title: Effect of incorporating early child development programme into existing monitoring and training system of primary health services: A cluster randomized controlled trial

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After the successful implementation of the previous study, we conducted another study using cascade model of training. This involved training government supervisors to train and supervise government clinic staff in intervention implementation. We selected two sub-districts of a periphery district, and randomly selected eight unions from each sub-district and randomized the unions to an intervention (n=8) or control (n=8) group. We listed all Community Clinics (CC) in the 16 unions and randomly selected 24 CCs (intervention =12, control=12) for inclusion in the study. We collected a list of children aged 6-30 months old living close to the CC and invited the first 24 children (N=576) successively from each CC for intervention. Selected mother/child dyads were invited to a 6-month intervention consisting fortnightly sessions with group of 4-5 mothers and children. We provided 'Training of Trainers' to the Health Inspectors, Assistant Health Inspector and Family Planning Inspectors who are the immediate supervisors of the health workers and these inspectors then trained and supervised the clinic staff. For evaluation, we randomly selected two clinics from each union and 12 children per clinic. Significant benefits of intervention were found for stimulation in the home (measured as a proxy for child development). There was no difference in burnout between the health workers of intervention and control CC. Although we found high compliance with training, health staff conducted the majority of the parenting sessions and high mother attendance at sessions, supervision levels by government

inspectors were low. Our findings suggest that implementing a parenting program using the health service and government monitoring system is feasible and effective. However, additional attention needs to be paid to implementation, especially relating to providing high quality ongoing supervision (**Chapter 5**).

The detail of the above three studies are presented in the subsequent chapters (**CHAPTER: THREE, FOUR & FIVE**).

CHAPTER: THREE

Title: Adapting an evidence-based, early childhood parenting programme for integration into government primary health care services in rural Bangladesh

3.1: Abstract

This paper describes the process of adapting an early childhood development programme, with proven effectiveness in Bangladesh, for integration into government health services in rural Bangladesh. Through a three-stage process, we adapted an evidence-based, home-visiting, programme (Reach-Up and Learn) for delivery in government health clinics by government health staff as part of their regular duties. Stage one involved preparing an initial draft of two parenting interventions for use with: 1) pairs of mother/child dyads, and 2) small groups of mother/child dyads. In stage two, we piloted the adapted interventions in nine clinics with a total of twenty-seven health staff and 357 mother/child dyads. We used data from mothers' attendance, feedback from participating mothers and health staff and observations of parenting sessions by the research team to revise the interventions. Stage three involved piloting the revised interventions in six clinics with eighteen health staff and 162 mother/child dyads. We gathered additional data on mothers' attendance and used observations by the research team to finalise the interventions. Through this three-stage process, adaptations were made to the intervention content, process of delivery, materials, and engagement strategies used. The largest challenges were related to incorporating the parenting programme into health staff's existing workload and promoting mothers' engagement in the programme. We also simplified the content and structure of the curriculum to make it easier for health staff to deliver and to ensure mothers understood the activities introduced. This iterative piloting was used prior to implementing and evaluating the interventions through an effectiveness trial.

Keywords: parent training, adapting interventions, early childhood, integrated services, low and middle-income country, Bangladesh, psychosocial stimulation.

3.2 Introduction

Worldwide 43% (250 million) children under-5 years of age in low- and middle- income countries (LMIC) are at risk of not attaining their full developmental potential due to poverty, malnutrition, and lack of appropriate early stimulation (Black et al., 2017). There is evidence from many efficacy trials that early parenting interventions are effective in preventing the loss of children's development potential (Richter et al., 2017). The challenge now is to implement these interventions at scale to large numbers of disadvantaged children by integrating them into government health, nutrition, social security or educational systems (Britto et al., 2017).

Poor Bangladeshi children show a significant cognitive deficit as early as seven months of age compared to their more affluent peers, and the deficit grows larger as children reach five years of age (Hamadani et al., 2014). These deficits are likely to lead to long term effects on their educational attainment and adult productivity. There is thus an urgent need for national dissemination of effective parenting programmes to promote young children's development. The evidence-based, Jamaica home-visiting early childhood intervention programme (now called Reach-Up and Learn) was previously adapted for Bangladesh (Hamadani et al., 2014). The programme has been evaluated in three efficacy trials with undernourished children and has shown significant benefits to children's development and behaviour and to mothers' parenting practices (Hamadani et al., 2006; Nahar, et al., 2012a; 2012b; Tofail et al., 2013). The next steps are to extend the reach of this programme in Bangladesh, while maintaining its effectiveness.

The Bangladeshi government delivers primary health care through community clinics (CCs) in rural areas across the country. The CC is the lowest tier of the health facilities providing primary health care, family planning and nutritional services. There are over 13,000 CCs and they are established in all rural areas including remote and hard to reach areas. Each CC is staffed by three

health workers: a Community Health Care Provider (CHCP), a Health Assistant (HA) and a Family Welfare Assistant (FWA). The CHCP works full-time in the clinic, and the HA and FWA spend two to three days at the clinic and the remaining days' work in the community. CCs provide services for six days a week with operating hours from 9am to 3pm. The majority of CHCPs and HAs have Masters degrees and the FWAs have usually completed secondary (grade ten) level education. Most patients attend clinic in the morning and CC staff generally finish their regular schedule work around noon. Given the reach, structure and staffing levels of the community clinics, they provide a logical service for integrating parenting sessions within the routine work of the clinic.

The aim of this study was to adapt the Reach-Up and Learn home-visiting programme so that it could be implemented through the CCs with sessions conducted by government health staff as part of their routine duties. The beneficiary target group was mothers of undernourished children aged 6-36 months. We targeted undernourished children as undernutrition is an important risk factor for poor development, is relatively easy to measure, and has high prevalence in Bangladesh (Hasan et al., 2020; UNICEF., 2019).

3.3: Methods

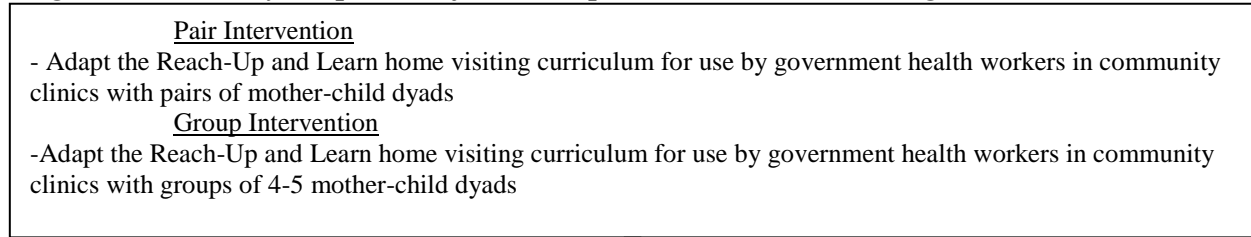
We developed two adapted versions of the Reach-Up and Learn home visiting programme for integration into the community clinic services including curricula for use with: 1) pairs of mother/child dyads, and 2) groups of four to five mother/child dyads. Both curricula have potential to extend the reach of the intervention, which was previously delivered with one mother/child dyad. The intervention development approaches used included: 1) the target population centred' approach that involves incorporating the views and actions of the participants and delivery agents, and 2) the 'implementation-based' approach that involves maximising the likelihood that the intervention will be used in the real world (O'Cathain et al., 2019). The study

was conducted from July to December 2014 and consisted of three stages of formative research **(Figure 3.1)**.

In stage one, we developed a first draft of the two new curricula. In stage two, we piloted these curricula in nine CCs and identified enablers and barriers of implementation related to the content, structure, materials, and process of implementation. The data gathered was used to revise the curricula and process of delivery. In stage three, we piloted the revised curricula and tested two different participant engagement strategies in six CCs. The results of this study were used to finalise the two parenting interventions for testing in an effectiveness trial. Ethical clearance for the study was obtained from Institutional Review Board of the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B). Informed consent was obtained from all health staff and parents participating in the study.

Figure 3.1: Stages Followed in Adapting Reach-Up and Learn for Integration into Government Health Services in Rural Bangladesh

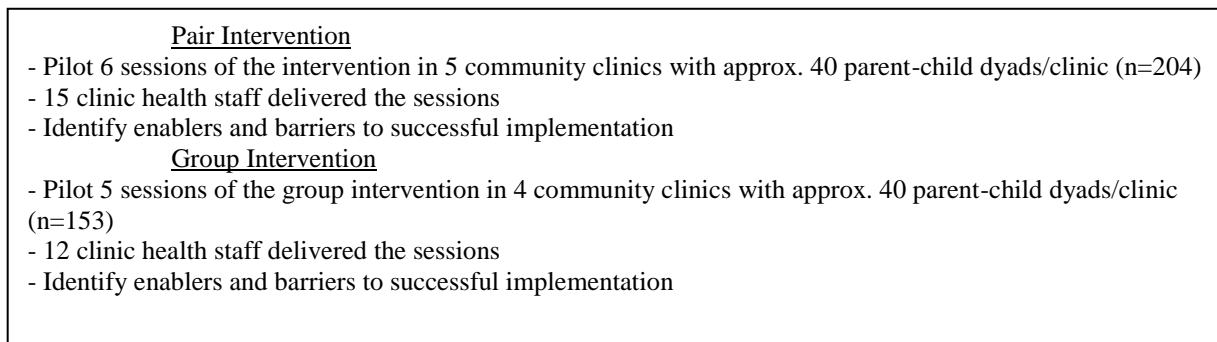
Stage 1: Preliminary adaptation of Reach-Up and Learn home-visiting curriculum



First draft of adapted pair and group curricula for testing



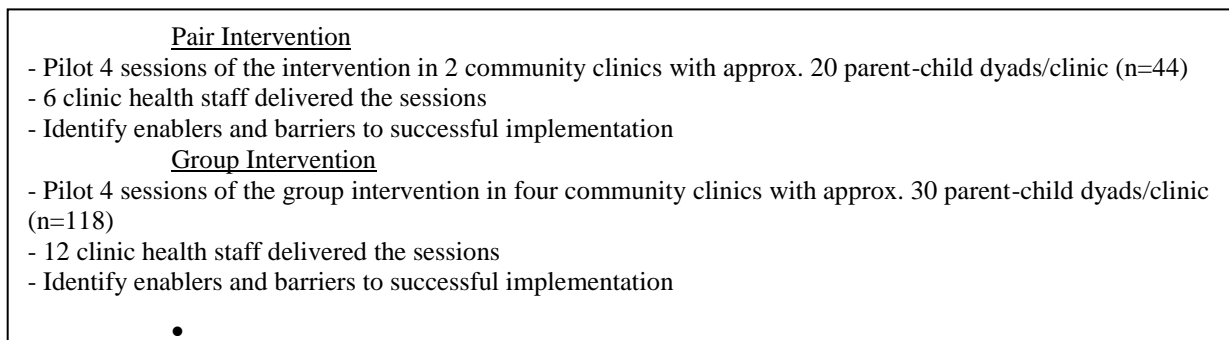
Stage 2: Piloting of adapted pair curricula and group curricula



Revised pair curriculum and group curricula
Engagement strategies developed to be tested in stage 3



Stage 3: Piloting revised pair and group curricula and engagement strategies



Final version of pair and group curricula and engagement strategies

Stage One: Preliminary Adaptation of Reach-Up Home-Visiting Curriculum

Reach-Up and Learn is a home-visiting, play-based intervention for mothers of children aged six months to four years that was developed from the Jamaican early stimulation programme (Walker et al., 2018). This programme has evidence for long term benefits to children's IQ, educational and economic achievement, mental health, and involvement in violence (Gertler et al., 2014; Grantham-McGregor & Smith, 2016). It has been replicated in several low- and middle-income countries (Walker et al., 2011), including Bangladesh (Hamadani et al., 2006; Hasan et al., 2020; Nahar et al., 2012; Tofail et al., 2013). The programme uses a structured curriculum, suitable for use by paraprofessionals, with developmentally appropriate activities organized to support weekly or fortnightly home visits. Emphasis is placed on parent-child interaction, praise for both parent and child, and encouraging parents to play and talk with their child during everyday routines and in structured play activities. The curriculum uses home-made toys (e.g. toys made from recyclable materials and soft toys such as doll, bean bag, ball), wooden blocks, picture books, puzzles, and games. One or two play materials are left in the home after each home-visit and then swapped for different materials at the next visit. To adapt this intervention for integration into the Bangladesh government health system we revised the curricula to make it suitable for use in the community clinic setting (rather than through home visits) and for use with either pairs or small groups of mother-child dyads to extend the reach of the programme. The content and structure of the first draft of the pair and group curricula is shown in **Table 3.1**. Each curriculum consisted of twelve parenting sessions, lasting between 45 minutes to one hour, designed to be delivered fortnightly and suitable for mothers of children aged 6-36 months. The most important adaptations involved 1) reducing the number of play materials used in the intervention due to cost, transportation, and storage problems associated with providing a wide variety of materials, 2) adapting the play activities to make them suitable for children of a wider age range, 3) ensuring the activities were suitable for use in a clinic rather than a home setting.

Table 3.1: Development of the Pair and Group Curricula

	Stage 1: First Draft of Adapted Intervention	Stage 2: Summary of Problems Identified in Piloting the Adapted Interventions	Stage 2: Revisions Made After Piloting the Interventions
Content and Structure of Pair Curriculum	<p>-Each session included four toy activities, one picture book activity, one language activity, a song and a developmental and nutritional message.</p> <p>- Developmentally appropriate toy, book and language activities were developed to be suitable for each month of a child's age (e.g. separate activities for 12 month olds, 13 month olds etc).</p> <p>- Nutritional and developmental messages and the song were conducted with both mothers together.</p> <p>- The curriculum was provided in one large manual divided into separate sections for each of the activities conducted during the session</p>	<p>- It was not feasible to introduce four toy activities in each session because: 1) It was difficult for the health workers to manage so many different activities, 2) there was too many different activities for the mothers to remember and, 3) due to the limited space, it was not possible to have so many different toys in each session.</p> <p>- It was difficult for the health workers to use the large curriculum manual.</p> <p>- The language activities were largely based on discussion and the health workers would often miss or dedicate insufficient time to these activities.</p> <p>-There was limited interaction between the mothers, especially if the children were of different ages.</p>	<p>- We reduced the number of toy activities to two per session (rather than four).</p> <p>- We produced two separate curriculum manuals, one for the play activities and a different manual for the other activities to make it easier for the health workers to navigate.</p> <p>- We made the language activities more practical and concrete by for example, including objects, actions and games.</p> <p>- We included a greater focus on encouraging interaction between mothers. This included adding some common activities with the picture book, singing together and ensuring the nutritional and developmental message were delivered in a collaborative and interactive way.</p>
Content and Structure of	- Each session included two toy activities, one picture book activity, one	-It was difficult for health workers to manage the children of different ages and to ensure that	- We reduced the number of toy activities to one per session (rather than two).

Group Curriculum	<p>language activity, a song and a developmental and nutritional message.</p> <ul style="list-style-type: none"> - Toy, book and language activities were developed for children in four age bands: 6-11 months, 12-18 months, 19-30 months & 31-36 months. - Nutritional and developmental messages and the song were conducted with all mothers together. - The curriculum was provided in one large manual divided into separate sections. 	<p>each mother-child dyad received the correct age-appropriate activity.</p> <ul style="list-style-type: none"> - Mothers were confused about the specific activities that they were supposed to do with their child at the end of the session. - The nutritional and developmental messages were too long and the children would become tired and fussy. - The health workers would often miss or dedicate insufficient time to the language activities. - Health workers found it difficult to navigate the curriculum manual during the session. 	<ul style="list-style-type: none"> - We asked mothers with children within the same age range (6-11 months, 12-18 months, 19-30 months, 31-36 months) to sit together so that it was easier for the health workers to conduct activities by child age. - We removed the developmental message from the curriculum. - We made the language activities more practical and concrete including objects, actions and games. - We prepared cards with a summary of each session to supplement the curriculum manual. These cards were used deliver the session.
Engagement of Mothers	<ul style="list-style-type: none"> - Mothers of undernourished living within forty-five minutes walk of the community clinic were recruited. - Health care staff set the schedule for the sessions. 	<ul style="list-style-type: none"> - Poor attendance of mothers due to 1) the distance from the clinic, 2) attitude of family members to the sessions, 3) lack of interest in attending the sessions, 4) expectation of receiving incentives and/or food for attending. - Mothers were left waiting prior to the start of the session because 1) other mothers were late and 2) health staff were engaged with patients. 	<ul style="list-style-type: none"> - We recruited mothers who lived within a 30-minute walking distance from the clinic only. - We designed two different engagement strategies to be tested in stage three: 1) community motivational meetings, and 2) giving bottles of oil as an incentive. - Health staff and mothers meet to set a convenient time for the sessions when the clinic was likely to be relatively quiet.

Engagement of Health Workers	<ul style="list-style-type: none"> - In community clinics piloting the pair sessions, between 9-11 sessions/week were conducted. - In community clinics piloting the group sessions, 4-6 sessions/week were conducted 	<ul style="list-style-type: none"> - the additional workload for the health workers in the community clinics was demotivating and they reported that it was too burdensome to conduct so many sessions. 	<ul style="list-style-type: none"> - We reduced the number mother/child dyads who would be enrolled in the programme (by 50% for the pair intervention and by 25% in the group intervention). - In community clinics conducting the pair intervention, the number of sessions was reduced to 4-5/week. - In community clinics conducting the group intervention, four sessions/week were conducted.
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Stage Two: Piloting of Adapted Pair and Group Curricula

Methods

The aim of stage two was to identify the enablers and barriers to implementing the adapted pair and group curricula within the community clinic network, using the existing health staff. This included factors relating to the content, structure, materials, and process of delivery of the curricula, the strategies used to recruit and engage the mothers in the session and the challenges faced by health staff in integrating the sessions into their regular workload.

Sample

The study was conducted in the Sonargaon sub-district, under Narayanganj district, located 80 km from Dhaka city. Sonargaon consists of thirty community clinics and nine clinics were purposively selected for easy accessibility and availability of transportation facilities. We screened all households with children aged between 6-33 months old living within 45 minutes walking distance from the selected clinics. All children were weighed and those with weight-for-age z-score of less than or equal to -2SDs of the WHO growth standards were eligible to participate in the study. We enrolled up to 40 children in each clinic; when more than 40 children were identified, we randomly selected 40 children to participate. The programme was discussed with the mother and other members of the household who were present and the mother was invited to participate in the parenting sessions. Children with severe malnutrition (<-3 SDs weight for age z-score) and children with disabilities were referred for specialist services and excluded from the study. Details of the number of clinics, health staff, and mother/child dyads participating in the piloting activities are shown in **Figure 3.1**.

Intervention Implementation

The research team provided two weeks training in how to conduct the parenting sessions to the Community Health Care Provider (CHCP), Family Welfare Assistant (FWA) and Health Assistant (HA) from each of the selected nine clinics. Training was conducted in two waves: health staff from five clinics were trained in the pair curriculum and health workers from four clinics were trained in the group curriculum. A member of the research team supervised the parenting sessions with a minimum of two visits per week to each clinic. During each visit, the supervisor assisted the health staff in preparing for the session, provided ongoing support during the session, and completed a monitoring form with input from the health staff to record enablers and barriers to programme implementation. During this pilot study, mothers attending clinics implementing the pair curriculum were offered a total of six parenting sessions, while five parenting sessions were offered to mothers attending clinics delivering the group curriculum. Each mother-child dyad attended fortnightly sessions. Health staff in pair clinics conducted 9-11 sessions/week and staff in group clinics delivered 4-6 sessions/week.

Data Collection

We collected data on parent attendance at each session and conducted semi-structured interviews with health care staff and a subsample of participating mothers. Twenty-three mothers were selected from two of the pair clinics based on session attendance to identify the enablers and barriers to attendance from the perspective of the mothers. The sample included five mothers who attended all six sessions, ten mothers who attended three sessions, four mothers who attended one session and four mothers who attended zero sessions. Nineteen mothers who had attended three or more sessions were selected from two of the group clinics to investigate the extent to which the mothers understood the activities that were introduced in the sessions. Mothers were asked to show the interviewer the

toy, book, and language activity that had been introduced in the previous session and to describe the developmental and nutritional message. This data was used to assess if mothers remembered and understood the activities and messages from the session. Mothers were also asked how many times a week they conducted the activities at home. Mothers were interviewed at their home by a female member of the research team using a semi-structured questionnaire. Mothers' responses were written verbatim. Each interview lasted approximately thirty minutes. We also conducted two group discussions with clinic staff to explore the enablers and barriers to implementing the parenting sessions from their perspective. A semi-structured interview was used and covered enablers and barriers relating to the curriculum content, the materials used, the process of delivering the sessions, mother engagement, and integrating the sessions into the regular clinic activities. Nine health staff from pair clinics and eight health staff from the group clinics participated in these discussions. Two researchers conducted these interviews with one moderating the discussion and the second keeping detailed notes.

Results

Mothers' attendance declined over time in both pilot studies (**Table 3.2**). **Table 3.3** shows the main reasons for non-attendance from the perspective of mothers in the pair clinics and the data on mothers' understanding of the activities from the interviews with mothers attending the group clinics. Many mothers expressed ambivalence about the sessions, describing the positive aspects of the sessions while also mentioning factors that limited their motivation to fully engage with the programme:

“The session is very much and he enjoyed the sessions. But the clinic does not provide any vitamin syrup. If the clinic gives medicine, nutritious food and advice about nutrition and sickness then I will come to the sessions.” (Mother from pair clinic)

In the group clinics, the majority of mothers (95%) reported doing the activities at home frequently with their child. However, the activities reported were not always age-appropriate, indicating that more clarity was needed during session delivery.

Key enablers and barriers from the perspective of the clinic staff and core observations from the supervisors are also given in **Table 3.3**.

Table 3.2: Mothers' Attendance at Parenting Sessions in Stage 2 and Stage 3

Stage 2 Piloting: Without Specific Engagement Strategy				Stage 3 Piloting: With Specific Engagement Strategy			
Pair Intervention n=204		Group Intervention n=153		Pair Intervention (motivational meetings) n=44		Group Intervention (half litre bottle of oil) n=118	
Session	n (%)	Session	n (%)	Session	n (%)	Session	n (%)
1	173 (85%)	1	121 (79%)	1	42 (95%)	1	100 (85%)
2	138 (67%)	2	100 (65%)	2	36 (81%)	2	108 (91%)
3	97 (47%)	3	82 (54%)	3	38 (87%)	3	109 (93%)
4	68 (33%)	4	83 (54%)	4	36 (81%)	4	109 (93%)
5	47 (23%)	5	67 (44%)				
6	30 (15%)						

Table 3.3: Supervisors', Health Staff and Mothers' Perceptions in Stage Two

Mothers' Perceptions and understanding of the Parenting Sessions			
Interviews with Mothers attending Pair Sessions		Interviews with Mothers attending Group Sessions	
Mothers opinions on the session	n=23 n(%)	Mothers understanding of the sessions	n=19 n(%)
Mother believes programme is important for her child's development	19 (82%)	Book activity reported by mother was appropriate to the child's age	10 (53%)
Mother reports other family members believe the programme is important	15 (65%)	Toy 1 activity reported by mother was appropriate to the child's age	12 (63%)
Likes the toys	10 (43%)	Toy 2 activity reported by mother was appropriate to the child's age	15 (79%)
Mothers' reasons for missing sessions	n=18 n(%)	Language activity reported by mother was correct for the child's age	12 (63%)
No incentive given	13 (72%)	Mother recalled the developmental message	12 (63%)
Family members discouraged attendance	7 (39%)	Mother followed the nutritional advice	15 (79%)
Sessions are not important for the development of their child	6 (33%)	Mother practiced the activity at home Every day 3-4 times a week 1-2 times a week	8 (42%)
Toys were not attractive and interesting	6 (33%)		10 (53%)
Live far from clinic	5 (28%)		1 (5%)
Involvement with earning sources	4 (22%)		
Perceptions of Health Staff on the Enablers and Barriers to successful implementation of the Parenting sessions			
Enablers			
<ul style="list-style-type: none">- CC staff believed that the activities introduced through the curriculum are suitable for young children and will help children's development- Most CC staff enjoyed conducting the sessions and believed that conducting the parenting sessions was an appropriate part of their role.			
Barriers			
<ul style="list-style-type: none">- Mothers expect to be provided with food supplements or medicine when they attend clinic.- Family members were not motivated well during the recruitment process and hence they were not always supportive of the mother attending the sessions- Some mothers do not like the home-made toys and they find them unattractive.- Delivering so many toy activities is difficult. It is hard to keep the interest of the mothers and children and to organise the materials.- The curriculum manual was difficult to use during the session: it was too large and difficult to navigate between the sections.- It was difficult to conduct so many sessions and continue to meet the demands of their regular workload.- It was difficult to handle children of different age groups, especially in the group curriculum.			
Observations of Supervisors attending the sessions			
Enablers			

- Health staff used many of the key training techniques while conducting the sessions including demonstrating the toy and book activities and the encouraging mothers to practice.
- Health staff had a positive attitude to conducting the sessions and were willing to make time in their schedule to conduct the sessions.

Barriers

- Language activities were often given insufficient emphasis. The health staff tended to be more didactic in introducing these activities and rarely asked mothers to practice the activities with their child.
- There was too much time spent on discussion, especially in the group sessions and the children became tired, fussy and restless when they were not engaged in activities.
- The health staff found it difficult to organise the materials for the session in the small space available.
- There were too many toy activities in the curricula and the health staff sometimes mixed up the toys and activities and delivered age-inappropriate messages.
- The curriculum manual was unwieldy to use as the CC staff needed to switch between several sections This led to pauses in the session as the CC staff found the correct page and children and mothers became distracted and bored.
- At times mothers and children would be required to wait for the CC staff as they continued to deal with patients attending the clinic.
- In the group clinics, it was difficult to gather all mothers at the same time and this could lead to long waits for mothers and children who arrived first.

The clinic staff recognized the value of and gained professional satisfaction from conducting the sessions; their main concerns related to the increased workload.

“I personally think the program is good. Sometimes I feel it is an extra work but not always. If children play well and do better then I feel good to see that the children are improving.” (Community Health Care Provider)

Other barriers to intervention implementation were related to the complexity of the curricula. For example, there were too many activities included in each session, the curriculum manuals were hard to use, and health workers spent insufficient time on some activities. Health staff were also overly didactic during the parts of the session that involved discussion. Based on the data collected, we made revisions to both the pair and group curriculum to make the sessions easier to conduct and to encourage more participatory and interactive delivery methods, and we adapted the process of implementation to ensure the programme could be managed within the staff workload (see **Table 3.1**). In addition, due to the poor mother

attendance, we limited eligibility for the programme to mothers who lived within a thirty-minute walk from the clinic and designed two recruitment strategies to be tested in stage three: 1) providing an incentive to attend the sessions, and 2) conducting community motivational meetings prior to restarting the parenting sessions.

Stage 3: Piloting revised pair and group curricula and engagement strategies

Methods

The main aim of the stage three was to evaluate the effectiveness of two different engagement strategies on mothers' attendance. We also continued to monitor the quality of the parenting sessions to identify if the changes made to the curricula led to more successful implementation.

Sample

For financial and logistical reasons, the pilot studies in stage three were conducted in only six of the nine selected clinics. From the original sample of forty parent-child dyads/clinic, we excluded parents who lived more than a thirty-minute walk from the clinic and then randomly selected twenty parent-child dyads from pair clinics and thirty parent-child dyads from group clinics to continue in the programme (**Figure 3.1**).

Engagement Strategies

In community clinics conducting the pair sessions, we organized community motivational meetings that were attended by village elites, local leaders, school teachers, health care staff and the selected mothers and their families. We provided psychoeducation around the importance of play and stimulation for child development and introduced the play materials used in the programme. The village leader also delivered a speech encouraging families to

engage with the programme. In the community clinics conducting the group sessions, we offered mothers an incentive of half a litre of cooking oil for every session attended.

Intervention Implementation

A further four parenting sessions were offered to mother-child dyads in all six clinics participating in the stage three piloting activities. Mothers attended sessions once a fortnight and a total of 4-5 parenting sessions/week were conducted in pair clinics and 2-3 parenting sessions a week were conducted in group clinics. Supervisors continued to attend a minimum of two sessions per week in each community clinic to provide ongoing support to the health staff and to document the quality of the sessions.

Data collection

Mothers' attendance at the sessions was recorded. Supervisors completed record forms on the enablers and barriers to implementation after each session.

Results

The adaptations to the curricula, including adaptations to the content, materials, and structure as shown in **Table 3.1**, led to higher quality implementation of the curriculum. Observations by supervisors indicated that the sessions were more organized and interactive and health staff were competent at conducting the age appropriate activities with each mother-child dyad. Sessions were usually held on time and the reduction in the number of sessions held per week made it easier for the health staff to schedule the sessions when the clinic was quiet

Mothers' attendance was greatly improved with both engagement strategies used (**Table 3.2**).

The incentive of a half-litre bottle of oil was highly successful at motivating mothers to attend with average attendance above 90%. However, there were logistical problems in

giving oil related to purchasing, delivery, storage, accountability, and record-keeping.

Furthermore, other members of the community started to gather at the clinic to ask for oil and the health staff also expected to be given a bottle of oil after each session. The use of community motivational meetings led to a slightly lower, but still acceptable average attendance of above 80%.

Final Versions of the Adapted Parenting Interventions

The final version of the curricula consisted of twelve fortnightly parenting sessions, suitable for children aged 6-36 months that were repeated every six months. Activities were divided into child age months for the pair curriculum and either six- or twelve-month age bands in the group curricula. Hence, when the sessions were repeated, most children would be introduced to activities in the higher age range. Each session included the following: 1) feedback from the previous session 2) a song 3) demonstration and practice of the toy, book and language activities, 4) developmental and/or nutritional message(s) and 5) review and reminder of home activities. Mothers were given at least one book and one toy during each session and these were swapped for a different book and toy at the next session. Given the cost and the logistical challenges associated with providing oil and the success of the community motivational meetings, we chose the latter strategy as the key engagement strategy to be used in the effectiveness trial. We also planned for quarterly refresher meetings within the community with small gifts provided to mothers with high attendance at the sessions to sustain mothers' engagement in the programme. We also decided to only recruit eligible mothers who lived within a thirty-minute walking distance from the community clinic. The revised curricula have since been evaluated with large benefits found for child cognition, language, motor development and behaviour in addition to home stimulation, maternal knowledge of child rearing and maternal depression (Hamadani et al., 2019). Interestingly,

the benefits were larger and more extensive than found in previous studies in Bangladesh possibly because the pair/group format provided social support and the health providers were better educated and more credible than previous home visitors.

3.4: Discussion

In this brief research report, we describe the process of adapting an early childhood parenting intervention with proven effectiveness in the Bangladeshi context for integration into the government health service including delivery by existing health staff. Adaptations were required to consider differences in the delivery location (clinic versus home), delivery agents used (health care staff versus persons hired by the research team), and the intended reach (higher number of mothers reached per delivery agent) of the intervention. The adaptation process involved two rounds of piloting and during the piloting process we 1) measured mothers' attendance at the sessions, 2) incorporated feedback from the intended beneficiaries (mothers) and the delivery agents (health staff), and 3) documented enablers and barriers to implementation through ongoing observations of the research team. Adaptations were made to the content of the curriculum, the materials used, the process of delivery, and the engagement strategies used. The paper illustrates the importance of thorough piloting of all aspects of an intervention, when moving from smaller-scale implementation in an efficacy trial to large scale implementation through an existing service. The value of investing resources to iteratively field test an adapted intervention in the context in which it is to be implemented is demonstrated by the large and wide-ranging benefits to children and mothers who later participated in an effectiveness trial (Hamadani et al., 2019).

There are examples in the literature relating to 1) transporting evidence-based parenting interventions across countries (Akter et al., 2020; Gladstone et al., 2018; Smith et al., 2018), 2) developing interventions specific for the context (Francis & Baker-Henningham, 2020;

Lachman et al., 2016; Miller et al., 2020), and 3) integrating interventions into government services (Gladstone et al., 2018; S. Walker et al., 2018). There is less literature on adapting an early childhood parenting intervention, with proven effectiveness in the setting, for wide-scale dissemination by integrating it into existing services. However, there are some common issues across this literature on developing, adapting and integrating early childhood interventions in LMIC.

Firstly, attention to staff workload is important, especially when integrating into an existing service. Through the piloting process, we aimed to incorporate the additional responsibilities into staff's existing duties without reducing their effectiveness in other aspects of their role, and without leading to staff demotivation. Other early childhood parenting interventions have reported that staff workload is problematic leading to high staff turnover (Smith et al., 2018) and/or a reduction in the number and duration of planned sessions (Walker et al., 2018). We designed a clinic-based intervention to facilitate the integration of the programme into the health staff's existing duties. Through piloting, we determined the number of weekly sessions each health worker could feasibly conduct.

Secondly, it is important to develop a feasible and effective strategy for engaging participants in the intervention. We found the strategies that we had previously used to engage mothers in a home-visiting intervention, were less effective at engaging mothers in a clinic-based intervention. The lack of an incentive and family members discouraging attendance were the most frequent barriers to mothers' engagement. These barriers have also been reported in a recent study in Bangladesh (Akter et al., 2020). We tried two specific engagement strategies, giving cooking oil as an incentive for attendance and community motivational meetings to engage all family members. Both strategies were effective although giving oil proved difficult due to logistical problems. The importance of community sensitisation to increase

participant engagement in parenting programmes has been reported in other studies (Akter et al., 2020; Gladstone et al., 2018).

Thirdly, it is important to ensure sessions are simple for staff to deliver and the messages and activities are easy for mothers to understand. We found the curricula manuals were too complex for the health staff to use during the sessions, particularly for the group sessions. Navigating through the different sections of the manual took their attention away from the mothers and children, leading to lower participation and interest. We therefore designed a laminated summary card for use during the session. Also, when many activities were introduced during the session, mothers were unable to recall the content. A simple, streamlined intervention with user-friendly manuals is recommended to maintain the interest and engagement of participants and to maximise the likelihood that the intervention will be delivered with fidelity (Akter et al., 2020). Reducing the complexity of the intervention to make it easier to deliver is also likely to lead to higher motivation among the health staff (Baker-Henningham, 2014).

Fourthly, using active learning and evidence-based behaviour change techniques (e.g. demonstration, practice, positive feedback, social support) are key characteristics of effective early childhood programmes (Briscoe et al., 2012; Yousafzai & Aboud, 2014). Through the piloting process, we identified opportunities for improving the intervention content, materials, and process of delivery to ensure that these techniques were embedded into the intervention design. For example, we adapted the content to promote mothers' interaction with each other and to ensure the sessions were collaborative and participatory. We also revised the activities that involved group discussion to make them more practical and concrete by incorporating games, objects, and actions to maintain participants' engagement.

Using hands-on, practical activities also ensured that the health staff dedicated sufficient time to these activities.

Fifthly, it is important to decide on the target population for the intervention as it may not be feasible to offer a parenting intervention for all families in need. For example, in Malawi, health staff were only able to reach 14.2% of eligible children, with an early childhood development intervention (Gladstone et al., 2018). We targeted undernourished children but even so, we were limited by the capacity of the health clinics and the programme was not suitable for mothers living far from the clinic. Alternative strategies are required to reach all young disadvantaged children and their families.

Finally, incorporating participant feedback including feedback from potential beneficiaries and from the delivery agents is an important part of the adaptation process (Akter et al., 2020; Francis & Baker-Henningham, 2020; Lachman et al., 2016; Miller et al., 2020), in addition to using observations from the research team during intervention implementation (Francis & Baker-Henningham, 2020). To adapt interventions for a new context, we recommend the use of iterative rounds of piloting with ongoing improvement and refinements to the intervention to promote the acceptability, relevance and feasibility of the intervention for participants and implementers.

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CHAPTER: FOUR

Title: Integrating a Group-Based, Early Childhood Parenting Intervention into Primary Health Care Services in Rural Bangladesh: A Cluster-Randomized Controlled Trial

4.1: Abstract

Background:

Over 250 million children globally do not reach their developmental potential. We tested whether integrating a group-based, early childhood parenting programme into government healthcare clinics improved children's development, growth and behaviour.

Methods:

We conducted a cluster-randomised controlled trial in 40 community clinics in the Kishorganj district of Bangladesh. We randomly assigned clinics (1:1) to deliver a group-based parenting interventions or to a comparison group that received no intervention. Participants were children aged 5-24 months, with weight-for-age z-score of ≤ -1.5 SDs of the WHO standards, living within a thirty-minute walking distance from the clinic (n=419 intervention, 366 control). Government health staff facilitated parenting sessions in the clinic with groups of four mother/child dyads fortnightly for one year as part of their routine duties. Primary outcomes measured at baseline and endline were child development assessed using

the Bayley scales, child behaviours during the test by tester ratings, and child growth. The trial is registered at ClinicalTrials.gov, NCT02208531

Findings:

91% of children were tested at endline (396 intervention, 319 control). Multilevel analyses showed significant benefits of intervention to child cognition (effect size 0.85 SDs, 95% CI: 0.59, 1.11), language (0.69 SDs, 0.43, 0.94), and motor development (0.52 SDs, 0.31, 0.73), and to child behaviours during the test (ranging from 0.36 SDs, 0.14, 0.58, to 0.53 SDs, 0.35, 0.71). There were no significant effects on growth.

Conclusion:

A scalable parenting intervention, integrated into existing government health services and implemented by government health staff, led to significant benefits to child development and behaviour.

Keywords: parenting, early childhood development, integrated services, low- and middle-income country, psychosocial stimulation.

4.2: Introduction

Poor development in disadvantaged children under five years of age is a major problem in low- and middle-income countries (LMIC), leading to lifelong functional and economic consequences (Black et al., 2017). There is strong evidence that early childhood development (ECD) parenting interventions, focusing on psychosocial stimulation, benefit these children's development (Jeong, Franchett, et al., 2021). To extend the reach of ECD parenting interventions, we need information on the best methods of implementing ECD programmes at

scale. Many experts recommend integrating into the health services (Richter et al., 2017). The goal is for health staff to run ECD interventions as well as their routine tasks, which is potentially cost-effective, but there are few evaluations of this approach (Chang et al., 2015; Yousafzai et al., 2014). Moreover, researchers have often funded the health workers (Grantham-McGregor S, 2016; Luoto et al., 2021).

In Bangladesh, children living in poverty show a rapid decline in cognitive and language development from 7-months through to 5-years of age (Hamadani et al., 2014). We have previously evaluated an ECD home-visiting, parenting programme in Bangladesh (adapted from the Jamaican home-visiting programme, now called Reach-Up) and conducted four randomized controlled trials in which locally-hired women conducted weekly parenting sessions with mother/child dyads at home or in a clinic setting (Hamadani et al., 2006; Hossain et al., 2021; Nahar et al., 2012a, 2012b; Tofail et al., 2013). The benefits to child development from this approach were small-to-moderate ($ES=0.21-0.38SD$). However, individual sessions are costly and it is difficult to reach large numbers of disadvantaged children.

We developed an ECD parenting intervention that could be integrated into the primary health care clinics and thus facilitate scaling-up ECD interventions for at-risk children and we conducted a trial using the health care workers (HCW) to deliver the parenting sessions as part of their usual tasks. In addition, instead of mother/child dyads attending individual sessions every week, they attended in pairs every two weeks. Surprisingly, the children showed much larger benefits to cognition and language development ($1.1-1.3SD$) than previously found in Bangladesh (Hamadani et al., 2019). Given the exceptionally large benefits to child outcomes compared with individual home-visiting interventions, or most other parenting interventions elsewhere (2), it was important to investigate the robustness of

the findings (JPA, 2005; National Science Foundation, 2018). We decided to replicate the intervention in another trial, but with several modifications to make it more suitable for wide scale dissemination. Firstly, groups of four mothers and children attended the session, potentially doubling the coverage per HCW. Groups of four were the largest number that could be accommodated inside the clinics due to space constraints. Secondly, we adapted the Reach-Up intervention to make it suitable for use with a wider age-range of children at each session by presenting play activities in six- or twelve-month age bands rather than into monthly age bands used in the pair curriculum. Thirdly, we reduced the variety of play materials used in the intervention by half, with children participating in one toy activity per session rather than two. Full details of the process of adaptation have been published previously (Mehrin et al., 2021).

In this study, we evaluated the effects of the ECD group-based parenting programme on child cognition, language and motor development, behaviour and nutritional status.

4.3: Methods

Study design and participants

In Bangladesh, there are more than 13,000 community clinics that deliver primary health care across the country. We conducted a two-arm, single-blind, cluster-randomized trial with parallel assignment in forty clinics in the rural Kishorganj district of Bangladesh, located approximately 100km from Dhaka city. Clinic was the unit of randomization to reduce contamination between the groups as the intervention was integrated into clinic services and was implemented by existing clinic staff. We selected two rural subdistricts in Kishorganj with a total of seventy-four community clinics. An independent statistician randomly selected

twenty clinics from each subdistrict (n=40 clinics) to participate in this study. No clinics refused to participate.

Inclusion criteria for children were: weight for age (WAZ) ≤ -1.5 SD, singleton birth, no obvious disability, no known chronic disease (e.g. epilepsy), not hospitalised or requiring ongoing monitoring for acute malnutrition and parental consent. We conducted a house-to-house survey around each clinic and all children aged 5-23 months, living within a thirty-minute walking distance from the clinic, were screened for inclusion. We limited the sample to mothers and children living within a 30-minute walk from the clinic based on prior piloting that demonstrated poor attendance among mothers living farther away (Mehrin et al., 2021). Children were weighed using standard methods and those with weights for age ≤ -1.5 SD of WHO standards (Organization, 2006) and meeting all other inclusion criteria were invited to participate in the study. We initially aimed to recruit children with a WAZ < -2.0 SD but fewer children met the criteria than anticipated. We recruited up to twenty-four children in each clinic. In clinics with more than twenty-four eligible children, a simple random sample of twenty-four children was selected. Written informed consent of mothers was collected at enrolment. Ethical approval was given by the institutional review board of the International Centre for Diarrhoeal Diseases Research, Bangladesh (ICDDR,B).

Randomization

The forty clinics were stratified by subdistrict and then randomly assigned 1:1 to intervention or control by an independent statistician, using a computer-generated randomization sequence. All clinics and mother/child dyads were recruited prior to randomization. Baseline measurements were conducted after randomization. Data collectors were masked to group allocation at baseline and endline.

Intervention

Mothers and children attending clinics allocated to the intervention group were invited to fortnightly parenting sessions for one year, held inside the clinic. The parenting sessions were facilitated by the clinic health workers. Each community clinic has three health staff: a Community Health Care Provider (CHCP) who works full time in the clinic and a Health Assistant (HA) and a Family Welfare Assistant (FWA) who work half-time in the clinic and half-time in the community. CHCPs and HAs have masters' degrees and most FWAs have completed high school. To promote co-ordination and cooperation, all three cadres of health staff conducted parenting sessions: CHCPs conducted 1-2 sessions per week, while HAs and FWAs who spend fewer days in the clinic conducted one session per week. Where necessary the CHCPs gave support to the FWAs. There was an average of four mother/child dyads in each group, with group size constrained by the available space within the clinic. The Group Reach-Up and Learn curriculum was used in the parenting sessions. This curriculum was adapted from the Jamaican Reach-Up home visiting programme (Mehrin et al., 2021). The health workers were trained and supervised by the research team. See **Table 4.1** for further details of the intervention. Mothers and children in control clinics were not invited to parenting sessions, but they used the clinic as usual for health care. We recorded attendance at parenting sessions.

Table 4.1: Description of the Group Reach-Up and Learn Parenting Intervention

<p>Content: The Group Reach-Up and Learn curriculum focusses on: 1) improving mothers' knowledge of parenting practices, promoting responsive parenting and stimulation in the home, and increasing mothers' self-confidence in parenting, and 2) increasing child's cognitive, language, motor and behavioural development. Mothers are encouraged to engage in responsive, playful interactions with their child using low cost play materials, books and materials in the home, and in everyday caregiving routines. Activities for children under 24 months are based on the constructs of object permanence, means-end causation, vocal and physical imitation, and exploration of objects. Activities for children 24 months and older aim to teach concepts including size, quantity, colour, shape, position, same/different, and classification. Activities to promote attention, persistence and problem-solving (e.g. puzzles) are also included.</p>

<p>Materials: Intervention materials for facilitators included a curriculum manual with twelve parenting sessions, to be repeated every six months. The curriculum is suitable for children aged 6-36 months with activities divided into four age bands (6-11, 12-18, 19-30 and 31-36 months).</p>
<p>We also prepared summary cards for each of the 12 sessions for facilitators to use during the session (so that they didn't have to manipulate the larger manual).</p>
<p>Intervention materials for parents and children included picture books, play materials made from recycled materials (e.g. shakers, stacking toys, push-a-long toys, nesting toys), wooden blocks, soft toys (e.g. doll, ball, bean bag), puzzle boards, matching games, and crayon and paper. Mothers were given at least one toy and a book at each session and these were swapped for a different toy and book at the next session. Mothers also received a recipe card with examples of nutritious recipes using readily available, low-cost food.</p>
<p>Procedure: Mothers attended with their child in groups of 4 to 5 mother-child dyads. Each session included the following activities: 1) feedback from the previous session, 2) a song, 3) demonstration and practice of a toy, book and language activity, 4) a nutritional message, and 5) review and reminder of home activities. Facilitators demonstrated each toy, book and language activity with mothers and children grouped by age range (i.e. 6-11 months, 12-18 months, 19-30 months, 31-36 months), and supported mothers as they practiced the activities with their child. Mothers were also encouraged to share ideas for other activities and songs and to continue with the activities at home. There was a strong focus on promoting mothers' self-efficacy and enjoyment of parenting and encouraging mothers to support and praise each other.</p>
<p>Who provided: Fifty-six frontline government health workers (20 Community Health Care Providers (CHCPs), 18 Family Welfare Assistants (FWAs) and 18 Health Assistants (HAs)</p>
<p>working in community clinics were trained to conduct the parenting sessions. Twelve (60%) CHCPs, nine (50%) HAs, and all eighteen FWAs were female. Health workers attended 10 days of initial training in batches of 12-15 participants and a 1-day refresher training every 3 months. We gave the health workers a stipend for attending training using the established government rates; all health workers attended the full complement of training. The training was practical and</p>
<p>participatory and involved demonstration and simulated practice of all activities followed by a practice session with mothers and young children. Trainers were child development specialists with prior experience implementing the Reach-Up and Learn curriculum in Bangladesh. The health workers were supervised by one of five supervisors hired by the research team. Supervisors had Masters degrees in Psychology or Social Science and received 20 days of initial training from the research team. Each supervisor was responsible for four community clinics and 10-12 health workers. Supervisors visited each health worker twice a month and observed a parenting session using a checklist to monitor quality of implementation. Supervisors provided support where necessary throughout the session and at the end of the sessions, a discussion was held with the individual health worker using the checklist as a guide.</p>
<p>Where: Parenting sessions were delivered inside the community clinics. The community clinics in the study area are small buildings with no outside waiting area (see supplementary figure 1). It is not possible to conduct sessions in the open air near the community clinics. It hot for almost 7-8 months per year, stormy and rainy for 2-3 months and too cold for the remaining months. We had initially planned to include 6-8 children per session, but our pilot showed that there was insufficient space. Health Assistants and Family Welfare Assistants split their working time between work in the clinic and work in the community. The parenting sessions were integrated into their work in the clinic as it was easier for them to fit the sessions into their existing duties on clinic days and to keep contact with clinic activities if necessary.</p>

<p>When and how much: Each mother-child dyad was invited to participate in fortnightly parenting sessions over the period of one year (a total of 25 sessions). Session duration was 40-50 minutes. Mothers were given a calendar and the next session date was marked on the calendar at the end of every session. In addition, health workers communicated with the mothers via mobile phone prior to each session to remind them to attend. Supervisors assisted the health</p>
<p>workers in making these calls when necessary. Before the start of the intervention, community motivational meetings were held in each area to encourage participation, and every four months, a refresher meeting was held in each village for all participating mothers and other family members to sustain engagement in the programme.</p>
<p>Tailoring/Modifications: The curriculum was adapted from a home-visiting curriculum that had been used previously in Bangladesh (now called Reach-Up and Learn). We reduced the number of play materials, designed activities that were suitable for children over a wider age range rather than the age-specific activities in the original curriculum, provided guidelines and activities to promote interaction between mothers, and made the language activities more practical and concrete. The final curriculum manual was mostly implemented in a standard way by all health workers.</p>

4.4: Measurements

Outcome measurements included child development, behaviour, and nutritional status and mothers' parenting knowledge and depressive symptoms, and stimulation in the home. All outcomes were measured at baseline (from Sept-Dec 2015) and after one year of intervention (from Oct-Dec 2016) and have been used previously in Bangladesh (Hamadani JD, 2002; Hamadani et al., 2006; Hamadani et al., 2010; Tofail et al., 2013). Children were tested in the presence of the mother either in a private room at the community clinic or an alternative location in the community.

Primary Outcomes

The primary outcomes were child development, behaviour, and nutritional status. Children's development was measured using the Bayley Scales of Infant and Toddler Development (Bayley N., 2005). We used three composite scores: 1) cognition, 2) language (combined score of the expressive and receptive language scales), and 3) motor (combined score of the fine and gross motor scales). Child behaviour was rated during the test using four Wolke's

behaviour rating scales: approach to examiner, emotional tone, cooperativeness, and vocalisations (Wolke D, 1990). Approach was rated during the first 10 minutes of the test; the remaining three scales were based on the child's behaviour throughout the test. Behaviours were rated on a 8-point scale with higher scores representing more of the characteristic. Child weight and length/height were measured by the testers after the Bayley test using WHO standard methods (WHO, 1983). The z scores of weight-for-age, weight-for-height, and height-for-age were calculated using WHO anthroplus (WHO, 2006). Children were tested at baseline and endline by one of eight testers. All testers had a Masters' degree in Psychology or related field. Testers received one-month training and they were masked to group allocation.

Secondary Outcomes

The secondary outcomes were mothers' parenting knowledge, stimulation provided in the home and mothers' depressive symptoms. Parenting knowledge was measured using a specially designed instrument consisting of 20 questions. Stimulation in the home was measured using an extended version of the Family Care Indicators (FCI) (Kariger et al., 2012). The FCI consisted of 24 questions including questions on the availability of play materials and the extent to which the mother and other adults in the home engaged the child in play activities. The FCI has been previously validated in Bangladesh and the items used in this study (variety of play materials and play activities) were shown to be highly correlated with the HOME ($r=0.72$ and $r=0.73$) and correlated with children's receptive and expressive language ($r=0.37$ to $r=0.48$) and Bayley scores ($r=0.19$ to $r=0.29$) (19). Maternal depressive symptoms were measured using six questions that are included in the FCI, taken from the Centre for Epidemiological Studies Depression Scale (Radloff, 1977). All interviews with

mothers were interviewer-administered and conducted after child measurements were completed.

Quality Control of Measurements

Before the study assessments began, interobserver reliabilities were measured between each tester and the trainer on 8-16 tests per tester. Inter-observer reliabilities were acceptable for all measures: intraclass correlation coefficients (ICC) >0.98 on Bayley composite scores, range of ICC=0.62-1.00 on behaviour ratings, and ICC>0.95 on anthropometric measures. Interobserver reliabilities were conducted on approximately 10% of all Bayley tests during the study and reliabilities were ICC>0.95 for all Bayley composite scores and ICC=0.67-0.99 for behaviour ratings.

All maternal questionnaires had good internal consistency at baseline (Cronbach's α mean 0.82, range: 0.68-0.89) and endline (Cronbach's α mean 0.84, range: 0.79-0.88) (**Table 4.1**).

Table 4.2: Internal reliabilities of questionnaires at baseline and endline

Outcome measure	Internal Reliability (Cronbach's α)	
	Baseline	Endline
Parenting knowledge	0.68	0.79
Family Care Indicators (Home stimulation)	0.89	0.86
Maternal depressive symptoms	0.88	0.88

The Bayley Scales scores at baseline and endline were significantly correlated with height-for-age ($r=0.18-0.30$), weight-for-age ($r=0.21-0.28$) and with maternal education ($r=0.10-0.19$) and paternal education ($r=0.12-0.24$), indicating good discriminant validity (**Table 4.3**).

Table 4.3: Correlations of child nutritional status and parental education with the Bayley test scores

Bayley Scales Scores	Maternal education (years)	Fathers' education (years)	Height-for-age z score at baseline	Weight-for-age z score
Cognitive composite baseline	0.10*	0.12*	0.28**	0.24**
Language composite baseline	0.19**	0.24**	0.28**	0.22**
Motor composite baseline	0.16**	0.17**	0.30**	0.25**
Cognitive composite endline	0.17**	0.13**	0.18**	0.21**
Language composite endline	0.12**	0.23**	0.22**	0.28**
Motor composite endline	0.16**	0.17**	0.24**	0.23**

* $p < 0.01$, ** $p < 0.001$

4.5: Statistical Analysis

The primary outcomes of the study were child development (3 scores: cognitive, language and motor development), child behaviour (4 scores: approach, emotional tone, cooperativeness, vocalisations) and child nutritional status (3 scores: weight-for-age, weight-for-height, height-for-age). To calculate the sample size, we used a significance level of 0.005 (instead of 0.05) to account for ten primary outcomes and we assumed an intracluster correlation coefficient of 0.05 (Chang et al., 2015). With an average of 21 mother/child dyads per clinic (378 mother/child dyads), and allowing for a loss of two clinics per group, (giving 18 clinics in each group), we had 80% power to detect an effect of 0.38 SD on the primary outcomes.

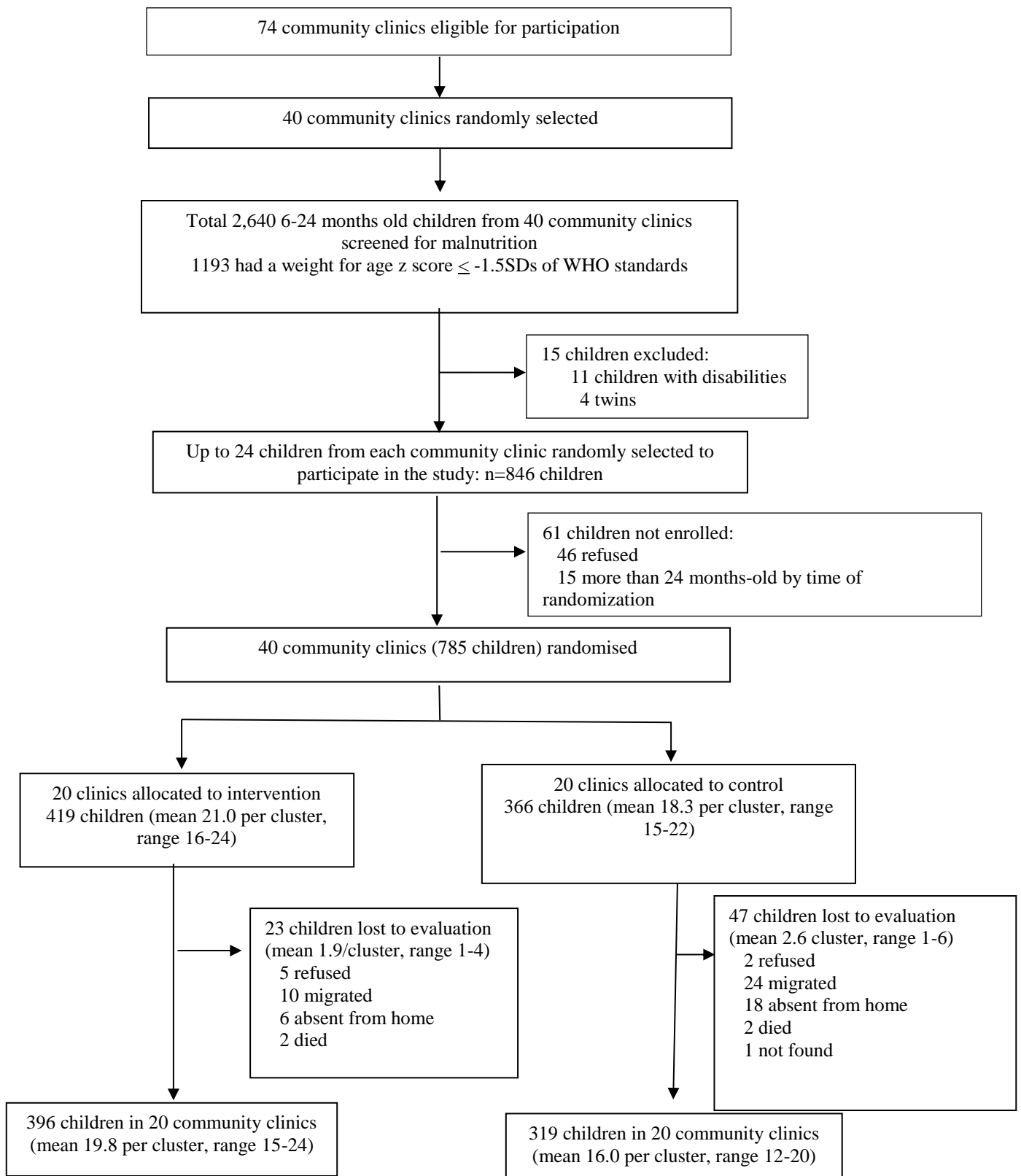
All analyses were prespecified. For each outcome, we fitted a multi-level random effects model that accounted for clustering at the clinic level. We adjusted for child age and sex, the

relevant baseline score and tester/interviewer. Study group was entered as a binary variable. For child development and behaviour outcomes, as children were tested either in the community clinic or in an alternative location in the community, we also entered place of test and an interaction term of place of test x group as fixed effects. Data completeness was excellent (>98%) for child outcomes. At endline, we had incomplete data for maternal outcomes (91% for parenting knowledge and home stimulation, 90% for maternal depression). We used multiple imputation, assuming data was missing at random, to account for missing data. Baseline sociodemographic variables and baseline scores of all child and maternal outcomes were included in the imputation model. We generated 20 datasets and ran a full multi-level random effects model using the whole dataset and to correct for overfitting, we implemented a bootstrap (200 samples) for each imputed dataset. The final models were obtained by fitting a multi-level model with all the above factors, and estimates were combined using Rubin's rules (Rubin, 2004). To allow for comparability across outcomes, effect sizes were calculated by using an internal standardization of the whole sample at baseline and endline separately. We used intention-to-treat analyses for all outcomes and we controlled for multiple primary outcomes using Holm step-down procedure. All analyses were carried out using Stata version 15. In post-hoc analyses, we examined whether parenting outcomes (home stimulation, child-rearing knowledge, mothers' depressive symptoms) mediated the effect of the intervention on child development and behaviour. Baseline and endline score for each parenting outcome were entered into the multilevel regressions on child outcomes and we used a Sobel test to assess the significance of the mediation effect. The trial registration number is NCT02208531.

4.6: Results

We weighed 2,640 children aged 6-24 months living within a thirty minutes walking distance from forty community clinics. We identified 1,193 (45%) children with a weight-for-age z-score $\leq -1.5SD$ of the WHO standard (**Figure 4.1**). We randomly selected up to 24 children from each clinic who met the inclusion criteria for the study to give a total of 846 children. Forty-six mothers (5.4%) refused to participate in the study and a further 15 children (1.8%) were more than 24-months-old by the time of randomisation (due to a delay in official procedures), leaving a total of 785 children in forty clinics. Clinics were then randomly assigned to the intervention (20 clinics, 419 children) or control group (20 clinics, 366 children). All clinics were retained in the study. 70 children (8.9%) were lost at baseline (23 (5.5%) intervention, 47 (12.8%) control). Reasons for loss are shown in **Figure 4.1**.

Figure 4.1: Trial profile



The only differences between children lost and those retained (**Table 4.2**) were in nutritional status: children tested had lower height-for-age (Mean (SD): tested=-2.44 (1.12) vs lost=-2.03 (1.67), $p=0.004$) and higher weight-for-height (Mean (SD) tested= -1.34 (0.10) vs lost = -1.65 (0.99), $p=0.02$) than those lost.

Groups were reasonably well-balanced at baseline with the only significant differences being higher scores for the control group on approach ($p<0.001$), emotional tone ($p=0.003$), and cooperation ($p=0.005$) (**Table 4.4**).

Table 4.4: Child and Family Characteristics and Child and Maternal Outcomes at Baseline and Endline by Study Group

	Baseline		Endline	
	Intervention n=419	Control n=366	Intervention n=396	Control n=319
Child and family characteristics				
Child sex: n (%) female	206 (49.2)	178 (48.6)	-	-
Child age (months)	16.89 (4.82)	17.16 (5.13)	-	-
Height-for-age <-2 z-scores	264 (63.5%)	229 (62.7%)	-	-
Weight-for-height <-2 z-scores	95 (22.7%)	80 (21.9%)	-	-
Weight-for-age <-2 z-scores	244 (58.5%)	214 (58.5%)	-	-
Mother's education n (%) \geq grade 5	272 (64.9%)	227 (62.0%)	-	-
Mother's BMI	20.30 (3.07)	20.21 (3.18)	-	-
Housing	8.37 (1.78)	8.21 (1.59)	-	-
Crowding index	0.29 (0.16)	0.29 (0.18)	-	-
Monthly income \geq 6000 BDT n (%)	222 (57.4%)	165 (42.6%)	-	-
Child Outcomes				
Cognitive composite score	91.17 (11.18)	91.75 (10.93)	89.32 (6.63)	83.32 (6.63)
Language composite score	85.17 (10.39)	86.20 (10.01)	90.29 (8.55)	85.48 (7.61)
Motor composite score	90.67 (11.32)	90.83 (10.58)	93.29 (9.56)	88.76 (8.31)
Approach	5.66 (0.92)	5.87 (0.84)	5.58 (0.91)	5.19 (0.87)
Positive emotional tone	5.26 (0.79)	5.43 (0.82)	5.50 (0.80)	5.28 (0.74)
Cooperativeness	5.14 (0.89)	5.32 (0.92)	5.46 (0.84)	5.18 (0.78)
Vocalization	3.72 (1.64)	3.88 (1.70)	4.74 (1.35)	4.34 (1.29)
Height for age z-score	-2.43 (1.15)	-2.38 (1.12)	-2.57 (0.94)	-2.45 (1.00)
Weight for age z-score	-2.24 (0.85)	-2.23 (0.81)	-2.21 (0.77)	-2.26 (0.81)
Weight for height z-score	-1.36 (1.02)	-1.37 (0.94)	-1.12 (0.90)	-1.29 (0.91)
Parenting and maternal depression				

Knowledge on child rearing practices	22.55 (4.98)	22.75 (5.55)	31.22 (4.49)	23.24 (5.06)
Home stimulation	20.75 (8.12))	21.26 (7.08)	20.30 (6.36)	14.88 (6.44)
Maternal depression	8.23 (8.44)	8.17 (7.91)	6.95 (7.36)	8.22 (7.63)

Values are mean (SD) unless otherwise stated. Housing index is the sum of ratings the quality of wall, roof and floor condition and the presence of electricity. Child cognition, language and motor scores were measured using the Bayley Scales of Infant & Toddler Scale-version III. Response to examiner, emotional tone, cooperativeness, and vocalization were rated during the test using the Wolke's behaviour rating scales (8-point scale: 1=low, 8=high). Knowledge of child rearing practices was measured with a structured questionnaire used in previous studies (20 questions, potential range of scores: 0-60). Maternal depressive symptoms were measured using a shortened Center for Epidemiological Studies Depression Questionnaire (CES-D) scale (6 questions, potential range of scores: 0-42), home stimulation was assessed using Family Care Indicators (24 questions, potential range of scores: 0-24). For maternal outcomes at baseline: parenting knowledge & maternal depression: n=417 intervention, 365 control; stimulation in the home: n= 361 intervention, n=305 control. At endline: parenting knowledge: n=396 intervention, n=318 control; parenting practices: n=393 intervention, n=322 control; maternal depression: n=391 intervention, n=312 control.

Mothers in intervention clinics attended a mean of 22.2 (SD=5.9) parenting sessions. 215 mothers (51.3%) attended all twenty-five sessions; only 11 mothers (2.6%) attended zero sessions. Out of 56 health workers trained to conduct parenting sessions, 47 (84%) conducted all sessions. Two (3.5%) refused (both HAs) and their sessions were conducted by the CHCP at their respective CC. Seven health workers (12.5%) missed one or more sessions due to sickness, leave, or competing duties.

Primary Outcomes:

We found significant benefits of intervention to children's score on the Bayley Scales across all developmental domains: cognitive (effect size (ES)= 0.85, 95% confidence interval (CI): 0.59, 1.11), language (ES=0.69 95% CI: 0.43, 0.94), and motor (ES=0.52, 95% CI: 0.31, 0.73) (**Table 2**). We also found significant benefits of intervention for child behaviour during the test, including approach (ES=0.53, 95% CI: 0.35, 0.71), positive emotional tone (ES=0.36, 95% CI: 0.14, 0.58), cooperativeness (ES=0.43, 95% CI: 0.20, 0.66), and

vocalisations (ES=0.40, 95% CI: 0.26, 0.55). Children's anthropometric measurements were not different between the groups (**Table 4.5**).

Table 4.5: Effect of Intervention on Primary and Secondary Outcomes at Endline

	Regression Coefficient B (95% CI)	ICC	Effect size (95% CI)	P value
Primary outcomes (all child outcomes)				
Cognitive composite score	• 6.17 (4.29, 8.06)	0.07	0.85 (0.59, 1.11)	0.001
Language composite score	• 5.81 (3.69, 7.94)	0.10	0.69 (0.43, 0.94)	0.001
Motor composite score	4.87 (2.91, 6.82)	0.03	0.52 (0.31, 0.73)	0.001
Approach	• 0.48 (0.32, 0.65)	0.01	0.53 (0.35, 0.71)	0.001
Positive emotional tone	• 0.29 (0.11, 0.46)	0.02	0.36 (0.14, 0.58)	0.001
Cooperativeness	• 0.35 (0.17, 0.54)	0.04	0.43 (0.20, 0.66)	0.001
Vocalization	• 0.52 (0.33, 0.71)	0.03	0.40 (0.26, 0.55)	0.001
Height for age z-score	• -	0.06	-0.16 (-0.31, -0.01)	0.06
Weight for age z-score	-	0.05	0.04 (-0.08, 0.15)	0.52
Weight for height z-score	-	0.05	0.20 (0.04, 0.35)	0.06
Secondary outcomes (parenting outcomes)				
Child-rearing knowledge	7.87 (7.00, 8.73)	-	1.27 (1.13, 1.41)	< 0.001
Home stimulation	• 5.35 (4.14, 6.56)	• -	0.77 (0.60, 0.94)	< 0.001
Maternal depression	-1.39 (-2.54, -0.23)	-	-0.18 (-0.34, -0.03)	0.02

ICC=intraclass correlation coefficient. 1=intervention, 0=control. Analyses were adjusted for child age and sex, tester/interviewer, baseline score as fixed effects and community clinic as a random effect. Analyses for child development and behaviour outcomes also included place of test, and a place of test x group interaction term as fixed effects. p values for all ten primary outcomes have been corrected for with Holm's stepdown procedure.

Secondary Outcomes:

Mothers in intervention clinics had significantly better parenting knowledge (ES=1.27, 95% CI: 1.13, 1.41) and fewer depressive symptoms (ES=-0.18, 95% CI: -0.34, -0.03), than mothers in control clinics (**Table 2**). We also found significant benefits of intervention for home stimulation as measured by the FCI (ES=0.77, 95% CI: 0.60, 0.94).

Post hoc Analyses

In mediation analyses, home stimulation and mothers' child-rearing knowledge significantly mediated the effect of intervention on child development (Bayley Scales) and behaviour (Wolke behaviour ratings) (**Table 4.6 and Table 4.7**), whereas maternal depressive symptoms was not a significant mediator of child outcomes (**Table 4.7**).

Table 4.6: Mediation analyses with stimulation in the home (Family Care Indicators)

	BAYLEY SCALES COMPOSITE SCORES			WOLKE BEHAVIOUR RATINGS			
	Cognitive composite	Language Composite	Motor Composite	Approach	Emotional Tone	Cooperativeness	Vocalisations
Intervention	5.86	3.54	3.69	0.34	0.17	0.19	0.27
B (95% CI)	(4.72, 7.00)	(2.19, 4.90)	(2.13, 5.26)	(0.18, 0.49)	0.03, 0.31)	(0.05, 0.33)	(0.06, 0.49)
P-value	P<0.001	P<0.001	P<0.001	P<0.001	P=0.02	P=0.01	P=0.18
	0.10	0.28	0.20	0.02	0.01	0.02	0.02
	(0.02, 0.19)	(0.18, 0.37)	(0.08, 0.31)	(0.01, 0.03)	(0.00, 0.02)	(0.01, 0.03)	(0.00, 0.03)
	P=0.02	P<0.001	P<0.001	P=0.003	P<0.001	P<0.001	P=0.03
Sobel-test statistic	2.43	4.89	3.16	3.16	1.96	3.72	2.43
P-value	P=0.02	P<0.001	P=0.002	P=0.002	p=0.05	P<0.001	P=0.02

1=intervention, 0=control. The dependent variables were child development measured using the Bayley Scales (cognitive, language and motor composite scores) and child behaviour using Wolke behaviour ratings (approach, emotional tone, cooperativeness, vocalisations). Independent variables were child age and sex, tester, baseline score, place of test, a place of test x group interaction term, baseline and endline score for the Family Care Indicators and study group. All analyses were multi-level models controlling for community clinic as a random effect.

Table 4.7: Mediation analyses with mothers' child rearing knowledge

	BAYLEY SCALES COMPOSITE SCORES			WOLKE BEHAVIOUR RATINGS			
	Cognitive composite	Language Composite	Motor Composite	Approach	Emotional Tone	Cooperativeness	Vocalisations
Intervention	3.71	1.68	1.67	0.18	-0.11	0.05	0.06
B (95% CI)	(2.22, 5.20)	(-0.22, 3.58)	(-0.29, 3.63)	(-0.05, 0.41)	(-0.30, 0.08)	(-0.16, 0.26)	(-0.18, 0.30)
P-value	P<0.001	P=0.08	P=0.10	P=0.13)	P=0.27	P=0.65	P=0.61
Child rearing knowledge	0.30	0.41	0.37	0.04	0.04	0.03	0.04
B (95% CI)	(0.20, 0.40)	(0.30, 0.52)	(0.24, 0.50)	(0.02, 0.05)	(0.03, 0.06)	(0.02, 0.05)	(0.02, 0.06)
P-value	P<0.001	P<0.001	P<0.001	P<0.001	P<0.001	P<0.001	P<0.001
Sobel-test statistic	5.53	6.48	5.38	4.95	6.93	5.55	4.28
P-value	P<0.001	P<0.001	P<0.001	P<0.001	P<0.001	P<0.001	P<0.001

1=intervention, 0=control. The dependent variables were child development measured using the Bayley Scales (cognitive, language and motor composite scores) and child behaviour using Wolke behaviour ratings (approach, emotional tone, cooperativeness, vocalisations). Independent variables were child age and sex, tester, baseline score, place of test, a place of test x group interaction term, baseline and endline score for the mothers' child rearing knowledge and study group. All analyses were multi-level models controlling for community clinic as a random effect.

Table 4.8: Mediation analyses with mothers' depressive symptoms

	BAYLEY SCALES COMPOSITE SCORES			WOLKE BEHAVIOUR RATINGS			
	Cognitive composite	Language Composite	Motor Composite	Approach	Emotional Tone	Cooperativeness	Vocalisations
Intervention	5.88	4.59	4.43	0.43	0.23	0.30	0.37
B (95% CI)	(4.51,	(2.75,	(2.64,	(0.22,	(0.06,	(0.12, 0.48)	(0.18,
P-value	7.25)	6.43)	6.22)	0.64)	0.40)	P=0.001	0.56)
	P<0.001	P<0.001	P<0.001	P<0.001	P=0.01		P<0.001
Mothers' depressive symptoms	-0.06	-0.09	-0.11	-0.01	-0.01	-0.01	-0.02
B (95% CI)	(-0.13, 0.01)	(-0.06, -0.16)	(-0.19, -0.03)	(-0.02, 0.00)	(-0.12, 0.00)	(-0.02, -0.00))	(-0.03, -0.01)
P-value	P=0.10	P=0.01	P=0.01	P=0.001	P=0.08	P=0.001	P=0.005
Sobel-test statistic	1.25	1.49	1.49	1.68	1.29	1.68	1.61
P-value	P=0.21	P=0.14	P=0.14	P=0.09	p=0.20	P=0.09	P=0.11

1=intervention, 0=control. The dependent variables were child development measured using the Bayley Scales (cognitive, language and motor composite scores) and child behaviour using Wolke behaviour ratings (approach, emotional tone, cooperativeness, vocalizations). Independent variables were child age and sex, tester, baseline score, place of test, a place of test x group interaction term, baseline and endline score for the mothers' depressive symptoms and study group. All analyses were multi-level models controlling for community clinic as a random effect.

4.7: Discussion

We integrated an ECD, group-based parenting programme into government primary health care clinics in rural Bangladesh, with parenting sessions conducted by existing health workers as part of their usual duties. Many of the enrolled children were moderately malnourished and at high risk for poor development. We found significant benefits to child cognitive, language and motor development, and to child behaviour with children in the intervention group rated as happier, more sociable, more cooperative and more vocal during the developmental test session. There were no benefits to children's nutritional status.

Mothers in the intervention clinics reported higher levels of stimulation in the home, better parenting knowledge and fewer depressive symptoms than mothers from control clinics.

The moderate to large benefits to child development and behaviour found in this study are considerably larger than those found in Bangladeshi studies that used a similar curriculum, but delivered by local women, in individual home or clinic sessions (Hamadani et al., 2006; Hossain et al., 2021; Nahar et al., 2012; Tofail et al., 2013). The benefits are also larger, (approximately double), than those reported in a recent meta-analysis of childhood parenting interventions that reported mean effect sizes and 95% CI of 0.41 (0.29, 0.53), 0.35 (0.21, 0.48), 0.26 (0.16, 0.36) for child cognitive, language and motor development respectively from studies in LMIC (Jeong et al., 2021). The behaviour ratings in the present study are not strictly comparable to the socio-emotional development measures but they also tended to have higher impacts.

In the previous Bangladeshi trial (pair study) using a similar delivery model but where pairs of mothers and children participated in the sessions, treatment effects were even larger on child development (ranging from 1.1-1.3 SD) and child behaviour (ranging from 0.7-1.1 SD) (Hamadani et al., 2019). The moderate to large treatment effects found in the present trial

partially replicates those findings but are somewhat smaller. The difference in treatment effects may reflect differences in delivery of the intervention. It is likely that groups of four are more challenging to handle than groups of two. Also, in the pair study, play activities were more closely targeted to each individual child's developmental level and staff used a more detailed curriculum. To make the programme more feasible at scale, the groups of four used fewer play materials and play activities were adapted for use across a wider age range. Another possibility is that children in the pair study were slightly more disadvantaged with more children being moderately undernourished and the parents being less educated compared with the present study. There is some evidence that interventions benefit disadvantaged children more than less disadvantaged ones (Dulal et al., 2021).

The larger benefits in both the present and the pair studies compared with individual intervention sessions may be due to several factors. The parenting sessions were delivered by government health workers who were better educated than paraprofessional facilitators and are well respected in the community, which may enhance credibility. Group sessions provide mothers with the opportunity to engage in peer learning and gain social support and may reduce feelings of isolation and promote group norms that support responsive and playful parenting (Gladstone et al., 2018; Gomez et al., 2021; Yousafzai et al., 2018). We also placed strong emphasis on making the sessions fun and interactive for mothers and children and group sessions may be more enjoyable than individual sessions in this context, thus leading to higher participant engagement and motivation (Baker-Henningham, 2014; Glanz & Bishop, 2010; Smith et al., 2018). Group-based ECD parenting interventions have been shown to be effective in other contexts, including when integrated into existing services and delivered by existing staff (Attanasio et al., 2018; Fernald et al., 2017; Luoto et al., 2021), and when implemented by community volunteers trained specifically to deliver the program (Aboud & Akhter, 2011; Aboud et al., 2013; Singla et al., 2015). In addition, there is some evidence that

group-based parenting interventions are more cost-effective than individual home-visiting and mixed group and home-visiting delivery models, leading to increased scalability (Grantham-McGregor et al., 2020; Lopez Garcia et al., 2021). Benefits to child development and parenting outcomes are more likely to be sustained when the immediate impacts are larger, and the moderate-to-large effect sizes reported in this and the pair study are encouraging (Jeong, et al., 2021). We are currently planning a follow-up study to examine whether benefits are sustained.

The treatment effect on child cognitive, language and motor development and behaviour during the test were mediated by increases in mothers' parenting knowledge and stimulation in the home. This is expected as the intervention aims to promote child development by supporting mothers in responsive and playful parenting practices (Walker SP, 2018).

Although we found significant reductions in maternal depressive symptoms, this reduction did not mediate the impact on child outcomes. Maternal depression is less commonly measured in evaluations of ECD programmes. but the studies available indicate that these programmes have potential to benefit maternal mental health, further strengthening their value (Evans et al., 2021). However, benefits have not been found consistently (Jeong, Franchett, et al., 2021).

There were no benefits from the parenting intervention on children's nutritional status. The parenting sessions included a nutrition education component and mothers were provided with a recipe booklet with low-cost, nutritious recipes suitable for undernourished children. Over 62% of children were moderately stunted and 58% moderately underweight at baseline. For gains to children's nutritional status, food supplementation is likely to be necessary and is more effective if begun in the first year before undernutrition develops (Park et al., 2019; Prado et al., 2019).

The study has several strengths including the use of a cluster-randomised study design leading to well-balanced groups, prespecified analyses, masked assessors, intention-to-treat analyses, adjustment for multiple outcomes, the use of direct assessments of child development and observational measures of child behaviour. The outcome measures had good psychometric properties and although the Bayley scales are not standardised for Bangladesh, they have good concurrent and predictive validity and scores correlate with child nutritional status and maternal and paternal education in a logical way in this population (Hamadani et al., 2019; Hamadani et al., 2014). The study also had some limitations. Stimulation in the home was assessed through self-report and hence may be subject to bias. Although assessors were masked to intervention group, it is possible that some mothers may have mentioned the intervention during endline data collection.

The intervention was implemented in government community clinics by government health workers, used low-cost play materials and activities, and was acceptable to mothers and health staff as shown by the high compliance with and engagement in the intervention. These factors make it suitable for wider dissemination within Bangladesh. The community clinics that participated in this study are similar to those in other areas of rural Bangladesh and hence the results should generalise to clinics across the country. However, there are some limitations to consider as the programme is scaled-up. Firstly, the research team trained and supervised the health staff which helped ensure high quality intervention implementation. In future, it will be important to test if implementation quality is maintained when government health supervisors provide the training and supervision or if it is necessary to hire new supervisors for child development. Secondly, health staff participated in ten days initial training and quarterly 1-day refresher trainings. This is lower than reported in many other group-based ECD programs (Attanasio et al., 2018; Fernald et al., 2017; Grantham-McGregor et al., 2020; Singla et al., 2015), although longer than may be readily available in

many government programmes. High quality training and ongoing supervision is a key requirement for quality implementation and we need to advocate for sufficient training as ECD programmes are scaled-up. Thirdly, provision of play materials is a core component of Reach up & Learn and is essential to maintain effectiveness of the intervention as suggested by a Madagascan study, which used the Reach up & Learn curriculum without leaving toys with the mothers, and found no impact on child development (Galasso et al., 2019). In this and previous studies, toys have been provided by the research team. Others have implemented effective programmes that require parents to provide home-available playthings for their children (Fernald et al., 2017; Jensen et al., 2021; Luoto et al., 2021; Yousafzai et al., 2014). Hence, we can explore to what extent the play materials can be made by the mothers or communities. Another limitation is the relatively small number of children who can be reached through this model. The existing 13,000 clinics could reach approximately 416,000 children a year. Therefore, this approach is targeted to the highest risk children only and there remains a need to explore ways of increasing coverage, including increasing the group size where practical. In this study and the pair study, we targeted undernourished children because undernutrition is an important risk factor for poor child development. Alternative strategies would be required for high-risk children living farther from the clinic. For example, integrating ECD content could be integrated into the home visits and community health sessions conducted by FWAs and HAs as has been reported in other studies in Bangladesh (Aboud et al., 2013; Chinen & Bos, 2016).

In conclusion, our results suggest that integrating an ECD parenting intervention into government primary health care services in rural Bangladesh was feasible and effective for groups of four mothers and children making the program most suitable for targeting high-risk children. The intervention has the potential to be scaled up to other areas thus increasing the coverage of ECD programming for disadvantaged children.

4.8: References

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CHAPTER FIVE

Title: Scaling-Up an Early childhood Parenting Intervention by Integrating into Government Health Care Services in Rural Bangladesh: A Cluster- Randomised Controlled Trial

5.1: Abstract

Aims

We evaluated the feasibility and effectiveness of utilising government health supervisors to train and supervise primary health care workers (HWs) in community clinics to deliver parenting sessions as part of their usual duties.

Methods

We randomly allocated 16 unions in the Mymensing district of Bangladesh 1:1 to an intervention or control group. HWs in clinics in the eight intervention unions (n=59 health workers, n=24 clinics) were trained to deliver a group-based parenting intervention, with training and supervision provided by government supervisors. We recruited twenty-four mothers of children aged 6-24 months to participate in the parenting sessions in each intervention clinic (n=576 mother/child dyads). Mother/child dyads attended fortnightly parenting sessions at the clinic in groups of four-to-five participants for six months (13 sessions). We collected data on supervisor and HW compliance in implementing the intervention, mothers' attendance and the observed quality of parenting sessions in all intervention clinics and HW burnout at endline in all clinics. We randomly selected 32 clinics

(16 intervention, 16 control), and 384 mothers (192 intervention, 192 control) to participate in the evaluation on mother-reported home stimulation, measured at baseline and endline.

Results

Supervisors and HWs attended all training, 46/59 health workers (78%) conducted the majority of parenting sessions, (only two HWs (3.4%) refused), and mothers' attendance rate was 86%. However, supervision levels were low: only 28/57 (49.1%) of HWs received at least one supervisory visit. Intervention HWs delivered the parenting sessions with acceptable levels of quality on most items. The intervention significantly benefitted home stimulation (effect size=0.53SD, 95% confidence interval: 0.50, 0.56, $p<0.001$). HW burnout was low in both groups.

Conclusion

Integration into the primary health care service is a promising approach for scaling early childhood development programmes in Bangladesh, although further research is required to identify feasible methods for facilitator supervision.

Keywords: parenting, early childhood development, integrated services, low- and middle-income country, psychosocial stimulation

Key Messages:

- Efficacy trials have shown that early childhood development parenting interventions benefit child development in low- and middle-income countries although scaling-up is a challenge.
- We evaluated the feasibility and effectiveness of integrating a parenting program into the primary health care system in rural Bangladesh with parenting sessions

implemented by government health workers in community clinics and training and supervision provided by government health supervisors.

- Government supervisors were able to train the clinic health workers as shown by acceptable levels of health worker compliance in implementing the programme and the observed quality of parenting sessions.
- Mother attendance was high and the intervention led to significant benefits to the quality and quantity of home stimulation, measured as a proxy for child development.
- Integrating a parenting intervention into health workers' existing duties did not lead to increased burnout.

5.2: Introduction

Globally over 250 million children younger than age five years are at risk for poor development, leading to life-long negative consequences to their educational and economic attainment (Black et al., 2017). Although there is compelling evidence from low- and middle-income countries (LMIC) that early childhood parenting interventions benefit young children's development (Jeong et al., 2021), few interventions have been implemented at scale (Araujo et al., 2021; Yousafzai et al., 2014; Zhou et al., 2022). Integrating into government health services is a promising approach to going to scale, with some evidence of effectiveness (Chang et al., 2015; Luoto et al., 2021; Yousafzai et al., 2014). However, there are also barriers to integration including limited capacity to reach large numbers of disadvantaged children (Gladstone et al., 2018), increased workload for frontline staff (Brentani et al., 2021; Smith et al., 2018; Walker et al., 2018), staff turnover and/or non-compliance (Brentani et al., 2021; Smith et al., 2018), and the potential for staff burnout which has high prevalence among primary health care workers in LMIC (Dugani et al., 2018).

In Bangladesh, primary health care is delivered through a network of community clinics across the country. We previously integrated a parenting intervention into clinic services and government health workers (HWs) delivered parenting sessions with pairs or small groups of mother/child dyads as part of their routine duties. In two effectiveness trials of this approach, we found benefits to child development (Effect Sizes (ES) ranged from 0.52-1.3SD) and behaviour (ES=0.36-1.1SD), and to mothers' child-rearing knowledge (ES=1.3-1.7SD) and practices (ES=0.77-0.80SD) (Hamadani et al., 2019; Mehrin et al., 2022). These benefits were larger than those found for individual home-visiting in Bangladesh (Hamadani et al., 2006; Hossain et al., 2021; Tofail et al., 2013), possibly because groups provided social support and the HWs were better educated and more credible than previous home visitors. However, in these trials, the research team trained and supervised the clinic HWs. For the intervention to be implemented at scale, training and supervision of the HWs needs to be conducted by government staff.

In this study, we assessed whether government inspectors were able to train and supervise HWs to run a high-quality programme. We assessed quality through: 1) data on intervention implementation including the observed quality of the parenting sessions, and 2) the effect of the intervention on mothers' reports of stimulation in the home. We also measured HW burnout.

5.3: Methods

Study Design and Participants

The health service in Bangladesh is organized in districts divided into subdistricts, then unions. Each union consists of 2-3 community clinics. Clinics are staffed by three cadres of health workers: Community Health Care Providers (CHCPs), Health Assistants (HAs) and Family Welfare Assistants (FWAs). CHCPs work full time in the clinic; HAs and FWAs

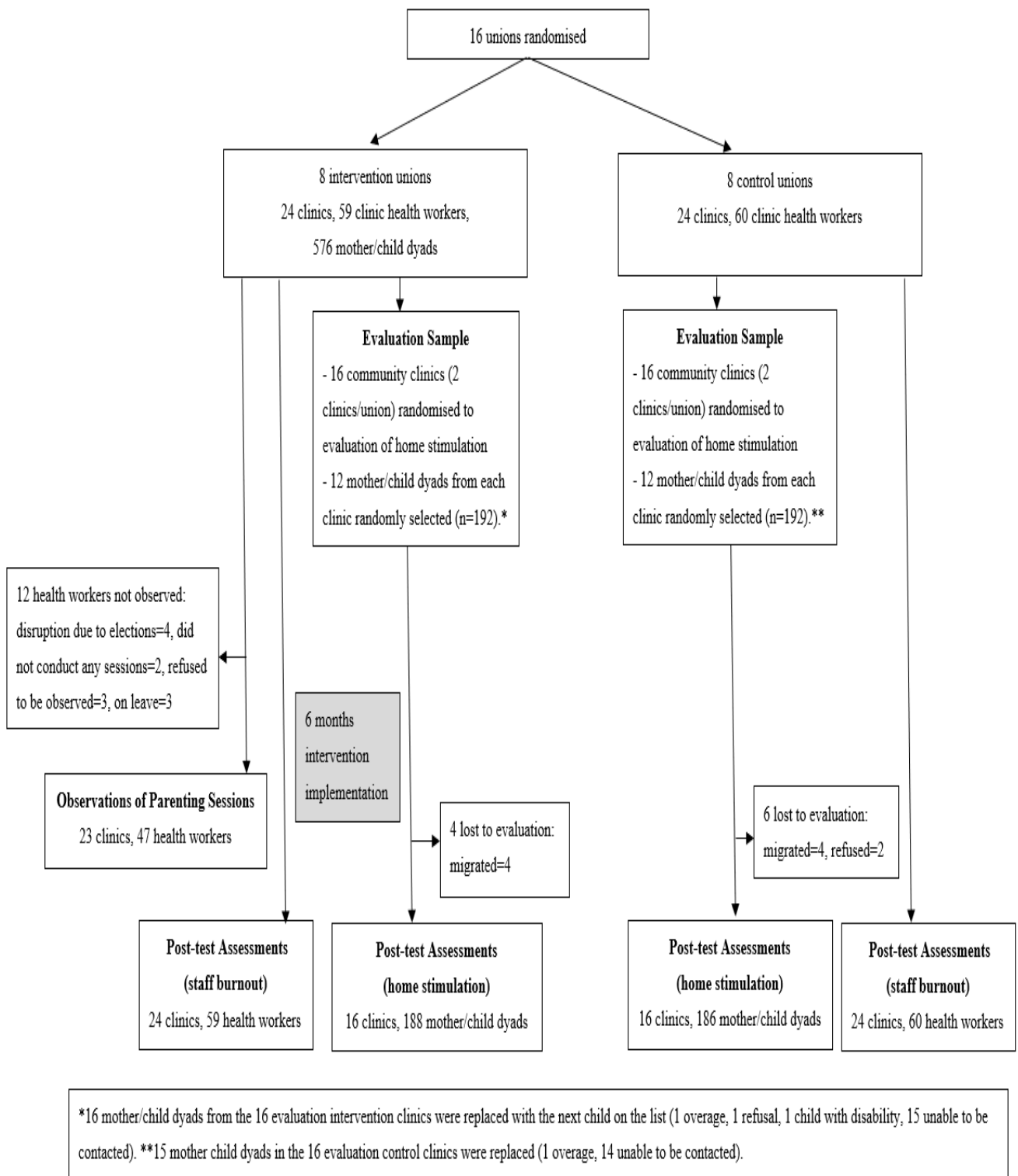
spend 2-3 days per week in the clinic and 3-4 days in the community. Inspectors based at the union-level supervise clinic HWs. Health Inspectors and Assistant Health Inspectors supervise CHCPs and HAs, Family Planning Inspectors supervise FWAs.

From July 2018 to March 2019, we conducted a cluster-randomized controlled trial in two subdistricts of the Mymensing district, located 116 km West of Dhaka city. Within each subdistrict, eight unions were randomly selected to participate in the study. Each union had three community clinics giving a total of forty-eight clinics. Unions (n=16) were stratified by subdistrict and then randomized 1:1 to an intervention or control group by an independent statistician using a computer-generated code. Union was the unit of randomization as supervision is provided at the union-level. HWs in clinics located in intervention unions (n=24 clinics) conducted parenting sessions in addition to their regular duties; HWs in clinics located in unions assigned to the control arm (n=24) continued with regular clinic services only. Clinics were randomized after recruiting HWs and before recruiting mother/child dyads. In the twenty-four clinics assigned to intervention, FWAs prepared a list of thirty young children aged 6-24 months old living within 30-minutes walking distance from the clinic. The FWAs then invited the mothers of the children serially until twenty-four mothers were recruited. When a mother was unavailable or refused, the mother of the next child from the list was invited to participate.

We randomly selected two community clinics from each union (16 intervention, 16 control) to participate in an evaluation of the effect of intervention on home stimulation. Within selected intervention clinics, twelve mother/child dyads were randomly selected to participate in the evaluation (n=192). Inclusion criteria for children were singleton birth and aged 6-24 months. Children with chronic illness or a disability were eligible to participate in the parenting sessions, but excluded from the evaluation sample. Within selected control clinics,

FWAs prepared a list of twenty-four children living within a thirty-minute walk of the clinic and twelve mother/child dyads were randomly selected (n=192) using the same inclusion criteria as for the intervention group. We did not track recruitment in the full sample of twenty-four intervention clinics. However, in the evaluation sample, sixteen mothers in the sixteen intervention clinics and fifteen mothers in sixteen control clinics were replaced mostly due to mothers being absent from home and/or having migrated prior to recruitment **(Figure 5.1)**.

Figure 5.1: Trial Profile



Written informed consent was obtained from government health staff and all mothers who participated in the study. The proposal was approved by the Institutional review board of the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B). The trial is registered at the American Economic Association Registry for Randomized Controlled Trials, number: AEARCTR-0006536.

Intervention

Mothers in intervention clinics attended fortnightly parenting sessions with their child in groups of 4-5 mother/child dyads for six months. The Group Reach-Up and Learn curriculum was used (Mehrin et al., 2021). Clinic HWs facilitated the parenting sessions: CHCPs conducted 1-2 parenting sessions per week, HAs and FWAs conducted one session per week. The research team trained government inspectors in the intervention unions to train and supervise HWs to facilitate the parenting sessions. See **Table 5.1** for details on the intervention content, process of delivery, structure, materials, and training and supervision of staff. Inspectors and clinic HWs in unions assigned to the control arm continued to provide regular health services with no additional activities.

Table 5.1: Group Reach Up and Learn Parenting Intervention

Content	The Group Reach Up and Learn interventions aims to promote responsive parenting and the quality of home stimulation, increase mothers' self-confidence and enjoyment in parenting, and promote young children's cognitive, language, motor and behavioural development. Mothers are introduced to developmentally appropriate play activities using low-cost play materials, books, and materials available in the home and are encouraged to chat and play with their child during everyday caregiving routines.
Process of Delivery	<p>Demonstrations, practice activities, group discussions, positive feedback, and home activities are used in the delivery of the intervention.</p> <p><i>Session Structure</i></p> <p>1) Feedback from the previous session, 2) Song, 3) Demonstration and practice of a toy, book and language activity (in four age bands: 6-11 months, 12-18 months, 19-30 months, 31-36 months), 4) Review and reminder of home activities.</p>
Structure	<p><i>Location:</i> Community clinic</p> <p><i>Frequency:</i> Fortnightly</p> <p><i>Duration of each parenting session:</i> 40-50 minutes</p> <p><i>Duration of intervention:</i> 6 months (13 sessions)</p> <p><i>Participants:</i> 4-5 mother/child dyads in each group</p> <p><i>Delivered by:</i> Three cadres of health staff in community clinics (Community Health Care Provider (CHCP), Health Assistant (HA), Family Planning Assistant (FWA))</p>
Materials	<p><i>Facilitator Resources</i></p> <ul style="list-style-type: none"> • Facilitator manual giving full details for each parenting session (used to prepare for the session) • Laminated summary card for each session (used during the session) <p><i>Mother / Child Resources</i></p> <ul style="list-style-type: none"> • Play materials from recycled materials (e.g. shakers, stacking toys, push-a-long toys, nesting toys, pegboard) • Wooden blocks • Soft toys (e.g. doll, bean bag, ball) • Puzzle boards • Matching games • Crayon and paper • Picture books <p>Mothers were given one toy and one book at each session and these were swapped for a different toy and book at the next fortnightly session.</p>
Training of Inspectors	The research team trained 19 inspectors (12 Health Inspectors and 7 Family Planning Inspectors) from the eight intervention unions to train and supervise clinic staff to conduct the parenting sessions. Inspectors attended eight days of training and were

	trained in two separate groups of 9-10 persons. Inspectors also participated in 2-day refresher training halfway through the intervention.
Training of Clinic Staff	<p>The government inspectors trained 59 clinic health staff (24 CHCPs, 17 HAs, 18 FWAs). Clinic staff received seven days of initial training, in groups of 13-15 participants, and a two-day refresher training midway through the intervention period (after 3 months).</p> <p>Sixteen inspectors provided supervision to the clinic staff. Each inspector was responsible for 2-3 community clinics and they were asked to attend a parenting session conducted by each health worker once a month during their regular clinic visits. Inspectors used a checklist to monitor the quality of the sessions and to guide them in providing appropriate support and feedback to the health worker. Health Inspectors provided supervision to CHCPs and HAs. Family Planning Inspectors provided supervision to FWAs.</p>

5.4: Measurements

We collected data on: 1) intervention implementation in intervention unions only, 2) burn-out of HWs in all forty-eight study clinics, 3) stimulation in the home in the subsample of thirty-two clinics. Data on HW burn-out and stimulation in the home were collected through interviewer-administered questionnaires by two female research assistants who were masked to group assignment.

Intervention Implementation

We collected data on HWs' and inspectors' attendance at training, number of parenting sessions conducted, number of supervisory visits, and mothers' attendance at parenting sessions in all twenty-four clinics assigned to the intervention group. We also assessed the quality of the parenting groups through structured observations. Observations were conducted in the final month of the intervention period by one of four observers. Each HW was observed conducting one parenting session. A structured observation checklist was used to rate HW's skills in conducting the activities, HWs' use of praise and encouragement, and the session atmosphere. Items were scored on a three-point scale, with descriptors on each point

of the scale. Definitions of each item were given in a manual. Interobserver reliabilities between the master coder and the observers were calculated for each item prior to data collection. Intraclass correlations coefficients were mean: 0.70 (range: 0.55-0.96) (**Table 5.2**).

Table 5.2: Interobserver reliabilities between master coder and observers (Intraclass correlation coefficients)

Items	N=13
Use of correct materials and activities as in curriculum	0.90
Explaining of the activities and objectives of the curriculum	0.96
Demonstration of the activities to the caregivers and children	0.58
Talked about the activities while demonstrating with the children	0.56
Praised the caregivers	0.72
Caregivers actively participated in the session	0.55
Praised the children when they attempted / completed an activity	0.92
Gave children enough time to explore the materials	0.58
. Helped mothers when they practice the play activities	0.66
. Atmosphere of the session	0.62
Feedback from last week	0.84
Book activity	0.58
Language activity	0.73
Toy activity	0.59
Review of home activities	0.75

Staff burnout

We measured HW burnout using the Maslach Burnout Inventory (MBI) (Maslach & Jackson, 1981) at post-test only. The MBI includes three subscales: emotional exhaustion, depersonalization and personal achievement and consists of 22 questions on a 7-point scale (0=never to 6=everyday). The measure was translated, independently back-translated and piloted with ten health staff who were not involved in the study. We reverse coded the personal achievement items and summed all items to create a total burnout score. Internal reliability using Cronbach's alpha (α) was 0.79. Test-retest over ten days with twenty participants was ICC=0.89.

Stimulation in the home

Stimulation in the home was measured for mothers only in the evaluation clinics at baseline and post-test using an extended version of the Family Care Indicators (FCI) (Kariger et al., 2012). The FCI has been previously validated in Bangladesh and correlates highly with the HOME ($r=0.72$ to 0.73), children' language skills ($r=0.37$ to 0.48) and Bayley test scores ($r=0.19$ to 0.29) (Hamadani et al., 2010). Data was collected at the mothers' homes. The extended FCI consisted of twenty-two yes/no questions about availability of a variety of play materials and the frequency with which caregivers in the home conducted various play activities with the child (e.g. looking at books, singing with child, playing with child). Internal reliability was $\alpha=0.79$ at baseline and $\alpha=0.86$ at endline; test-retest over 10-14 days with twenty mothers was $ICC=0.75$.

5.5: Statistical Analysis

The study was powered based on the outcome of stimulation in the home. With twelve mothers evaluated in each clinic and using an intraclass correlation coefficient of 0.05, we required a sample size of 177 per group to detect an effect size of $0.4SD$ on home stimulation at 85% power at 0.05 level of significance. We recruited 192 mother/child dyads per group allowing for 8% loss.

Multilevel regression analyses, using MLWin v3.05 (Charlton et al., 2020), were used to examine the effect of intervention on home stimulation and HW burnout. The residuals were tested for normality. Normality was rejected for HW burnout and the raw scores were log-transformed. For stimulation in the home, we controlled for child age and sex, interviewer, baseline score and any differences between the groups at baseline as fixed effects and union and clinic as random effects. For staff burnout, we controlled for interviewer as a fixed effect

and union and clinic as random effects. Effect sizes were calculated by dividing the regression coefficient with the SD of the control group at baseline.

5.6: Results

Intervention Implementation

All nineteen inspectors in intervention unions attended all training. Sixteen out of the nineteen inspectors trained were responsible for supervising clinic staff and all except one provided some supervision in the field. However, supervision levels were low (**Table 5.3**).

Table 5.3: Implementation Data

	N (%)
Number of parenting sessions conducted by health workers	
• Number of health workers who conducted all 13 sessions	33/59 (56.0%)
• Number of health workers who conducted 10-12 sessions	13/59 (22.0%)
• Number of health workers who conducted 7-9 sessions	11/59 (18.6%)
• Number of health workers who conducted 1-6 sessions	0/59 (0.0%)
• Number of health workers who conducted 0 sessions	2/59 (3.4%)
Frequency of Supervision	
• Number of health workers who received at least one supervisory visit	28/57 (49.1%)
• Number of health workers who were visited more than once	11/57 (19.3%)
• Number of health workers who were visited three or more times	4/57 (7.0%)
Mother Attendance	
• Mean (SD) number of sessions attended	11.2 (3.0)
• Number of mothers attending all 13 sessions	342/576 (59.4%)

CHCPs conducted mean (SD) 12.29 (1.60) sessions; HAs conducted mean 10.71 (3.46 sessions); FWAs conducted 9.89 (3.23) sessions.

All fifty-nine HWs in intervention clinics attended the full complement of training. HWs conducted a mean (SD) of 11.1 (2.9) sessions (out of 13) (**Table 2**). The main reasons for missed sessions were leave, sickness and competing work duties although two HWs refused

to conduct any sessions. The majority of missed sessions were covered by the CHCP in the respective clinic.

For the 576 mother/child dyads recruited in the intervention unions, the attendance rate was 86% (**Table 5.3**). Seventy-four mothers (12.8%) dropped out of the programme (53 no longer wanted to participate, 8 migrated, 13 as provider did not deliver the sessions).

Forty-seven (79.7%) HWs were observed conducting one parenting session. We were unable to observe twelve HWs (**Figure 1**). The majority of HWs reached acceptable levels of quality on items related to using the correct materials, explaining and demonstrating the activities to the mothers, encouraging caregiver participation, praising the children, allowing the children to explore the materials, supporting mothers as they practice the activities with their child, and creating a positive atmosphere (**Table 5.4**). However, there was no item for which >50% of the HWs were rated as very good. The aspects of the sessions conducted less well (>50% scoring poorly) were praising the mothers, asking mothers for feedback on last session's activities, conducting the language activities and reviewing the activities at the end of the session.

Table 5.4: Quality of Parenting Sessions Conducted by Clinic Health Staff by Observation

Items	Very good	Acceptable	Poor
Use of materials	All correct n (%)	Some correct n (%)	Few correct n (%)
Use of correct materials and activities as in curriculum	21 (44.7)	23 (48.9)	3 (6.4)
Methods used to introduce activities	Very well	Adequately	A little
Explaining of the activities and objectives of the curriculum	8 (17.0)	31 (66.0)	8 (17.0)
Demonstration of the activities to the caregivers and children	18 (38.3)	21 (44.7)	8 (17.0)
Talked about the activities while demonstrating with the children	12 (25.5)	23 (48.9)	12 (25.5)
Praise and Encouragement of Caregivers & Children	Most of the time	Some of the time	Rarely or not at all
Praised the caregivers	1 (21.1)	12 (25.5)	34 (72.3)
Caregivers actively participated in the session	21 (44.7)	21 (44.7)	5 (10.6)
Praised the children when they attempted / completed an activity	6 (12.8)	24 (51.1)	17 (36.2)
Gave children enough time to explore the materials	19 (40.4)	19 (40.4)	9 (19.1)
Providing appropriate support to mothers	All mothers	Some mothers	Few or no mothers
Helped mothers when they practice the play activities	12 (25.5)	22 (46.8)	13 (27.7)
Session atmosphere	Very happy	Happy	Neutral
Atmosphere of the session	6 (12.8)	31 (66.0)	10 (21.3)
Session Activities	Done very well n (%)	Done Adequately n (%)	Done poorly n (%)
Feedback from last week	5 (10.6)	8 (17.0)	34 (72.3)
Book activity	8 (17.0)	28 (59.6)	11 (23.4)
Language activity	7 (14.9)	10 (21.3)	30 (63.8)
Toy activity	14 (29.8)	25 (53.2)	8 (17.0)
Review of home activities	1 (2.1)	8 (17.0)	38 (80.9)

n= 47 clinic staff observed through independent observations using a checklist with clear definitions on each point of the scale.

Staff burn-out

All HWs reported on burnout (59 intervention, 60 control). Scores were low in both group (Table 5.4) and there was no significant difference between HWs assigned to intervention or control (Effect size (ES)= 0.10 (-0.14, 0.36), $p=0.68$) (**Table 5.6**) Burn-Out by Study Group.

Table 5.5. Baseline Characteristics and Endline Scores for Stimulation in the Home and Staff

Baseline characteristics	Control n=192	Intervention n=192	P-Value
Gender: female, n (%)	99 (51.3%)	101 (52.6%)	0.80
Child's age (months)	18.33 (6.24)	17.18 (6.24)	0.07
Mothers' Education (\geq grade 5), n (%)	119 (61.7%)	140 (72.9%)	0.02
Fathers' Education (\geq grade 5), n (%)	108 (56.0%)	114 (51.4%)	0.50
Housewife mothers, n (%)	176 (91.2%)	180 (93.8%)	0.34
Fathers' Occupation (semi-skilled), n (%)	103 (50%)	103 (50%)	0.99
Total assets	6.44 (1.93)	6.44 (1.68)	0.99
Housing	5.27 (1.20)	5.26 (1.17)	0.98
Crowding	2.94 (1.35)	3.01 (1.33)	0.60
Stimulation in the home (Family care indicators (FCI))	4.98 (3.46)	5.42 (3.80)	0.24
Endline Scores	n=186	n=188	
Stimulation in the home (FCI)	7.02 (4.05)	9.42 (4.72)	<0.001
Burnout (median (interquartile range))	5 (3-9)	6 (3-11)	0.79

Data are mean and SD unless otherwise indicated. Total assets are the number of different items owned from the following: dressing table, television, computer, mobile phone, fan, clothes stand, refrigerator, duck or hen, cow or buffalo. Housing index is the sum of ratings the quality of wall, roof and floor condition and the absence or presence of electricity. Crowding is the number of persons/room. FCI=12 questions, potential range of scores 0-12; higher scores indicate higher levels of stimulation in the home. Burnout=22 questions, potential range of scores 0-132; higher scores indicate higher burnout.

Table 5.6: Effect of Intervention on Stimulation in the Home and Health Worker Burn-Out

	Regression Coefficient B (95% CI)	ICC union-level	ICC clinic-level	Effect size (95% CI)	P value
Stimulation in the home ¹	• 2.13 • (2.02, 2.25)	• 0.01 •	• 0.05	• 0.53 (0.50, 0.56)	<0.0001
Health worker burn-out ²	• 0.04 • (-0.05, 0.13)	• 0.00	• 0.16	• 0.10 (-0.14, 0.36)	• 0.68

ICC=intracluster correlation coefficient. 1=control, 2=intervention. ¹Measured using the Family Care Indicators. Analysis was adjusted for child age and sex, interviewer, maternal education, and baseline score as fixed effects and community clinic and union as random effects. ²Measured using the Maslach Burnout Inventory. Scores were normalized with a log transformation and analysis was adjusted for interviewer as a fixed effect and community clinic and union as random effects. Effect sizes were calculated by dividing the regression coefficient with the standard deviation of the control group at baseline.

Stimulation in the Home

384 mothers were recruited into the evaluation (192 intervention, 192 control). At post-test, ten (2.6%) mothers were lost (4/192 (2.1%) intervention, 6/192 (3.1%) control) (**Figure 1**).

The only significant difference between the groups at baseline was for maternal education (**Table 5.5**).

In the evaluation subsample, mother attendance was similar to the full sample: 115/192 (60%) mother/child dyads in intervention clinics attended all thirteen sessions and the mean (SD) attendance was 11.4 (2.9). Twenty-six mothers (13.5%) dropped out of the programme: four migrated, twenty-two no longer wanted to participate.

We found significant benefits of intervention for home stimulation measured using the FCI (ES=0.53 (0.50, 0.56), $p<0.0001$) (**Table 5.6**).

5.7: Discussion

In this study, we report on an early childhood parenting programme that is fully integrated into primary health care services in rural Bangladesh with parenting sessions conducted by government health workers and training and supervision provided by government supervisory staff. We tested this model in a small cluster-randomised trial and found that it was feasible and effective. For example, government health staff attended all training sessions, most HWs conducted their allocated parenting sessions with acceptable levels of quality, mothers' engagement was good, and the intervention led to significant benefits to mothers' reports of stimulation in the home. Furthermore, the additional duties involved in implementing parenting sessions did not lead to higher burnout among HWs in intervention clinics compared to control clinics. Some challenges were also identified. Government inspectors provided limited field supervision and we identified a need to strengthen the quality of the parenting sessions.

This study extends the results from our two previous trials of integrating this parenting intervention into government health services in Bangladesh in which the researchers did the training and supervision. We report the same high HW compliance with training (100% compliance across all trials), similar HW compliance with delivering the sessions (78% of HWs conducted the majority of sessions versus 84-92% in previous trials), and similar levels of mother engagement (attendance rate of 86% versus 76-89% in previous trials) (anonymized). We also found moderate benefits of intervention to stimulation in the home ($ES=0.53SD$), but less than reported in the previous trials ($ES=0.77-0.80SD$). However, this intervention was six months shorter (thirteen sessions) than twelve months (twenty-five sessions) in the previous (Hamadani et al., 2019; Mehrin et al., 2022). In a recent meta-analysis, the effect size for parenting practices from early childhood parenting interventions

in LMIC was 0.47SD (Jeong et al., 2021), similar to the effect size in this study. Home stimulation was measured as a proxy for child development as the intervention benefits child development by increasing the quality, frequency and variety of playful parenting practices (Walker et al., 2018). In addition, HW burnout was low among the clinic staff and there was no evidence of increased burnout among intervention HWs. These results are encouraging as they indicate that the intervention maintains its feasibility, acceptability and effectiveness when training and supervision of the HWs is integrated into the routine duties of government health inspectors.

Although government inspectors attended all the train-the-trainer workshops and delivered all training sessions to the clinic staff, field supervision was limited. Inspectors are required to visit each community clinic monthly and we encouraged inspectors to plan these visits to coincide with the schedule of the clinic parenting sessions. However, we found that these monthly visits were not conducted routinely. It is possible that alternative supervisory arrangements are necessary for wide-scale implementation. For example, it may be possible to utilize peer support mechanisms in which CHCPs, who work full-time in the clinic, provide mentoring to FWAs and HAs. Alternatively, a new cadre of supervisory staff may be necessary. This would need to be tested in future studies.

High quality implementation of early childhood parenting interventions is associated with increased parent engagement and better caregiver and/or child outcomes (Araujo et al., 2018; Bernal et al., in press; Luoto et al., 2021). Through the observations of the quality of the parenting sessions, we found that the majority of HWs reached an acceptable level of quality in using the participatory, interactive training methods (e.g. encouraging caregiver participation, creating a positive atmosphere) and using the behaviour change techniques (e.g. demonstration and practice) required for intervention delivery. However, there is room for

improvement as only a minority of HWs were rated as very good. Some aspects of intervention delivery were weak, including praising the caregiver, conducting the language activities, and conducting feedback from the previous two weeks activities and reviewing activities to be done at home in the following two weeks. These relative strengths and weaknesses of the HWs in delivering the sessions were similar to those reported from home-visiting early childhood parenting programmes (Leer & Lopez-Boo, 2019; Rubio-Codina et al., 2019). With ongoing training and supervision, implementation quality of parenting programmes increases over time (Luoto, et al., 2021; Yousafzai et al., 2018). Hence, it will be important to ensure HWs receive ongoing support.

The strengths of the study are the use of a cluster-randomised design, good psychometric properties of the assessments used, outcomes measured by masked interviewers and the quality of the parenting sessions measured through structured observation. As clinic HWs delivered the parenting sessions with training and supervision from government inspectors, the model should be feasible at scale. Clinics were randomly selected from all clinics in the subdistricts to participate in the study and the results should be generalizable to other clinics in rural Bangladesh. The study also had limitations. We had insufficient resources to include measurements of child development; however, the FCI has been shown to predict child cognition and language in rural Bangladeshi children (Hamadani et al., 2010). In addition, the burnout questionnaire has not been validated for use in Bangladesh and although interviewers were masked to group assignment, it is possible that respondents talked about the intervention during the interview. To maintain quality at scale, further attention needs to be given to ensuring HWs receive ongoing supervision and support.

In conclusion, we found that utilizing government health inspectors to train primary health care workers to conduct parenting sessions as part of their usual duties is a promising

approach for scaling early childhood development programmes in Bangladesh. However, it may be necessary to use alternative staff to provide ongoing supervision by either hiring new supervisors for child development and/or using peer support mechanisms.

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CHAPTER SIX

6. Discussion

6.1: Integrated Early Childhood Development studies in Bangladesh:

The journey of the early childhood development research program in Bangladesh began in the late 90s. To date, eleven randomized controlled trials of early childhood, parenting interventions have been conducted with parents of children younger than five years and found consistent benefits to child development. To extend the reach of these programmes, they need to be integrated into government services. We performed a pilot study, where we: 1) adapted the Reach Up and Learn home-visiting programme for integration into the government primary health care services and delivery by existing staff, 2) tested the adapted intervention in two effectiveness trials, one with pairs and one with small groups of mother/child dyads and 3) conducted an additional cluster randomised trial to assess the feasibility of utilising government inspectors to train and supervise health staff to implement the intervention. In the two effectiveness trials we found significant benefits to child development (Effect sizes ranging from 0.85 to 1.3 SD) for cognition, 0.69 to 1.1 SD for language, 0.52 to 1.2 SD for motor development), behaviour (with effect sizes ranging from 0.36 to 1.1 SD) and for mothers' parenting knowledge (effect sizes ranging from 1.27 to 1.7 SD) and home stimulation (effect sizes ranging from 0.77 to 0.80 SD). We also found that the benefits to child development and behaviour were mediated by improvements in mothers' knowledge of child-rearing practices and increased stimulation in the home. This is consistent with the theory of change underpinning the group Reach-Up and Learn (RuL) intervention (RuL). RuL aims to support parents to use responsive and stimulating caregiving practices and these improvements in parents' behaviours then lead to improvements in children's development

(Walker et al., 2018). Other studies have reported that the benefits to child development from the RuL intervention are mediated by changes in mothers' parenting practices (Attanasio et al., 2022; Walker et al., 2004). The benefits to child development and behaviour from these group parenting interventions, integrated into the primary health care services and delivered by existing government staff, are larger than in previous studies where locally recruited community health workers delivered the intervention. One reason behind this might be the educational qualification of the government health workers. These health workers are mostly well-educated and experienced in delivering public service, which may increase their competence in delivering parenting sessions. In contrast, previous Bangladeshi studies used community health workers with lower levels of education to deliver the program (Hamadani et al., 2006; Hossain et al., 2021; Nahar et al., 2012; Tofail et al., 2013). In addition, the government health workers are respected in the community and have good relationships with the villagers. Their reputation in the community may have increased peoples' interest in the program. In another Bangladeshi study, interactive relationships and rapport building among the health workers and the families were reported to have a beneficial impact on program delivery and acceptance in the community (Jahir et al., 2021).

In one study, we involved government Inspectors who are the immediate supervisors of the frontline health workers to train and supervise the health workers to implement the parenting sessions. We found the supervisors were willing and competent in delivering the training to the health workers. However, the supervision rate was low (Mehrin et al., submitted, Chapter 5). We assessed health worker burnout and found no significant difference between the health workers of the intervention and control arm (Mehrin et al., submitted). With training and supervision provided by government inspectors, the intervention led to significant benefits to home stimulation with an effect size of 0.53. Therefore, we found, that integrating parenting

training into the community clinic service is a promising approach for improving children's early development.

6.2: An overview of the context: Challenges and mitigation:

Despite these successes in beginning to scale ECD parenting interventions using the government primary health care services in Bangladesh, there were barriers in using the government infrastructure and engaging government health workers. Integrating ECD sessions into the regular work schedule of government health staff without providing any extra benefit, incentive, or additional assistance may lead to staff dissatisfaction. For example, previous studies have reported workforce challenges when integrating ECD programmes into health services including: insufficient staffing leading to large workloads, low compliance, and difficulties in communicating with participating mothers due to no provision for communication costs (Brentani et al., 2021; Chang et al., 2015; Gladstone et al., 2018). In Brazil, health workers were offered additional salary for conducting home visiting sessions, and compliance was still low indicating that providing an additional stipend was not an adequate solution in this context (Brentani et al., 2021). In addition, adding extra incentives or salaries may restrict the scope for scaling up. The success of a program largely depends on the health workers' capacity, skills and motivation to implement the programme. They play a central role in supporting parents to develop skills in providing an enabling, stimulating and secure environment for their children. They are also the first contact in the community for parents eligible to receive the service and need to motivate parents to participate in the programme. Although providing incentives is often not feasible given the budgetary constraints within the health service, well-planned training with supportive supervision can be effective for enhancing and sustaining HW's motivation for the program. Previous studies have highlighted that participatory, collaborative and interactive training

methods with ongoing supportive supervision is helpful not only for increasing health workers' skills, but also for motivating them to deliver the parenting session more efficiently (Gomez et al., 2021, Yousafzai et al., 2015). In the work presented in this thesis, the research team provided high quality initial training and ongoing supervision to clinic staff implementing the programme in the pair and group effectiveness trials. The training and supervision were collaborative and participatory and a focus was placed on building positive relationships among all staff involved in intervention implementation. In the effectiveness trials, we report high compliance in conducting the sessions by health staff and large benefits to child development and behaviour and to mothers' child-rearing knowledge and practices, indicating that the HWs did deliver the programmes effectively (Hamadani et al., 2019; Mehrin et al., 2022). When training government inspectors to train and supervise the health workers, we maintained good interpersonal relationships with the inspectors to enhance their motivation to monitor the program efficiently (Mehrin et al., in submitted). However, high quality training and ongoing supervision also incurs more costs.

Another challenge was adjusting the curriculum according to the health workers' capacity, considering the context in which they work. In our study, the program was delivered by the government frontline health workers: Community Health Care Providers (CHCPs), Health Assistants (HAs) and Family Welfare Assistants (FWAs) who are involved in providing basic health services in the community. Early childhood development content was new to them, and they found that demonstrating the sessions was labour-sensitive task and time-consuming. Based on lessons learned in the pilot study, the curriculum was simplified by reducing the number of activities and verbal messages in each session and we made summary cards for HWs to use during the sessions so that they didn't need to manipulate a full manual (Mehrin et al., 2021). In our pilot study, we reported how we adapted the RUL intervention to make it suitable for integration into the government health service. This need for

simplification has been reported in other studies. For example, in a recent study in Bangladesh that reported on the development of an integrated child development, nutrition and maternal mental health, group-based parenting intervention, the group parenting sessions were delivered by locally recruited community health workers and demonstrating multiple activities using different toys was time-consuming, resulting in a loss mothers' interest (Akter et al., 2020). The researchers found that simplification and streamlining of the intervention content was required to increase program acceptance and compliance among the local health workers. In addition, interactive role-play activities and visual cues were added to the session to retain mothers' interest throughout (Akter et al., 2020).

In addition to adapting the RUL curriculum from being an individual home visiting programme to be suitable for use with pairs and small groups of mother/child dyads, we also adapted the curriculum from weekly sessions to fortnightly sessions to extend the number of children who could be reached through the programme. A fortnightly curriculum has been adapted or use in other settings, for example, in Brazil and Zimbabwe, to increase the reach of the programme and reduce implementation costs per child (Smith et al., 2018).

The success of any early childhood development program depends on the program's acceptance to families and the wider community, as this helps to increase mothers' participation and engagement in the program. In our studies, this was the first time that health workers delivered ECD sessions and the importance of play, stimulation and responsive care for young children's development were largely unfamiliar within the communities in these rural areas. This lack of knowledge of the value of ECD programmes affects the program acceptance in the community. For example, in Pakistan, mothers were sceptical about the benefit of an ECD parenting intervention initially and were less interested in attending the session (Yousafzai, Rasheed, & Siyal, 2018). In our pilot study, we also found that initially

some mothers did not value the sessions and did not believe the sessions were important for the development of their children. Moreover, they expressed concern at the lack of provision of nutritious food or vitamin for their malnourished children and this caused a lack of interest among the mothers to participate in the program (Mehrin et al., 2021). Nutritional supplementation is supposed to be provided through the government, however, supplies are unreliable and are not always available. Given our budgetary constraints, we were also unable to provide nutritional supplementation. We piloted an approach that involved community sensitization meetings to increase program acceptance among the families. Creating community awareness of the value of ECD programmes can help to promote interest in the programme among other members of the household (e.g. father, grandparents), thus promoting mothers' engagement in the program. We invited key local stakeholders and family members to community awareness meetings and these community meetings were successful in creating a positive attitude among the family members resulting increase in mothers' attendance at the parenting sessions (Hamadani et al., 2019). The need to increase community awareness to ensure the success of ECD programmes has also been reported elsewhere. For example, in Uganda, community elites made an important contribution to mothers' engagement in an ECD programme by reminding the mothers about the session schedule after participating in the community mobilization meeting (Singla & Kumbakumba, 2015). In a review of behaviour change strategies used in health interventions in low- and middle-income countries, thirteen studies used community mobilization meetings to provide social support for programme participation and to create awareness of the importance of the programme among the participants (Briscoe & Aboud, 2012).

We found challenges related to maintaining intervention fidelity using the government monitoring system. However, incorporating program supervision into government monitoring system is crucial for implementing a quality intervention at scale. We incorporated program

supervision into the regular government monitoring schedule successfully to some extent. We trained the supervisors to train the HWs and monitor the sessions. We incorporated session monitoring system into the inspectors' regular clinic visit schedule.

In reality, the government monitoring system is poor. The supervisors are reluctant to maintain their supervisory schedule regularly and they do not visit community clinics as per their workplan, consequently, many health workers remain unsupervised. We observed a similar trend in the session monitoring system in our study; only 56% of the health workers received at least one supervisory visit by their supervisor and only 23% were visited more than once over six months of intervention implementation (see Chapter 5). Although the supervision rate was low, incorporating the programme into the government monitoring system leads to a progression to scale. In addition, the lessons learnt can inform improvements to the guidelines for the training and monitoring system as the programme moves to scale. For example, alternative supervisory arrangements can be explored. This could involve remote supervision, embedding more regular refresher trainings into the programme to compensate for the lower levels of supervision, and/or using peer supervision.

To mitigate the challenges associated with low levels of supervision, we used a supportive supervision strategy to enhance both the Inspectors' and health workers' accountability in monitoring and delivering sessions respectively. The research team maintained good rapport and interpersonal relationships with government staff across all levels. In Colombia, the importance of this collaborative approach and supportive supervision were recognized, by intervention supervisors and frontline facilitators, as key enablers for successful implementation of an ECD programme integrated into an existing government programme (Gomez et al., 2021). Supportive supervision not only increases facilitators' compliance and motivation, but also helps to increase facilitators' skills and confidence in delivering sessions

(Yousafzai, Rasheed, & Siyal, 2018). A review on implementation strategies used in integrated programs highlighted that supportive supervision with positive and constructive feedback is a key indicator for enhancing facilitator's performance (Yousafzai et al., 2014). Programme supervisors require high quality training to develop their supervisory skills. Practical training with role-play of monitoring session using positive feedback needs to be included in training module of the supervisor training (Yousafzai et al., 2014). Although several studies have integrated ECD programming into the existing duties of government staff, the staff have generally been trained and supervised by the research team. There is little evidence of utilising existing government supervisory staff to train and supervise the frontline government staff involved in intervention implementation. More research is needed to investigate how to embed supportive supervision into existing government monitoring and supervision systems so that quality at scale can be maintained.

Another challenge is the provision of the play materials. This requires sourcing of the raw materials, making the play materials, storage, and maintaining an adequate number of play materials to ensure the clinics have the resources they need to conduct the sessions. In our studies, toys were delivered to the community clinics at regular intervals. However, this is a logistical challenge and also has financial costs which need to be borne by the health service. As the programme is scaled up, it may be necessary to explore alternative ways of providing the play materials. For example, it may be possible to encourage mothers to make play materials, for example by adding a special toy making session into the session schedule. We may need to further reduce the number of play materials used and/or substitute these with materials available in the home.

6.3: Enablers of integrating an ECD program with the Primary Health Care Service:

The major strength of the studies was creating a potentiality for scaling through integrating with Primary Health Care Service, using the community clinic, and involved the government Inspectors and a large number of health workers and we designed a feasible intervention model for clinic context. The studies were successful in improving children's development using government frontline health workers and benefits to child and maternal outcomes were larger than in the previous Bangladeshi trials (Chinen et al., 2019; Hamadani et al., 2019; Hossain et al., 2021; Nahar et al., 2012; Tofail et al., 2013). Our findings align with other integrated studies that showed benefits to child development when ECD parenting interventions were delivered by existing staff working within the government system (Attanasio et al., 2022 & Yousafzai et al., 2014). We worked in approximately 100 Community Clinics and trained approximately 250 health workers to deliver the program. Health worker compliance in training was excellent and compliance in conducting sessions was also high (Hamadani et al., 2019; Mehrin et al., 2022; Mehrin et al., in prep). Mothers' mean attendance at the parenting sessions ranged from 78% to 92% (Hamadani et al., 2019; Mehrin et al., 2022; Mehrin et al., in submission) which is higher than found in previous studies reporting ECD interventions integrated into existing government services where the program was run by government staff (Brentani et al., 2021; Ndayizigiye et al., 2021; Sylvia et al., 2020; Luoto et al., 2020).

The health workers showed competency in delivering the parenting sessions successfully without any extra incentive. They were able to use the Reach up & Learn curriculum correctly according to the age of the children which is reflected in the study findings. The RUL curriculum has also been successfully implemented by government workers in studies in Colombia and China (Attanasio et al., 2022; Heckman et al., 2020; Luo et al., 2019). However, in studies in Brazil and Madagascar that involved integrating the RUL intervention

into government services, no benefits were found for child development (Brentani et al., 2021; Galasso et al., 2019). The studies identified possible reasons for not achieving the expected program benefits including staff dissatisfaction due to lack of sufficient funds for communication and transport, insufficient time to conduct the sessions, inability to provide the play materials to families due to cost constraints, long distance of the households, and families' lack of engagement in the programme (Brentani et al., 2021; Galasso et al., 2019). In our studies, we found that the health workers were able to manage groups of mothers and children. However, groups were small with only two mother/child dyads in one study and groups of four-to-five mother/child dyads in the other studies. In another Bangladeshi study that delivered the intervention to groups of four-to-six mother/child dyads, local CHWs reported difficulties in handling children of different ages and demonstrating activities according to child age during the group session (Jahir et al., 2021). The health workers in our studies were government staff who were accustomed to working with groups in their health promotion activities, whereas the health workers in the above-mentioned study were locally recruited women with no previous experience which may explain these differences. Both in the pair and group intervention studies, the HWs enjoyed conducting the groups and reported that they valued learning new knowledge of early childhood development, and had acquired new skills in demonstrating activities with mothers and children. These factors enhanced their professional skills. This aligns with a report from a clinic study in the Caribbean, in which health workers reported gaining personal benefits such as increased job satisfaction, self-efficacy and knowledge of child development (Walker et al., 2017). In Colombia, FAMI mothers, (who were the frontline facilitators of the programme), also reported increased confidence and increased knowledge related to child development (Gomez et al., 2021).

The government supervisors also reported benefiting from their participation in the programme. For example, they gained communication skills, gained skills in training and

supervision which are important for their professional development and they gained knowledge on child development which was useful for their personal and professional life.

The high levels of mothers' engagement in the programme highlights the potential to scale-up the intervention. We found, that the mothers also valued the content of the intervention, and attendance was relatively consistent across all studies. Mothers reported feeling more confident in child care than before and they had increased knowledge and skills related to child development (Mehrin et al., 2020). Other studies have reported caregivers' positive experience and perception about the benefit of the program on their children's growth and development as well as increased social support and improved knowledge of nutrition and child development (Gomez et al., 2021; Walker et al., 2015).

A major strength of our study is the attention paid to maintaining intervention fidelity. We developed a session reporting form that was incorporated into the existing government reporting system. The HWs submitted the session report to their respective authority every month along with their regular report on clinic activities. The record contained information on the number of children who attended each session, the session number, and the date of each session. Based on their report, it was possible to assess the session status of the individual clinic and to provide follow-up for the poor-performing clinics.

We also developed a session monitoring form to monitor the quality of implementation for use by the project team members and the government supervisors during clinic visits.

However, the supervisors were less competent in addressing the flaws of the session and providing constructive feedback to HWs. They had no previous experience of using this type of monitoring form. In response to these difficulties, we developed a training package focused on how to provide supportive supervision based on sessions observations, using role-play, video recordings, and practice. We also developed a series of problem-solving activities

to help supervisors manage the most common issues identified. Problem-solving skills have been recognized as essential skills for facilitators and supervisors in other studies (Yousafzai et al., 2014; Tomlinson et al., 2018).

We also designed an observational checklist to assess the quality of parenting session as the programme is scaled up. The checklist was developed to cover topics related to the facilitators' relationship with mothers and children, their attitude towards session, the session atmosphere, the quality of demonstration and the quality of implementation of the different activities (e.g. feedback, play activities, language activity etc.). We used a three-point scale with descriptors on each point of the scale to make it easy to use and feasible for use by government staff. Tools to monitor quality are an essential component to scaling ECD interventions as it is important to monitor implementation quality as these programmes are disseminated more widely. Implementation quality has been shown to predict mothers' attendance and home stimulation in a group-based parenting programme in Kenya (Luoto et al. 2021), and to predict child development in a large-scale, ECD home-visiting programme in Peru (Araujo et al., 2018). Measuring tools need to be reliable, easy to administer and low cost (Rubio-Codina, Dormal, & Araujo, 2019; Schodt et al., 2015). The tool developed in this study met these criteria. Further research is required to validate the tool by examining if quality predicts child and/or maternal outcomes.

Through this work, we tested different delivery models and found consistent benefits to children's development and/or maternal outcomes using parenting intervention delivered with pairs or small groups of mother/child dyads (Hamadani et al., 2019; Mehrin et al., 2022). We used rigorous evaluation techniques including using cluster-randomized controlled trial designs, direct testing of child outcomes by masked assessors, and using measurements that have been validated for use in Bangladesh. The findings are thus promising as they indicate

the potential for integrating the ECD parenting program into the existing government health platform.

6.4: Further Initiatives for taking to scale:

We are gradually moving towards scale up; to date, we have completed three research trials of the group RuL integrated into the government primary health care service in Bangladesh. Based on the success of those projects, we are now further scaling up the intervention with the aim of fully integrating the intervention into the services provided by community clinics. The detail of the project is given below:

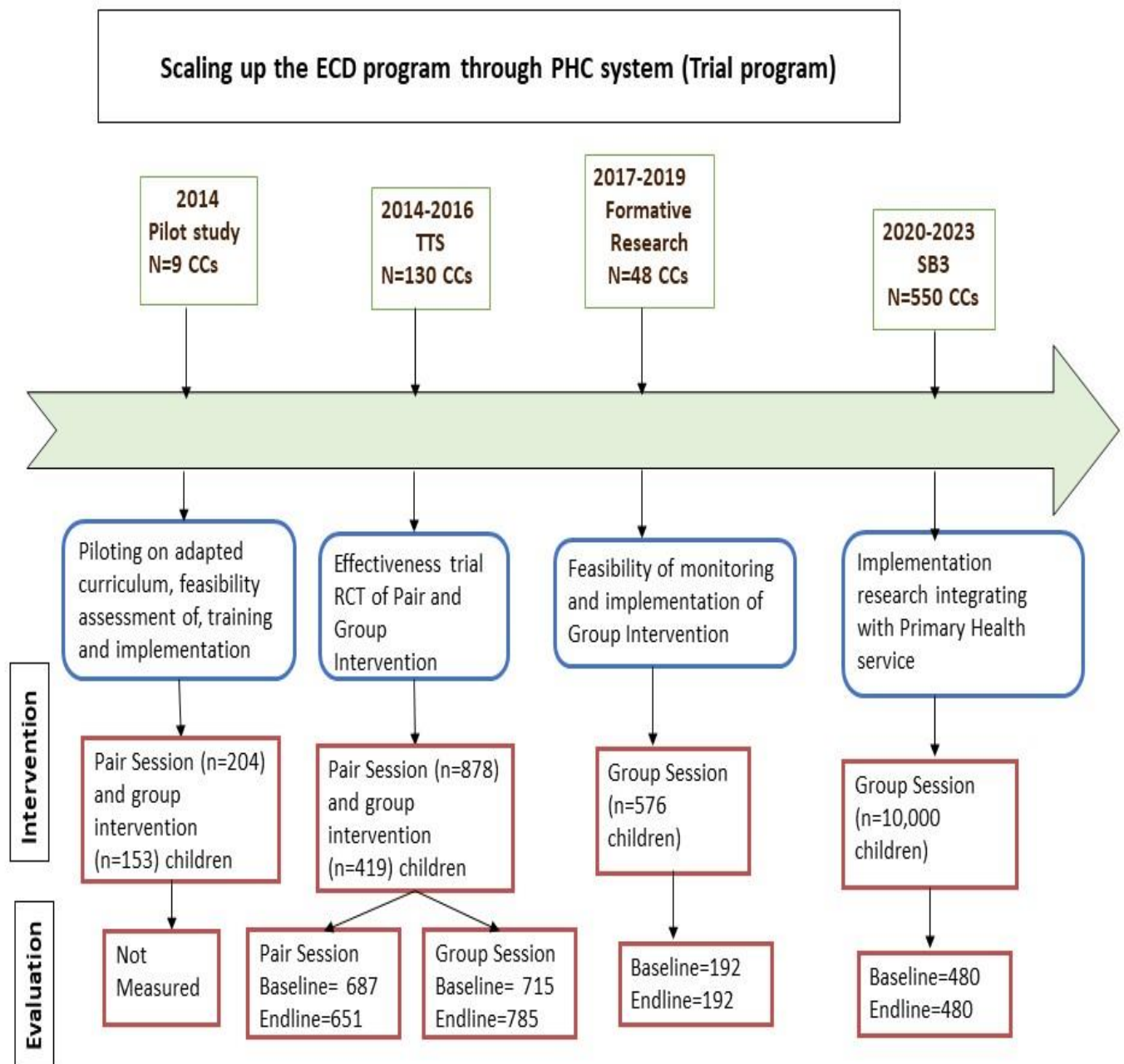
Strengthening Bangladeshi Babies' Brains (SB3):

In this project, we are increasing the coverage of the programme with the aim of reaching up to 10,000 children. Currently, the intervention is being implemented in 550 community clinics in 21 sub-districts within four districts of Bangladesh. Our aim is to establish an organizational structure for the programme that is sustainable, including a mechanism for sustainability at the national, district, and Upazila levels. This includes paying attention not only to the implementation of the sessions within the clinic, but also the associated training, supervision, monitoring and reporting required for long-term programme success. We are enrolling up to forty children per clinic and selecting children with mild-to-moderate malnutrition. Malnutrition is defined as a Mid Upper Arm Circumference (MUAC) less than 13.5, measured by the health workers. The reason for using MUAC measurements is because: 1) MUAC measurement tapes are available in the clinics, 2) it is easy to train the health workers to conduct the measurements reliably, and 3) MUAC can be measured during household visits or during child visits to the clinic. Community clinics are not routinely provided with weighing scales and height/length boards to measure child growth. The main difference of this trial from the previous studies is that we are following a cascade model of

training from Master Trainers (staff from ICDDR,B) down through three levels: the district, the Upazilla, and the clinic staff, with the long-term goal of handing over the program to the government. We train the district-level staff of the health and family planning sector who are responsible for the health system within their district. The district-level tier includes district level Medical Officers, the Medical Officer for Family Planning, the Medical Officer for Disease Control, the Upazila Family Planning Officer, and the District level Health Education Officer. These district level government health staff then deliver training to Health Inspectors, Assistant Health Inspectors, and Family Planning Inspectors who are directly responsible for supervising the health workers in the community clinics. These inspectors then train the clinic health staff in intervention implementation. District-level staff and inspectors receive training on how to provide training monitoring and supervision, in addition to learning about the curriculum. The district-level trainers attend the first two days of the health worker training by the inspectors to ensure an adequate standard of training and they use a checklist to monitor the quality of the training. In this study, we are using the same adapted version of the Reach Up & Learn curriculum that was used in the previous studies. We have incorporated the session monitoring schedule and the supervisory report for this ECD parenting programme into their regular reporting system so that it becomes an integral part of the services provided in the community clinics within each district.

We are evaluating the programme using a cluster-randomised design using a subsample taken from the larger project. We randomly selected eight sub-districts from the four districts, followed by a random selection of six unions from each subdistrict with a total of forty-eight unions randomly allocated to intervention and control. We then randomly selected ten children per union (n=480) to participate in the evaluation of child outcomes. This study is still in progress.

Figure 6.1: Pathways of integrated studies

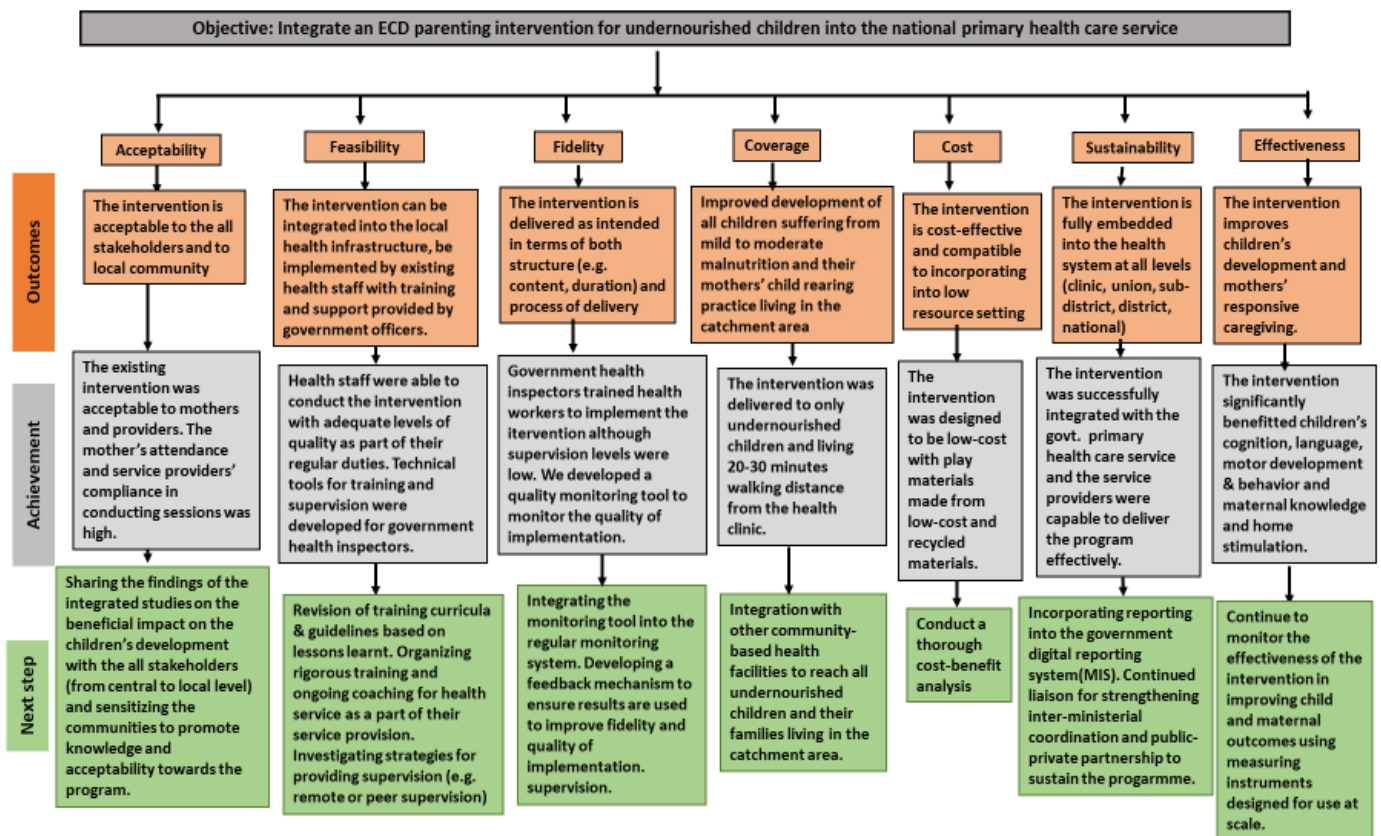


After completing the above trials, we will continue the process of scaling up the program. In future, our plan is to utilise implementation research including mixed method methodologies. Implementation research will help to explore the process of integrating the evidence-based, early childhood, parenting interventions into an existing infrastructure (the health service) to increase the potential for sustainment with the system and sustained effectiveness of the

intervention on child and maternal outcomes. As implementation science involves integrating interventions into the broader setting, it focuses not only beneficiary outcomes but also to outcomes at the provider, organization and policy level (Bauar et al., 2015). Relevant research questions relate to training and supervision of intervention staff, monitoring fidelity, acceptability (to all stakeholders), adoption of the intervention, intervention coverage and cost, and sustainability within the system (Peters et al., 2013). In investigating implementation outcomes, there is scope to utilize both quantitative and qualitative methodology, both as a method of triangulation and to ensure that the perspectives of key stakeholders are included. For quantitative methods, the use of effectiveness-implementation hybrid designs is recommended (Curran et al., 2012). These designs include a quantitative evaluation of the effectiveness of the intervention in addition to a quantitative evaluation of the effectiveness of the implementation strategies used. In our future trials, we will include 1) implementation outcomes (e.g. adoption of the intervention, appropriateness, feasibility, fidelity, cost, coverage and sustainment over time), and 2) beneficiary outcomes (e.g. child development, maternal outcomes) (Proctor et al., 2011). Using qualitative methodology in trial research is beneficial to gain a pragmatic understanding of the research context, explore the need for refining the intervention, address the challenges of implementation, investigate potential reasons for research findings, and to develop new research questions (Lewin et al., 2021).

A diagram on a future direction of implementation outcomes model is given below:

Figure 6.2: Implementation outcome diagram of a sustainable integrated Early Childhood Development model



The figure depicts implementation outcomes of an integrated ECD programme within primary health care services. The aim of the programme is to develop a sustainable early childhood development programme targeting the high-risk children aged below 3 years integrated with the health facilities. We have included seven implementation outcomes that are most relevant for scaling this programme: 1) acceptability, 2) feasibility, 3) fidelity, 4) coverage, 5) cost, 6) sustainability, and 7) effectiveness. The diagram includes a definition of each implementation outcome (orange boxes), the lessons that we have learnt to date (grey boxes) and our planned next steps (green boxes).

As indicated in the figure, through the work presented in this thesis, we partially achieved some key aspects of scaling the programme. We adapted a low-cost intervention and

integrated it with the rural health facility. The government frontline health workers successfully implemented the programme as a part of their routine duty. We produced training manuals and technical to build health workers' capacity to implement the programme and found benefits to child and maternal outcomes. However, in the future, attention should be given to organising ongoing coaching sessions for the weaker health workers to increase their skills in intervention implementation. The programme supervision was integrated with the current government monitoring system and we developed a monitoring tool and guideline for use by the supervisors. However, the monitoring system is poor; this area requires strengthening in future work. In addition, the reporting system needs to be incorporated into the government electronic reporting system to maintain the programme fidelity and promote sustainability. We targeted children with malnutrition, (who are at heightened risk for poor development), who were living close to the community clinics. However, this limits the coverage of the intervention. To mitigate this barrier, the programme may be integrated with other possible community-based delivery platforms under the primary health care. The health workers' compliance in training and delivering the intervention was high and the attendance rate of the mothers was also reasonably good, which reflects the acceptability of the programme to the health workers, families and the community. The intervention was effective in improving the development of the children. The caregivers gained knowledge and confidence in delivering the responsive caregiving and stimulation to their young children resulting in reduction of their depressive symptoms. Dissemination of the study findings from the central to sub-district level government stakeholders is crucial to uphold their interest in regularizing the intervention in the health facilities and producing materials and strategies to increase community acceptance towards the programme. Finally, rigorous advocacy for strengthening inter-ministerial coordination may be included in future planning to establish a sustainable organisational infrastructure for this integrated ECD programme.

6.5: Limitations:

During the expansion of the program, we have identified several limitations at the system level that need to be addressed while scaling up the programme nationally across Bangladesh. These limitations are presented briefly below:

Inclusion of limited number of children: In our previous studies, we only invited mothers of children with mild to moderate malnutrition to participate in the programme. In addition, we limited the number of children accessing the service in each community clinic to twenty-four whereas the clinic catchment area covers around 6000 households. Given the total population under the catchment area of the CC, only 10% of the children under 5 years of age are able to access the program. To adjust the session to the current workload of the health workers, we also only selected children who live within 20-30 minutes' walking distance from the clinic (Mehrin et al., 2021). In scaling-up the programme, we are evaluating a model in which we have extended the number of children to be served to from twenty-four to forty children per clinic. Mother/child dyads are attending in groups of five, rather than four. This means that each clinic is conducting four sessions per week, rather than three sessions as in the previous group study. In the pair study, each clinic conducted six sessions a week, (although working with pairs requires less preparation than working with small groups of four-to-five), and so we anticipate that this will be feasible within their workload. However, the reach of the programme remains low and this is an important limitation to taking the program to scale. Similar problems with population-reach have been reported in other country contexts and government health workers are unlikely to be able to reach all disadvantaged children (Gladstone et al., 2018; Jeong et al., 2021). Hiring additional staff can be a viable solution to reduce the existing health worker's workload. In China, an additional cadre of staff were recruited by government to run ECD sessions in two studies and both found significant benefits to children's cognitive skills (Heckman et al., 2020; Sylvia et al.,

2021). In addition, it is important to explore other relevant delivery platforms in addition to the community clinic so that more children can have access to the program. For example, it may be possible to integrate ECD parenting interventions into satellite clinics that run immunization and other health promotion activities. Satellite clinics may be a convenient place for the Health Assistants to run the ECD sessions. This needs to be tested in future studies.

Lack of manpower:

Another limitation is lack of manpower in some community clinics. There is a shortage of service providers in some clinics due to maternity leave, sick leave and/or retirement. The regular session activities are hampered in those clinics and we need to reduce the number of children reached to match the number of available staff. Similarly, the study also suffers from a lack of supervisors (government inspectors) in some areas. Some inspectors are old, close to retirement and/or sick and unable and/or unwilling to travel to conduct training and supervisory activities. There is no alternative resource person available thus reducing the levels of training and supervision of the clinic staff. Staff workload has been reported to be a key limitation in the other studies involving integrating ECD parenting interventions into health services with staff turnover and staff leave being the major problems and creating an extra work burden for remaining health workers (Brentani et al., 2021; Gladstone et al., 2018; Walker et al., 2015). This indicates a need for health-system strengthening including ensuring temporary staff are available to cover for absent workers.

6.6: Possible steps for increasing coverage of children:

To reach the goal of establishing an ECD platform that is accessible countrywide; we need to identify a variety of ways of integrating the program into existing services. The primary health service is arguably the most promising venue as this is universally accessed by

pregnant women and mothers of young children. However, health facilities have limited capacity and are unlikely to reach all children in the community. Nutrition services are another potential platform to deliver ECD services. The National Nutrition Service (NNS) in Bangladesh is working on establishing a feasible acute malnutrition management and severe acute malnutrition service point at the community and hospital levels. They are providing training to community level stakeholders, members of community groups and community support groups on nutrition care practice. Therefore, incorporating ECD into the training of these National Nutrition Service activities may be another way of expanding programme coverage. Other possible platforms are be the Integrated Management of Childhood Illness (IMCI)-nutrition corners and Kangaroo Mother Care (KMC) Centres in Sub-district level hospitals, Union Health Centres (UHC), and Family Welfare Centres (FWC) under the Family Planning services. The government safety net program is another promising sector for delivering ECD services in Bangladesh, especially in urban areas. Studies in Mexico, Ecuador, and Colombia have integrated ECD parenting interventions with a cash transfer program and shown significant benefits to children's cognition, language, and motor development (Attanasio et al., 2014; Fernald & Hidrobo, 2011; Fernald et al., 2017). The Ministry of Women and Children Affairs (MOWCA) of the Government of Bangladesh (GOB) provides a maternity allowance of taka 500 (\$6.25) for rural poor mothers; an unconditional cash transfer under the safety net program of GOB. The mothers also receive a limited health education (HE) program. The mothers receive the cash every six months for two years. The objective of the cash and health education (UCT-HE) training program is to reduce maternal and child morbidity and mortality, and increase well-being during pregnancy and lactation for both mother and child. In a Bangladeshi study involving integrating psychosocial stimulation with an unconditional cash transfer program significant benefits were found for child cognitive and language development (Hossain et al., 2021). Hence, the

social safety net program for pregnant women and lactating mothers, run by the Bangladesh government, is another potential delivery platform for ECD services.

6.7: Recommendations:

Currently, studies from multiple disciplines emphasize the importance of investing in ECD programs to promote lifelong well-being and to maximize the return of human capital in any country (Naudeau et al., 2011). To develop a sustainable model of an ECD program, attention needs to be given to the wider context of the programme. Some of these factors are discussed below:

Pursue of integrated approach through public-private partnership:

Partnership between the local government, NGOs, and community stakeholders is required to implement a sustainable program of ECD at the community level. Along with the government running programmes in the community, the private sector can also play an influential role in implementing the program. Involving the private sector increases the likelihood of additional workforce investment with no or minimal cost, which may aid to increase coverage. For example, the Ministry of Primary and Mass Education (MoPME) is running the pre-school programme countrywide with the support of BRAC, a leading NGO in Bangladesh. The pre-school program is integrated with the education system, and primary schools are running the program. BRAC is delivering training to the preschool teachers and are also involved in monitoring the programme. In Bangladesh, there are many NGOs running different development programmes in both urban and rural areas. Collaboration with these NGOs is a potential approach that could accelerate the expansion of the programme and create community demand. The joint venture of public-private partnership would help to increase community engagement, maintain quality and building district-level capacity (Bhatta et al., 2020).

Community engagement through community advocacy:

Successful implementation of ECD programmes requires engagement of the community, families and the workforce involved in the program. Therefore, community mobilization is a key element for programme sustainment at the community level. Sensitizing the community leaders and local stakeholders can increase the community's links with the health facilities and play a significant role in identifying those children who need special assistance by the health professionals. Community mobilization requires varied techniques and can include placing posters in public places such as schools, health centres, and clubs; distribution of leaflets to household consisting of information on importance of early childhood programme; organizing workshops with the community leaders; using religious leaders to motivate the families during prayer gatherings; and using local social media. Allocating funds for community advocacy activities is recommended when designing action plans for a sustainable ECD program.

Using digital technology:

Using mobile technology has several advantages in strengthening community awareness towards the program and enhancing communication between the participants and the health workers. Nowadays, most families in rural areas own cellular phones. The mothers can be encouraged and educated through voice or text messages focusing on the role of parenting in child development and/or the importance of participating in the program. In addition, this technology can be used to send reminder messages to the participants to attend the sessions and to practice activities introduced during the session with their child at home. In one study in Bangladesh, health workers used a tablet with the session content uploaded onto the system. The CHW reported that using the tablet was convenient, they felt more confident talking to mothers during the session, and using tablets helped increased their importance and

acceptance among the mothers and in the community. (Jahir et al., 2021). A digital reporting system is a powerful tool for monitoring intervention implementation and tracking sessions through real-time data. In Guatemala, mobile technology was used by the Community Health Nurse (CHNs) to maintain a registry, for surveillance and for data collection. In addition, the CHNs received weekly one-hour virtual education session on child health and development from expert group (Domek et al., 2017). Using telehealth education in training had been proven to be effective and feasible way of distance training reducing the travel cost (Domek et al., 2017). The Bangladesh Government have established an electronic reporting system and developed software which called Management Information System (MIS). The software is operated centrally by the IT department of the Ministry of Health and Family Welfare. The CHCPs submit their day-to-day patient care report through this software. In our programme, we were unable to incorporate electronic reporting system of parenting session into the government MIS. The CHCPs prepared the session report in hard copies and submitted to their respective authorities. We are currently working on incorporating the session reports into this Government MIS to establish a countrywide reporting system to allow the government to monitor program implementation using real time data.

Strengthening monitoring system:

Supportive supervision is a key factor in implementing a quality program and it helps to promote facilitators' accountability and sustain their interest in delivering the program (Yousafzai et al., 2014). In our programme, we found a low supervision rate. The existing supervision system is already poor and, in our study,, the inspectors were unable to maintain supervisory schedule regularly. One viable alternative may be to utilize peer supervision. The CHCP is the full-time worker in the community clinic and they lead the clinic activities and have overall responsibility for managing the clinic. Inspectors could train the CHCPs to

provide support and assistance to the other health workers (the HAs and FWAs) within the clinic. In addition, it may be possible to involve other relevant local government or private organizations in monitoring the program. For example, the Community Group (CG) under the Ministry of Local Government and Rural Development (MoLGRD) are tasked with promoting the proper management, maintenance and quality of care at the community clinics. They may be able to provide assistance in monitoring of the programme. Alternatively, it may be necessary to recruit a new cadre of staff to support the ECD intervention at the union level. District-level collaboration with other public and private organizations may assist with providing an additional workforce in the monitoring of the program.

Inter-Ministerial collaboration:

Currently, Bangladesh Government intends to take the ECD program to scale. However, it is not the responsibility of Ministry of the Health and Family Welfare (MoHFW) alone to endorse the program. Hence a combined inter-ministerial effort is required to accelerate the expansion of the program nationwide. The Ministry of Women and Children Affairs launched a Comprehensive Early Childhood Care and Development (ECCD) policy consisting of a comprehensive ECD program from conception to age eight, though the implementation of the policy is at a very preliminary stage. In addition, the Ministry of Primary and Mass Education (MoPME) have approved a Pre-Primary Educational Framework and have taken several initiatives to universalise quality pre-primary education countrywide. The pre-primary education is now an integral part of primary education, run by MoPME, with the support of different NGOs. The MoHFW has a well-organized infrastructure to deliver the program in hard-to-reach areas and is willing to foster improved inter-ministerial and inter-sectoral coordination. The collaboration and coordination among the above three ministries can play a crucial role in achieving the goal of scaling up the program.

6.8: Limitations of the thesis:

There are strengths and limitations of the work presented in this thesis and many of these strengths and limitations are detailed in the research articles in chapters 3, 4 and 5. There are two additional limitations worthy of note.

The first limitations relates to the literature reviews presented in chapter two. My thesis included the findings of three trials integrating with the primary health service: one pilot study and two effectiveness trials. Considering the type of intervention used in the studies and the process for integrating with an existing service, chapter 2 includes literature reviews relating to trials of early childhood parenting interventions including 1) research from Bangladesh, 2) intervention studies conducted with groups of parent/child dyads and 3) studies that involved integrating the early childhood parenting programme into an existing government programme. The articles used in the study were retrieved from different sources, such as Pubmed, Google scholar, ResearchGate and from experts in the field. However, as I conducted the search as an ongoing process while conducting the work on this thesis, I did not do a systematic review. In conducting a systematic review, reporting guidelines such as the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) (Page et al., 2021) and/or the Cochrane Handbook (Higgins et al., 2022) are recommended. By following a systematic approach, the search is comprehensive, including all relevant research and selection bias is minimised.

The second limitation is that in the pilot study described in chapter 3, we interviewed the mothers and the health workers using a semi structured questionnaire to explore the enablers and barriers related to programme implementation (Mehrin et al., 2021). This research was conducted to inform the development of the intervention and to maximise the likelihood that the intervention would be feasible, acceptable, relevant and effective in the setting. We utilized rapid cycle, iterative research and we did not have the resources to use structured

qualitative methodology. Our decision to utilize less structured methods was largely due to the short span of the pilot and budgetary restrictions. When conducting formative research, it is advisable to conduct more structured and rigorous qualitative research. This involves following the guidelines for qualitative research – for example, the COREQ guidelines (Tong et al., 2007) and the Standards for Reporting Qualitative Research (SRQR) (Brien et al., 2014). For more rigorous qualitative research, interviews are audio recorded, transcribed and coded using a thematic framework. In other work, we have utilized the Framework Approach to analyse data which is appropriate for applied policy research (Ritchie and Spencer, 2022). The framework approach allows researchers to analyse qualitative data that is designed to answer specific questions and is efficient and robust. In our research, we utilized the data from the semi-structured interviews with parents and health staff to get a quick snapshot relating to the challenges and potential mitigation procedures to design an effective implementation plan for the subsequent studies (Hamadani et al., 2019 & Mehrin et al., 2022). The interventions led to large benefits to child development and mother practices showing the benefit of using formative research, even when time and resources are limited.

Conclusion: We hope our experience and evidence will add impact in the global database. We assume our national resources, infrastructure, and political commitments are adequate to expand the access of ECD support for underprivileged children. Government have to recognize the value of the ECCD model and set the strategic plan and allocate funding in the national budget for achieving the desired coverage of ECD program countrywide.

CHAPTER SEVEN

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CHAPTER EIGHT

Appendix 8.1

Title: Integrating an early childhood development programme into the Bangladeshi Primary Health Care Services: A cluster randomised trial.

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Contribution of authors: JDH and SGM developed the original concept, analyzed data and drafted the initial manuscript. SFM, FT, MIH, and SNH contributed to the concept, implemented the field activities, helped in data analysis and reviewed the manuscript. HBH helped in writing the proposal, and contributed to the concept, data analysis and reviewed the manuscript. DR contributed to the study design, conducted the main analysis, and reviewed the manuscript. All authors have read and approved the manuscript and take full responsibility for all aspects of the work.

Abstract

Background

Poor development in young children in developing countries is a major problem. Professionals are calling for child development interventions to be integrated into health services but there are few robust evaluations of such programmes. Previous small Bangladeshi trials of interventions using individual play sessions with mother and child at home or clinic run by especially employed women found moderate effects on child development. We integrated a modified intervention into government health clinics and evaluated effects on children's development in a cluster randomised trial.

Methods

Ninety clinics were randomised to intervention or control clusters and up to 25 underweight children aged five to 24 months living in the areas surrounding the clinics were enrolled (n=2423). Eight children from each clinic (n=718) were randomly selected for impact evaluation and were assessed at pre-test and post-test on the Bayley Scales and Wolke's behaviour ratings. The intervention lasted for one year and consisted of 25 sessions where mothers were shown how to support their child's development through play and interactions. Government health workers ran play sessions at the clinics as part of their routine work and, mothers and children attended fortnightly in pairs instead of individual weekly home visits as designed for the original programme.

Findings

Mean attendance at the sessions was 86%, 92% of planned sessions were run and 688 children (96% of evaluation sample) were assessed at endline. Intent to treat analysis, showed intervention had substantial benefits on children's cognition, language and motor composite

scores (effect size[95%CI]1.3SD[1.1,1.5], 1.0SD[0.9,1.2], and 1.2SD[1.0,1.3] respectively) and behaviour ratings (ranging from 0.7 to 1.1SD) but not on growth. Home stimulation, maternal child-rearing knowledge and depressive symptoms improved significantly (effect sizes 0.8, 1.7 and -0.3SD respectively).

Interpretation

The size and range of benefits are encouraging and the intervention model is promising to take to scale in that the HWs ran most of the sessions effectively and attendance was good. However researchers trained and supervised the health workers and the next step will be to determine if the Ministry of Health can perform these tasks. More attention needs to be paid to the nutrition of the children.

Trial registration number: ClinicalTrials.gov NCT02208531

Funding: Grand Challenges Canada (Saving Brains)

Research in Context Panel

Evidence before this study

We searched for reviews of trials of early childhood psychosocial interventions since 2007, in Medline and PschINFO databases to identify randomised trials of early childhood interventions integrated into the health services with child development outcomes. Few trials were found, the best study was in Pakistan but treatment group was confounded by geographical region.

Added value of this study

It is feasible and highly effective for the Bangladeshi clinic workers to run an early childhood development intervention for high risk children. Further research is required to determine if the health services can also conduct training and supervision.

Implications of all the available evidence

There remains a need for well evaluated trials of implementation strategies to determine the most effective models. The ability to integrate early child development interventions into health services will likely depend on the work load, educational level, supervision and motivation of the health workers and will vary by country. In Bangladesh it was feasible for the clinic workers to run this intervention for high risk children; however alternative implementation strategies will be needed for children who live far from the clinics. The process required careful piloting with adaptations.

Introduction

Early brain development is particularly sensitive to the environment in the first 5 years and risks such as poverty can affect brain structure and function, the stress response system, and genetic expression,¹ which can have long term consequences on adult functioning. It is well established that children living in poverty have poor levels of development compared with their more affluent peers.² In Bangladesh compared with children in the highest wealth quintile, children in the lowest quintile have cognitive deficits as early as 7 months of age that increase to 5 years when the children are substantially behind in language and cognitive development.³ These children are likely to do poorly in school with subsequent life time disadvantages. Many small, well run efficacy trials (RCTs) of early childhood psychosocial interventions have shown benefits to children's development,⁴⁻⁶ and a few have shown long term benefits.⁷ The 2016 Sustainable Development Goals (SDGs) aim for all children to have access to "quality early childhood development, care and pre-primary education" and the recent Lancet series on early childhood called for large scale early child development programmes to be integrated into government health and nutrition services,⁶ however, there is limited data on the effectiveness of large scale integrated programmes and a need for robust evaluations.⁸

We previously adapted the Jamaican home visiting intervention (Reach Up)⁹ which aims to help mothers promote their child's development through demonstration and coaching in home visits. We have conducted three small RCTS (< 225 intervened children) in which play sessions were run by specially hired facilitators either at home or in local clinics.¹⁰⁻¹² All interventions had moderate effects (0.33 - 0.38 standard scores) on the children's Mental Development Index of the Bayley Scales of Infant Development. Another study in Bangladesh used a mixture of government family welfare assistants and hired facilitators to run mothers' groups with some home visits and this was also effective.¹³

There are over 13,000 Bangladeshi government primary health care community clinics (CCs) throughout the country. To develop an early childhood intervention model targeting undernourished children that could be integrated into the clinics at scale, we modified the Reach Up intervention to increase coverage and reduce costs. We trained all health workers (HW) in the intervention clinics and therefore a cluster trial was required to avoid contamination. The health workers ran play sessions at the clinics as part of their routine work and mothers with their underweight children attended in pairs every two weeks instead of conducting individual weekly home visits as in the original model. The aims were to evaluate the effects on child cognition, language and motor development, growth and behaviour in a subsample. Secondary outcomes were mothers' knowledge of child rearing, stimulation in the home and maternal depressive symptoms.

Ethics

The proposal was approved by the Institutional Review Board of ICCDR,B. At enrolment parents were asked to sign the written informed consent form. Children with developmental delay or other associated illnesses were referred to the nearest health centre for treatment.

Methods

Formative research

In an initial five-month pilot study we examined cooperation of the health staff and mothers' attendance at CCs. We subsequently reduced the sample in each CC to a maximum of 25 and included only those children living within a 20-30 minutes walking distance from the centre, because it was difficult for mothers to bring their children from far places.

Study Design and Participants

The study was an open-label, cluster randomized controlled trial in 90 CCs (**Figure 1**). The intervened mothers and most of the researchers were inevitably aware of the group status. However the testers of child development measures were blind to the study group.

CCs are the first level one-stop service centers for Primary Health Care with emphasis on maternal and neonatal health. The main services of the clinics are maternal and neonatal health care, nutrition and health education, treatment of minor ailments, etc. CCs are managed by Community Health Care Providers (CHCP) supported by a Family Welfare Assistant (FWA) and a Health Assistant (HA). CHCP and HA generally have a Bachelors or Master's degree and FWAs have mostly completed Higher Secondary education. The male/female ratio among CHCPs was approximately 1:2, while it was 1:1 among the HAs, and all the FWAs were female.

We got permission from the Ministry of Health and Family Welfare to use the clinic staff through a signed Memorandum of Understanding. Narsingdi district was selected for this study because it had sufficient number of CCs and was within 80 kilometres of Dhaka city. Three rural sub-districts, with between 18 and 102 CCs were selected in Narsingdi, and 90 CCs were randomly selected from amongst those. A house to house survey of the area surrounding each CC was conducted and all homes that the surveyor and mother estimated were within 20-30 minutes' walk of the CC were included. All children aged 5 to 23 months were weighed using standard methods. Children with weights-for-age [WAZ]<-2SDs of the WHO standards¹⁴ were identified and all available up to 25 from each clinic were enrolled with their mothers, only 30 (1.2%) refused to participate. In 4 intervention CCs there were more than 25 available children so 25 children were randomly selected from the total making a total of 859 children who were finally selected for intervention.

Sample Size

Ninety clinics with 8 children each were necessary to detect a 0.25 SD difference in Bayley scores between the groups at 80% power and 5% significant levels with an intraclass correlation of 0.01.

Randomisation and masking

Following initial screening and enrolment in the study, the CCs were stratified by sub-district and were then randomised to intervention or control by a researcher not part of the study using a computer-generated code. All participants were enrolled prior to randomisation. Measurements were conducted after randomisation at baseline and at the end of intervention by interviewers and testers blind to study group. We kept the testers blind by separating them from the researchers concerned with the intervention and not informing them about intervention groups in each clinic. The tests were conducted before the start and after the end of the intervention and therefore the play materials were not available in the clinics. However, as in all interventions of this type, the occasional mother may have mentioned the intervention during the test session.

The total children enrolled in intervention were used to assess if providing such intervention at CCs was feasible, while a subsample of 8 mother-child dyads were randomly selected from each of the intervention and control CCs for evaluation of the impact.

Outcome measures

The primary outcomes were assessed on the evaluation subsample and included the composite scores on the Bayley Scales of Infant and Toddler Development 3rd version (Bayley-III).¹⁵ These scores are standardised on a USA population to have a mean of 100 and SD of 15 and include language (expressive and receptive language scales combined), motor (fine and gross

motor scales combined) and cognitive scores. Their stability from baseline to endline in the controls was at the expected levels (cognition $r=0.24$, language $r=0.37$, motor $r=0.39$, $p<0.001$ for all),¹⁶ and scores were significantly correlated with height-for-age ($r=0.229$, $p<0.001$), the wealth factor ($r=0.111$, $p=0.004$) and years of maternal education ($r=0.109$, $p=0.004$). The Bayley was translated and adapted for Bangladesh to remove culturally inappropriate pictures, which were redrawn to reflect the local context; for example pictures of a washing machine and a vacuum cleaner were changed to washing clothes by hand and sweeping the room with a broom. We did not change underlying concepts or the order of the items.

Children were tested at baseline and after a year at the CCs in the presence of their mothers by one of 8 testers. All testers had a Masters degree in psychology or social sciences. Before the study began each tester attained satisfactory interobserver reliabilities with the trainer ($r=1.0$ on composite scores and ranged from 0.60 to 1.0 on scaled scores, (number of tests=8 to 16 per tester). The children's behaviour was rated during the test on five Wolke scales: Approach to the tester in the first 10 minutes, Emotional tone, Cooperation with tester, Vocalisation, and Activity level throughout the test. The ratings have been used in several Bangladeshi studies.^{10,17,18} Interobserver reliabilities for all testers with the trainer were assessed before the study and intraclass correlations were satisfactory (response to examiner: $r=0.91-1.0$, emotional tone: $r=0.64-1.0$, cooperativeness: $r=0.81-0.99$, vocalization: $r=0.96-1.0$, and activity: $r=0.67-0.97$), except one tester only attained $r=0.51$ for activity and was given additional training. Approximately 10% of Bayley tests were observed throughout the study and interobserver reliabilities for each tester for all Bayley composite scores were $r>0.8$ and for all the behaviour ratings the range was $r=0.67-0.99$ (total number of tests=71).

The children's weight, length/height, and head circumference were measured by the testers after completion of the Bayley test using standard methods.¹⁹

Secondary outcomes included maternal knowledge of child rearing measured with a specially designed instrument used in previous studies,⁹ and the Family Care Indicators (FCI), which measures quality of home stimulation and symptoms of maternal depression. FCI was developed by UNICEF²⁰ and validated in Bangladesh.²¹ The six questions on maternal depression were taken from Center for Epidemiological Studies-Depression (CES-D) scale.²² The shortened versions of the CES-D have been found to discriminate between depressed and non-depressed adults elsewhere.²³

In an initial survey beginning November 2014 information was collected by the field workers from all enrolled families including demographic, socioeconomic information, and the FCI.

Intervention

The intervention was phased in by districts beginning March 2015. Two mothers at a time brought their children to play session at the clinic every fortnight for one year.

On average, the CHCP, who attend the CCs six days a week, ran three play sessions a week, while the FWA and HA, who attend two days a week, ran one session each. In the following, we refer to these three cadres as ‘health workers (HWs)’ to facilitate the intervention description. There was a manual with the curriculum in which sessions were arranged in developmental order for children from age 6 to 42 months. Children were initially placed at their chronological age level on the curriculum and progressed from one session to the next more difficult one. If necessary their position on the curriculum was changed to match the child’s rate of progress. Play sessions with mother and child were participatory and followed a set format including: review of the previous home activities with discussion, a local song, looking at a picture book, a developmentally appropriate toy, language activities, nutritional messages and a review of activities to be continued at home. Activities and materials were specified for every session, they were planned to be at the child’s appropriate developmental

level so that they were challenging but the child could experience success. Some activities were done with both mother-child dyads together whereas the toy activities were done separately to ensure developmentally appropriate activities were used.

The HWs demonstrated activities/interactions with the children to the mothers then encouraged the mothers to repeat and expand the activities and suggest new ones. Mothers were asked to continue the activities at home and use everyday activities and materials for further learning opportunities. Mothers were lent the book and toy to take home, and these were exchanged for new ones at each session. Emphasis was placed on developing good relations with the mothers. Mothers were encouraged to respond to their child's interests and vocalisations, and give them praise and positive feedback. Every effort was made to make the sessions enjoyable. Further details are available on the website (<http://www.reachupandlearn.com>) and in papers.^{9,24-25}

The adjustments for Bangladesh included redrawing all books and pictures to reflect the local context and printing them locally, replacing songs and games with local traditional versions. Some toys were made from waste material and where the available waste was different we occasionally modified the toys. The methodology and underlying concepts of the Jamaican curriculum were unchanged.

Before starting the intervention, meetings were organized in each CC with parents, family members and community leaders. Information on early child development was presented and details of the project discussed to motivate the community.

Training and supervision: The research team trained 130 HWs in batches of 12-15 for 10 days each. Supervisors with Masters Degree in psychology or other related subjects were recruited and trained for 20 days to mentor the HWs. Each supervisor monitored four CCs and there were between one to three HWs per CC. The supervisor met with each HW twice a month and observed a play session using a check list of desired activities for guidance. Some HWs, whose

performance was poor, were initially visited more frequently. The supervisors provided feedback at the end of the session. We ran a half-day refresher workshop for the HWs every three months.

Control group: the controls had no extra attention but used the clinic as usual for treatment if they were ill and some of them were immunised at the clinics. We did not record their attendance.

Statistical Analysis

A wealth factor was computed from the sum of the assets the family owned and a housing factor from the quality of materials used for the wall, roof, and floor of the house, presence or absence of electricity at home, and a sanitary toilet.

All data was checked for normality and socio-demographic characteristics were compared between the control and intervention groups using a two-sample t test. The baseline outcome variables were compared between the groups using a multi-level random effects model, with child nested within CC, nested within sub-district; tester was included in the model where appropriate.

For each of the outcome measures at endline we fitted a similar multi-level random effects model, with child nested within CC, nested within sub-district. Group was included as a binary factor and we adjusted all models for age at follow-up, sex, and relevant baseline measure; additionally we adjusted for testers in analyses involving the Bayley scores and behaviour ratings. We investigated interactions for group with parental education, gender, and SES.

Data completeness was good (>92%) for the majority of outcomes, with the exception of maternal depression (82%) and knowledge of child rearing (82%). Multiple imputation (assuming data was missing at random) was used to account for missing data for these two

outcomes. The imputation models included the socio-demographic variables and all baseline and endline variables for all other outcome measures (which we assume includes all predictors of missingness). We generated 20 data sets and ran a full multi-level random effects model, using the whole data set and implementing a bootstrap (200 samples) for each imputed data set to correct for overfitting. The final models were derived by fitting a multilevel model with all aforementioned factors and the estimates were combined using Rubin's rules.²⁶ The results using the imputed data were similar to those using the observed data, therefore we present the estimated, adjusted intervention effect from the latter for all outcomes. In addition, since the outcomes are recorded on different scales, we present the results for the estimated intervention effect on a standardised scale for the same models. We transformed the data using an internal standardisation on the whole sample, at baseline and endline separately. This allows the comparison of the relative effect of the intervention on each of the outcome measures. We used intention to treat analyses for all models and to account for multiplicity comparisons at endline, P-values presented have been corrected for all 10 outcomes using the Holm's stepdown procedure.²⁷

In a post-hoc analysis we measured feasibility by the percent of health staff who attended the training, ran sessions and the number of sessions they ran and the percent of mothers with eligible children who agreed to enroll and their attendance at the sessions.

All analyses were performed in Stata²⁸ and for all significance test results presented, a P-value < 0.05 was considered statistically significant.

Role of the funding source

The donor had no role in study design, data collection, data analysis, data interpretation, or writing of the report. They had assigned platform teams who helped the research group during

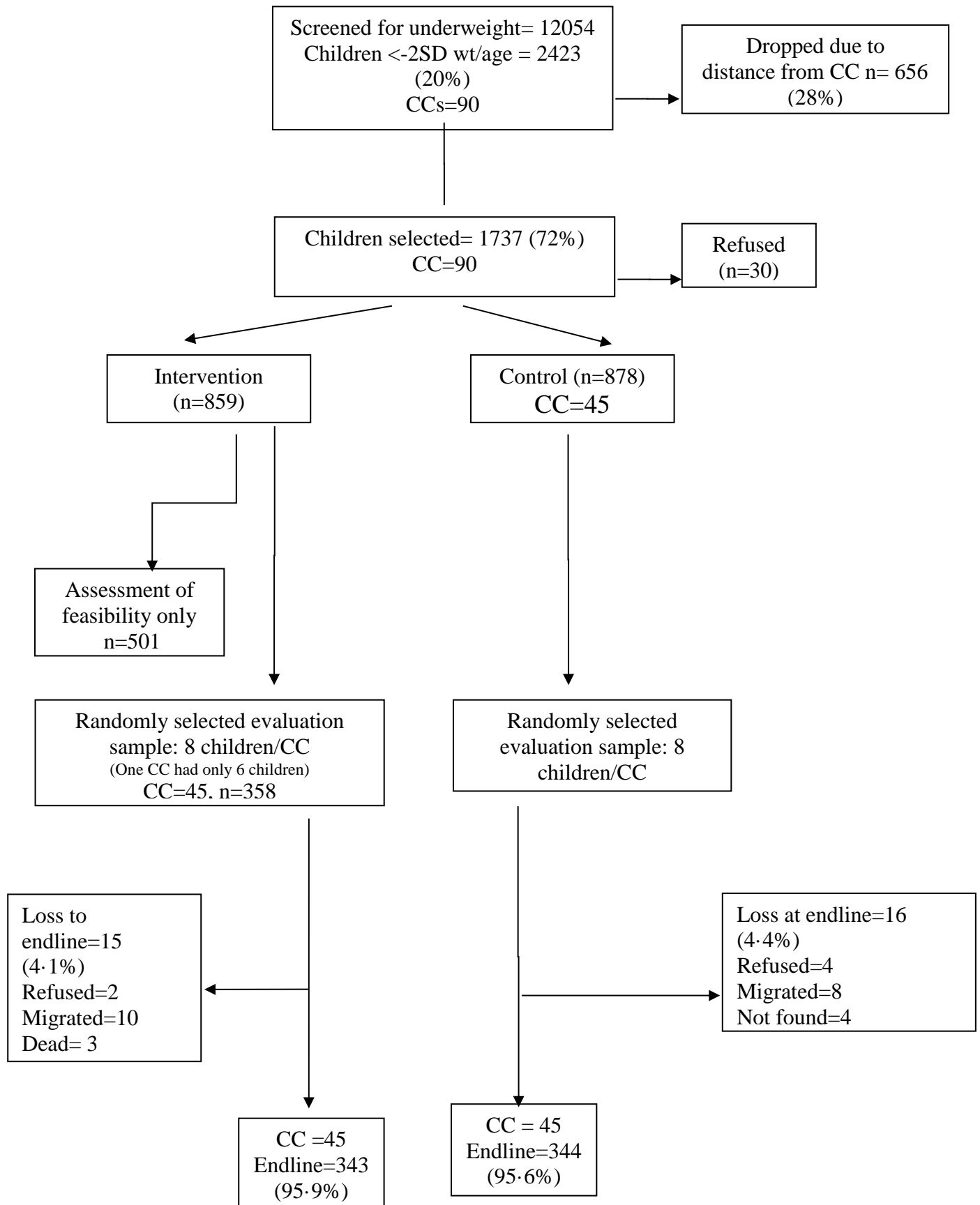
the study with trouble shooting, if required. The authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

We screened 12,054 for wt/age <-2SD and identified 2423 (20%) to be underweight. We dropped 656 (27%) who lived further than 30 min walking distance from the CCs and 30 (1.2%) refused to participate. We therefore enrolled 1737 (72%) children.

In the evaluation sample, we tested 718 children at baseline and 688 children (96% of initially tested) at endline. Loss from the study was not different between the groups (**Figure 1**) and the reasons for loss were mostly due to migration to other places and refusals.

Figure 1: Flow chart



The intervened and control evaluation groups were not significantly different at baseline in wealth, housing quality, children's nutritional status, quality of home stimulation, parental education, or maternal knowledge of child rearing (**Table 1**).

Table 1. Sociodemographic characteristics of the participants by group

	Control n=344	Intervention n=350	P value
Age at baseline (month), Mean (SD)	15.8(5.2)	16.1(4.9)	0.538
Male child- n (%)	188(55)	188(55)	0.514
Fathers education- n (%) 0-4 yrs 5 yrs >5 yrs	133(39) 77(23) 130(38)	136(40) 73(21) 133(39)	0.999
Mothers education- n (%) 0-4 yrs 5 yrs >5 yrs	102(30) 72(21) 166(49)	89(26) 77(23) 176(51)	0.313
Wealth factor, quintile 1 st 2 nd 3 rd 4 th 5 th	66(19.5) 85(25) 53(15.6) 77(22.7) 58(17)	63(18.5) 76(22) 49(14.4) 76(22.3) 77(22.6)	0.160
Housing factor, Mean (SD)	-0.012(1.1)	-0.0004(1.0)	0.882

Table 2. Characteristics of the participants by group at baseline

	Control n=360, CC=45 mean (SD)	Intervention n=358, CC=45 mean (SD)	Difference[§] in means (95%CI)	P value
Age (months)	15.8 (5.2)	16.1 (4.9)	0.2 (-0.5, 1.0)	0.52
Cognitive composite scores	87.4 (11.9)	90.0 (12.2)	2.4 (0.7, 4.2)	0.01
Language composite scores	80.3 (10.8)	82.3 (11.2)	1.4 (-0.1, 3.0)	0.08
Motor composite scores	86.2 (12.4)	88.0 (11.8)	1.6 (-0.3, 3.4)	0.09
Response to examiner	5.3 (0.9)	5.3 (0.9)	0.04 (-0.1, 0.2)	0.68
Emotional tone	4.9 (0.9)	5.1 (0.9)	0.1 (-0.02, 0.3)	0.09
Activity	4.8 (0.9)	4.9 (0.9)	0.1 (-0.03, 0.3)	0.12
Cooperativeness	4.9 (1.0)	5.0 (1.0)	0.1 (-0.06, 0.3)	0.18
Vocalization	3.4 (1.6)	3.5 (1.5)	0.1 (-0.2, 0.4)	0.47
Mothers knowledge [*]	21.9 (5.6)	22.5 (5.4)	0.4 (-1.0, 1.7)	0.59
Maternal depressive scores ^{*#}	11.9 (8.7)	10.1 (9.0)	-1.8 (-3.3, -0.2)	0.03
Home stimulation (FCI) ^{***}	6.7 (4.2)	6.9 (4.0)	0.1 (-0.7, 1.1)	0.66
HAZ ^{**}	-2.6 (1.0)	-2.5 (1.2)	0.03 (-0.2, 0.2)	0.74
WAZ	-2.4 (0.7)	-2.4 (0.7)	0.05 (-0.06, 0.2)	0.38
WHZ ^{**}	-1.5 (1.0)	-1.5 (1.1)	0.03 (-0.1, 0.2)	0.68
OFC	43.2 (1.8)	43.4 (1.7)	0.1 (-0.01, 0.5)	0.05

[§]Difference refers to Intervention – control

P value (95%CI of the mean difference) adjusted for clustering effects at the clinic and subdistrict levels and the Bayley scores are also adjusted for testers

All values are mean (SD) using t-test except for [#]MannWhitneyU test

*n=334 for control group and n=269 for intervention, **n=341 for intervention group at baseline

***n=340 for control group and n=342 for intervention.

However, the intervention children had significantly higher cognitive scores and their mothers had fewer depressive symptoms at baseline (**Table 2**).

All intent to treat analyses of child development outcomes were adjusted for the relevant initial scores. Maternal depression was not significantly related to any of the outcomes and the analyses were not adjusted for it.

Intent to treat analyses showed significant large intervention effects on the Bayley cognitive (effect size 1.3SD), language (effect size 1.3SD) and motor (effect size 1.2 SD) composite scores (**Table 3**).

Table 3. Multiple regression analysis of the effects of intervention on outcome measures

Outcome at follow-up n=687	Intervention Effect B (95% CI)	Effect Size (SDs) (95% CI)	Corrected P value^{\$}
Cognitive composite score	13.5 (11.8, 15.2)	1.3 (1.1, 1.5)	0.006
Language composite score	9.4 (7.9, 10.9)	1.1 (0.9, 1.2)	0.01
Motor composite score	12.6 (11.1, 14.2)	1.2 (1.0, 1.3)	0.006
Response to examiner	1.0 (0.8, 1.1)	1.1 (1.0, 1.2)	0.007
Emotional tone	0.8 (0.7, 0.9)	0.9 (0.8, 1.1)	0.01
Cooperativeness	1.0 (0.8, 1.1)	1.0 (0.9, 1.1)	0.008
Vocalization	1.1 (0.8, 1.4)	0.7 (0.5, 0.9)	0.02
FCI * (n=669)	4.1 (2.9, 5.3)	0.8 (0.6, 1.0)	0.03
Maternal Depression* (n=593)	-2.9 (-4.9, -1.0)	-0.3 (-0.6, -0.1)	0.05
Knowledge of child rearing* (n=595)	15.9 (14.6, 17.1)	1.7 (1.5, 1.8)	0.005
Model: Multi-level random effects model, with child nested within CC, nested within sub-district adjusted for age at follow-up, sex, testers and relevant baseline measure *Testers not included in analysis. ^{\$} Corrected for all 10 outcomes using Holm's stepdown procedure			

Similar analyses showed the intervened children were more responsive to the examiner (effect size 0.8 SD), more cooperative (effect size 1.0 SD), happier (effect size 0.8 SD), and talking or vocalising more during the test (effect size 1.1SD). There were also benefits from intervention to the quality of home stimulation (effect size 0.9 SD), maternal child-rearing knowledge (effect size 1.7SD), and depressive symptoms (effect sizes -0.3SD). There were no treatment effects on children's anthropometry, both groups improved in weight for height z

scores with a mean (95%CI) increase of 0.27 (0.19, 0.35) z scores but deteriorated in height for age with a decrease of -0.20 (-0.27, -0.13) z scores during the study ($P < 0.001$ for both).

The main outcome measures had intraclass correlation (95%CI) of 0.23 (0.16, 0.32) for cognition, 0.17 (0.11, 0.26) for language and 0.11 (0.06, 0.19) for motor composite scores at cluster level.

There was no differential effect of treatment by gender, maternal education, or wealth.

Post-hoc analysis for feasibility of the study

Health staff and mothers appeared to accept the program, compliance was good and mean (SD) attendance at the sessions for the entire intervention sample ($n=859$) was 19 (9) sessions and 394 (46%) attended all sessions. Attendance of the evaluated children was 21 (7.4) while 192 (54%) 95%CI (49%, 60%) attended all 25 sessions and the difference in attendance between the evaluated and not evaluated sample was significant (95%CI: 2.2, 4.6, $p<0.001$). Compliance by staff was also good; 100% attended the training and out of 123 HWs only 10 (8%) did not run all the sessions. Among the 10 HWs, eight missed between one to nine sessions while only two missed 13-24 sessions. The reasons for missing the sessions were illness ($n=5$), maternity leave ($n=2$), leave ($n=2$) and only one refused to conduct the sessions though initially he had conducted between one to seven sessions for some of the children.

Discussion

The child development intervention integrated into primary health care clinics had large comprehensive effects on high risk children's cognitive, language and motor development and behaviour. Home stimulation, maternal knowledge and depressive symptoms also improved. The size and range of benefits were extremely encouraging and were larger and more extensive than found in three previous Bangladeshi studies using a similar curriculum in individual home

or clinic visits.^{10–12} We hypothesize that implementation modifications made in this study accounted for the larger effects. The mothers appeared to be more comfortable in pairs when they interacted more with their children and with each other, than in individual sessions, when they were often inhibited. The health workers were generally better educated than other local women previously employed as home visitors and it is possible that they were more respected by the mothers.

The post-hoc analysis of the feasibility measures suggests that it is feasible to integrate the intervention into the clinic service. Very few mothers refused to enrol, and those enrolled attended reasonably well. Although the evaluated children attended significantly more sessions, it could be because the parents became more motivated due to the initial baseline measurements. The HWs and supervisors did not know the evaluation sample and hence the children in the evaluation sample were not given priority. All health workers attended training and ran most of the sessions without extra incentives. However, we only reached approximately 25 children per clinic, giving a maximum of six sessions a week per clinic, which seemed feasible based on the routine of activities of the HWs and the results of our pilot. We did not want to overburden the staff with more sessions and unfortunately, we did not collect data to see if our intervention interfered with their other duties. In future, it would be possible to increase the size of the groups to four, which is the maximum possible due to limited clinic space. We ran three monthly workshops for the staff, which had a cost including transport and refreshments but it appeared to be needed to keep them motivated and solve problems.

Very few studies have integrated child development interventions into the health services with robust evaluations and these results compare favourably with studies in Pakistan and Jamaica.^{29–30}

Strengths of the study include the robust design with cluster randomisation, assessing child development with full development scales and using the health staff to conduct the play sessions which would facilitate going to scale.

The limitations are that only 72% of targeted children served by the CCs participated so an alternative strategy has to be designed to reach children living further away. The FWAs are responsible for reproductive health and family planning and HAs are in charge of immunisation. They are supposed to make very short home visits to a large number of approximately 600 to 2,000 households every 2 months and it is possible that they could organise group meetings on ECD in the community but this needs piloting. A disappointment was the lack of improvement in the children's nutritional status. We largely depended on other services to address nutrition, although we included some limited nutritional education in the play sessions and provided mothers with nutrition cards with a recipe for diets for underweight children. Many clinics did not have weighing scales and the government has begun a program to upgrade nutritional care in these clinics.

Perhaps the most important limitation when considering going to scale is that the research group was highly motivated and experienced with the intervention. They trained and supervised the health workers and for future scale-up, these activities would have to be performed by the Ministry of Health (MOH). However, the MOH employs a supervisor for every three clinics and many of them showed an interest in the programme. The next step would be for those supervisors to take over the training and supervision of the HWs. We are presently piloting this approach and it appears to be feasible. We are also exploring with the government how to transfer the overall responsibility for the programme from researchers to the district and central health officers.

Another limitation is that the Bayley Scales were adapted but not standardized for Bangladesh. In previous studies, the Bayley-II scores at 18 months had good concurrent and predictive validity of IQ at age 5 years.^{3,10-12} In this study the Bayley III scores had adequate test-retest reliability, stability over the year and discriminant validity, with scores being significantly correlated with height-for-age, the wealth factor and years of maternal education. Therefore it is likely to be valid.

A further limitation is that the children were assessed at the clinics, where the intervention took place and it is possible that the intervened group benefited from the venue being familiar. However, in a companion randomised trial half the intervened and control children were tested in clinics familiar to the intervention group only and half in unfamiliar locations and we found almost identical intervention impacts in both halves, suggesting that the test location was not a major influence (Mehrin, in prep).

We were only able to work in 90 CCs out of over 13000 CCs in the country. However, these clinics are representative of other areas. Most rural areas in Bangladesh are poor and have limited resources and therefore we may be able to generalize the data across the country.

In conclusion, the intervention model was feasible and very effective and justifies moving to the next stage of going to scale.

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Appendix 8.2: Summary of integrated studies									
Author/ Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Brazil Brentani et al., 2021	Community-based cluster- Randomized Control Trial A total of 826 children were enrolled from ESF (Estratégia Saúde da Família) a community based health program running area where CHW deliver health service and non ESF area and then both area randomized into 2 groups: a. ESF area (n=498) i. Intervention= 249 ii. Control=249 b.Non ESF area (n=328) i.Intervention (n=164) ii. Control (n=164)	9-15 months Duration: 12 months	Community Health Workers (CHW) are the staff of local ESF primary care, full time Government staff. Each CHW was responsible for 10 children and two visits per child. Child Development Agent (CDA) was recruited locally in non ESF area and they were responsible for ECD home visits where CHW is not available. Education: Higher level education Each CDA assigned for 35-40 children	Training: 10 days training. Training includes 30 sessions on: (i) concepts on how to conduct effective home visits; (ii) activities and toys in the curriculum; and (iii) role play (iv) Field practice with non study children Refresher training: 2 days after 6 months Supervision: Monthly. Each supervisor was responsible for 15 CDAs. Supervisor attended session of each CDA once in a month and checks fidelity and provided feedback. In addition, they had weekly meeting with the CDAs to discuss the field related issues	24 biweekly sessions	Culturally adapted version of Reach up early childhood development parenting program The intervention focuses on positive parenting practice and includes activities to improve cognitive, language and motor development of children. The intervention includes age appropriate activities using low cost materials.	Home visit Session duration: unknown The CDA showed the caregivers how to interact with child and create a nurturing care environment at home. CDA demonstrated age appropriate activities with child. CDA/CHW used a set of toys in each home visits and left in the home to increase caregiver-child interaction. Attendance: In the ESF area 9.1% mothers received 10 or more sessions and 82.9% children never visited by CHW. In the non ESF area, 61% children received at least 10 and 33% children received 20 or more visits. Cost: Average cost per child in CDA arm is USD393 and in CHW arm is USD24	Primary outcomes: <i>Regional Project on Child Development Indicators (PRIDI):</i> direct observation tool: - Cognition and - Language <i>Anthropometry Measurement:</i> Height for age Weight for age Secondary outcome: <i>Edinburg Postnatal Depression:</i> Maternal depression	Primary outcome: <i>Regional Project on Child Development Indicators (PRIDI):</i> Non ESF Intervention (CDA) VS non ESF control arm PRIDI Cognition: ES=0.22, P=0.05 PRIDI Language: ES=0.22, P=0.015 ESF intervention (CHW) VS ESF control PRIDI Cognition: ES= -0.15, P=0.70 Language: ES= -0.11, P=0.70 Secondary outcomes: No group difference is found in maternal depression score in both arms. No intervention effect had been found in between the children attending creche and not attending creche at baseline.

Author/ Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Lesotho Ndayizigiye et al., 2021	Prospective Case Control study i. Intervention: 130 mother- child dyads ii. Control: 125 mother- child dyads	7-11 months Duration: 2 months	The group sessions were delivered by a nurse at health center. The village Health Workers (VHW) are involved with Primary Health Service at rural areas and conducted home visits.	Training: Three days basic training. Training comprised with lecture based session and video session on key topics. Refresher training: 2-3 hours monthly session	Seven caregiver education session held at weeks 6,8, 10,12, 14, 16 & 18	The ECD intervention packages CASITA was adapted from a Peruvian program. It focuses on: (1) knowledge sharing about child development and child observation; (2) demonstration and initiation of social interaction activities tailored to the child's development. (3) caregiver encouragement on caregiving behavior and development interactions and (4) caregiver social support and reassurance.	Group session: Session duration: unknown Group size: 4-6 mother-child dyads The nurses used an assessment form to check whether all activity was completed or not., They reviewed the form with the VHW after each session and trained them on demonstration of missing parts with individual child. Attendance: 100% (n=119) mothers completed session no. 6, 10 and 14 weeks and 70% (n= 83) completed final session at 18 weeks. The VHWs conducted the absent session on week no. 8, 12 & 16.	Primary Outcomes: <i>Extended versions of Ages and Stages Questionnaire (E-ASQ)</i> <ul style="list-style-type: none"> • Problem solving • Personal social skill • Communication • Fine motor • Gross motor Secondary outcome: <ul style="list-style-type: none"> • <i>UNICEF Multiple Indicator Cluster Survey (MICS) and</i> • <i>Parent Ladder:</i> Caregiver practices 	Intervention VS control: <i>Extended versions of Ages and Stages Questionnaire (E-ASQ):</i> Children in the intervention group scored higher in all domains. Communication: Mean difference=0.27, P<0.05, Social development: Mean difference= 0.27, P<0.05 and Motor development: Mean difference =0.46, P<0.05 Total EASQ score :0.24, P<0.05 Secondary Outcome: <i>Parent Ladder:</i> Mother child interaction: Book reading (adjusted OR (AOR): 3.77, P<0.05 Story telling: AOR: 13.75, P<0.05 Singing song: AOR:2.29 , P<0.05 Naming/counting: AOR: 2.05; P<0.05

Author/ Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
China Sylvia et al., 2020	Randomized Effectiveness Trial Townships (mid tier of rural structure) consisting 12 villages (lowest tier) were selected from four county (upper tier). Two 2 villages (n=131) were randomly selected from each township and randomized into intervention (n=65) and control (n=66). All children (n=592) of the selected villages were enrolled in the study.	18-30 months old children Duration: 6 months	Parenting Trainers were selected by the Family Planning (FPC) Gender: Male=60% & Female=40% Marital Status: Married and have children Age: Mean age 34 years Education: Most of them have Higher Secondary level education and 29% have Bachelor degree. Experience: 12 years	Training: - 1 week intensive training on theoretical and practical session. The training comprised with class room session and field practice. Refresher training: Periodical training over phone in throughout the intervention period. Supervision: Unknown	24 weekly home visits	ECD curriculum: The curriculum is adapted from Jamaican Reach up & Learn curriculum. The curriculum includes age-based activities. Each Weekly activities focusing on cognition, language, motor and socio-emotional development. The curriculum also includes weekly module on health or nutrition. The goal of the curriculum is to increase quality of mother-child interaction.	Home based session: The caregivers were given on activity from each category in every two weeks. At the end of the session, the toys were left in the house to practice with the child. Duration: Unknown Attendance: Mean of home visit is 16.4 (out of 24 visits) .	Primary Outcomes: <i>Children younger than 30 months were assessed by Bayley Scale of Infant Development II:</i> - Mental Developmental Index (MDI) - Psychomotor developmental Index (PDI) <i>Children more than 30 months were assessed by Griffith Mental Developmental Scale :</i> <i>Ages and Stages Questionnaire (ASQ):</i> Social-emotional development Secondary outcome: <i>A structured Parenting questionnaire:</i> To assess parental knowledge and confidence	Primary outcomes: Intervention vs control group: <i>Bayley Scale of Infant Development II:</i> Mental Developmental Index (MDI): ES=0.292, P=0.035 <i>Griffith Mental Developmental Scale :</i> Cognition: ES=0.280, P=0.026 Overall infant skill factor: ES=0.259, P=0.002 No intervention effect had been found on psychomotor and socio-emotional development of the children. Secondary outcomes: <i>Parenting Questionnaire:</i> Intervention vs control group: Overall parenting skill: ES=0.323, P=0.003 Parental investment in child development activities were increased with ES=0.825. Differential effect had been found by parental investment before the intervention. Children who received low level of parental investment were more benefited by the intervention with effect size 0.456.

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Kenya Luoto et al., 2020	Cluster Randomized Community Effectiveness Trial 60 villages were randomly assigned into 3 arms: i. Only group session (n=376) ii. Mixed session- (n=400) iii. Comparison group (n=376)	6-24 months old children Duration: 8 months	Forty Community Health Volunteer (CHV) of primary health service Gender: Male=10 & female=30 Age: Mean age 44 years Education: 11 years Experience: 9-11 years	Training: - 8 days initial training for session number 1-8 - 8 days training on session number 9-16 after 6 mothers Refresher training: 1 day in every month. Supervision: Skills rated during supervisory visit: discussions, coaching parents, answering questions and engagement. Supervisory visits: Group session: 496 (89%) Of 560 mothers were monitored by a SWAP supervisor Home visits: 122 (9%) of 1411 home visits were supervised.	16 fortnightly session	ECD curriculum: Focused on 5 key messages; i. Responsive play ii. Responsive communication iii. Hygiene, iv. Love and v. Respect in the family.	Group session: Group size: Median=13 (range: 10-15) Duration: median is 90 minutes Both fathers and mothers attended together in 12 sessions and separately in 4 sessions. Emphasis in father's session: i. Practicing respectful communication, ii. Father involvement in child-care, and iii. Emotional support Attendance: Average attendance 13% Mixed delivery arm is 74% (n=11.9) Group only is 64.3% (n=10.3) .	Primary Outcomes: <i>Bayley Scale of Infant and Toddler Development III:</i> <i>Developmen III:</i> - Cognitive - Language and - Socio emotional development Secondary outcome: <i>Home Observation and Measurement of Environment (HOME)</i>	Primary outcomes: <i>Bayley Scale of Infant and Toddler Development III:</i> Only group intervention vs comparison group: Cognition: ES=0.52, P<0.0013 Receptive language: ES=0.42, P=0.017 Socio-emotional development: ES=0.23, P= 0.024 Expressive language score was not differed among the group (ES=0.08, P=0.56) Mixed intervention vs comparison group: Cognition: ES=0.34, P=0.021 Socio-emotional development: ES=0.22, P=0.011 Receptive Language and expressive language score was not differed among the group (ES=0.20, P=0.20) and (ES=- 0.09, P=0.45) respectively. Secondary outcomes: <i>Home Observation and Measurement of Environment (HOME):</i> Only group intervention vs comparison group: ES=0.80, P<0.0001 Mixed intervention vs comparison group: ES=0.77, P<0.0001 No differential effect had been found in groups by maternal education and age.

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Peru Fernández et al., 2020	Prospective interventional study 240 children were randomly allocated to: i. Intervention communities (IC, n =113 children) ii. Control communities (CC, n= 127 children). Integrated with Government Health Program	0-3 years Duration : 2 months	Fifteen Communit y Health Providers (CHP). The CHPs are governmen t staff. Each CHP was responsible for 7-11 families.	Training: Eight CHPs received ICDP training 6 weekly sessions for 3 hours. Training was delivered to general to specific focused topic using step-by-step learning method. Step 1: At first they practiced ICDP methodology with their own children. Step 2: Then they received 8 facilitator level training session for 2 hours focusing on the sensitizing 7 principles of ICDP approach. The training sessions includes story telling, role play session, listening and giving simple examples. Supervision: Local research team had weekly meetings with the CHPs. CHPS shared their experience, difficulties and findings. The research team provided feedback where required. A validation checklist was developed to evaluate ICDP. In the last 2 sessions caregivers interacted with their child and the nurse observed from a distance. The nurse checked how the caregivers used 8 ICDP guideline.	Home based session: - Weekly home based session - Eight workshops for ICDP program	Intervention arm includes 3 categories of intervention:- i. Home and community garden ii. Conscious nutrition iii. Parenting workshop following the international child development program (ICDP) ICDP focused on 8 guidelines: i. Show love and positive feelings to your child, ii. Follow and adjust to your child's initiatives, iii. Establish close communication, with or without words, and iv. Praise and appreciate on child's efforts and achievements. v. Establish shared focus and attention with your child, vi. Provide meaning by naming and describing things and actions, and vii. Expand on meaning by connecting, comparing and using creativity (songs, stories, painting etc.)	Home visiting session Session duration: unknown Story book and wooden toys were used in the session. The intervention was provided step-by step.	Primary outcomes: <ul style="list-style-type: none"><i>Pan-American Health Organization age-specific developmental milestone</i> Secondary outcomes: <ul style="list-style-type: none"><i>Caregiver- child interaction</i><i>Caregiver's stress</i><i>Food insecurity</i><i>Morbidity</i>	Primary outcomes: <i>Pan-American Health Organization age-specific developmental milestone</i> IC VS CC group: Reduced the risk of language delay: Adjusted Risk Ratio =0.39 (95% CI : 0.19 to 0.82) Multiple micronutrient supplementation decreased the risk of motor delay: Adjusted Risk Ratio=0.12, (95% CI: 0.03 to 0.56). Secondary outcomes: <i>Caregiver child interaction:</i> IC vs CC group <ul style="list-style-type: none">Showing love: P = 0.015Praise and appreciate your child's efforts :P< 0.0001Provide meaning by naming and describing things and actions : P= 0.0001Expand on meaning by connecting, comparing and using creativity: P< 0.0001 <i>Child and caregiver stress:</i> IC vs CC group: Higher stress scores: P= 0.030 and P<0.001, respectively Food security improved: IC: 75.2%, CC: 59.1%, P= 0.017

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China Heckman et al., 2020	Randomized Controlled Trial 111 Villages were randomly allocated into: i. Intervention (n=56 villages/715 children) ii. Control (n=55/8520 children) Integrated with Govt. Health Program	0-24 months Duration : 21 months	91 Home Visitor recruited by local Govt. authority. Education: The Home Visitors' with primary level educational qualification (education was similar to maternal education).	Training: The Home Visitors were taught following points through role play: i. How to conduct home visits ii. How to help children learn iii. How to praise children iv. Listen, understand and respond to children v. Build a good relationship with caregiver vi. Understand difficulty vii. Use daily activities to help children learn viii. Involving other family members ix. Promote positive behavior Supervision: The Supervisors supervised and support home visitors. The Supervisor visited each household once in a month and recorded monthly observation of the caregiver, child and home visitor. In addition, they organized weekly meeting with home visitors to provide feedback to improve the program.	Weekly home visits	ECD intervention: China REACH curriculum was developed based on Jamaican Reach Up and Learn Curriculum. The curriculum includes activities on cognition, language, gross & fine motor and social-emotional skill. The curriculum includes more than 200 tasks related to language and cognitive skill development and 20 tasks targeting gross motor skills development. The activities were organized from easy to difficulty order.	Home visit Duration: 1 hour The home visitor guided caregivers on parenting practice and recorded information about parental engagement. The home visitor introduce new activities to the child during visits. Activities such as making toys, completing puzzles, and making picture. The home visitor left the toys to the households to practice.	Primary outcomes: <i>Denver Developmental Screening Scale II</i> - Cognition - Language - Motor - Socio-emotional development <i>Anthropometric measurement:</i> -Height for Age - Weight for Age - Head Circumference	Primary outcomes: <i>Denver Developmental Screening Scale II</i> Intervention vs control group: Cognition: ES=0.75, P<0.001 Language : ES=0.75, P<0.001 Fine motor: ES=0.73, P<0.001 Social-emotional: ES=0.40, P<0.001 No intervention effect was found in gross motor skill. The intervention benefitted the boys more than girls. The effect size is 0.9 for girls and 1.1 for boys. Girls performed better in social-emotional scale than boys.

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Colombia Attanasio et al., 2020	Randomized Control Trial. Government FAMI programs running: 87 towns were randomly allocated into 2 arms i. Intervention :46 towns (n=702) ii. Control: 41 towns (n=758)	0-24 months Duration: 15 months	171 govt. FAMI mothers involved in the treatment arm. Mean age: 42 years Education: 13 years of education (high school degree) Experience: 12 years of working experience in the Govt. FAMI program.	Training: FAMI mothers received 3.5 weeks training. Refresher training: In every 6 months in throughout the intervention period. The refresher training includes feedback session. Supervision: The Supervisors supervised the FAMI mothers in the throughout the intervention period	Home visiting session: Monthly 24 sessions Group session: Weekly 20 group sessions Additional 4 group session for 0-5 months old children.	ECD intervention: The curriculum is adapted based on Jamaican Reach up and learn. Age appropriate activities using age appropriate books, puzzles, homemade toys. Emphasis on improving cognition, language and motor development, maternal knowledge and responsive parenting. Nutritional supplementation: Monthly nutritional supplement with 35% daily calorie and 54% daily protein intake.	Group session: Group size: 5 mother child dyads Duration: 1.10 hours Group session comprised with 6 components; - Feedback from the previous group session (10 minutes) - Song (5 minutes) - Demonstration and practice of age appropriate play activity and language activity for the week with material (30minutes); - Discussion on parenting theme or activity (15minutes) - Review of the session (10 minutes) Mothers were splitted into 3 groups: pregnant to mother having 6 months old children, 6-11 months old children and 12 to 24 months. Cost: per child cost 320\$ per year which include 28\$ for toy and print material,\$82 for supervision, \$212 for additional nutritional supplements)	Primary outcomes: <i>Bayley Scale of Infant and Toddler development III:</i> - Cognition, - Language and -Motor development Ages and Stages <i>Questionnaire</i> ; Socio-Emotional (ASQ:SE) <i>Anthropometric Measurement:</i> - Weight for age and - Length for age Z score Secondary outcomes: i. <i>Home Observation and measurement of Environment (HOME):</i> Home Stimulation iii. <i>Maternal knowledge on child development and child rearing practice</i> iv. <i>Maternal self-efficacy</i> v. <i>Food insecurity</i>	Primary outcomes: <i>Bayley Scale of Infant and Toddler development III:</i> Intervention vs control: Expressive language: ES=0.151, P=0.016 Cognition: ES=0.142, P=0.069 Receptive vocabulary: ES=0.105, P=0.066 Motor skill was not differed between the groups: ES=0.083, P=0.206. Secondary outcomes: Intervention vs control: <i>Home Observation and measurement of Environment (HOME):</i> Home stimulation: ES=0.34, P<0.001 Maternal knowledge on child development, self-efficacy and food insecurity was not differed between the groups. The differential treatment effect had been found between the group by maternal education and sex. The effect of family wealth on the outcomes had been found in the intervened group with effect size 0.22SD, P=0.029. Children from poorer families scored higher in cognition comparing to the children from affluent families.

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China Luo et al., 2019	Cluster Randomized Controlled Trial 43 villages were randomized into i. Intervention (n=222 children) ii. Control (n=227 children) Integrated with National Health Commission service.	6-18 months Duration : 1 year	Community Health Workers (CHW). They conducted home visits as part of the Nutrition Health Care service.	Training: 1 week extensive training on basic theories of ECD and on communication, coaching and counseling skills from three ECD experts. The training program consisted of 5 days of classroom-based instruction and 2 days of field practice. Supervision: The supervision was implemented by Government. Each CHW was visited by county level or township level officials in every 3 months. They supervised a home visit of CHW without notifying them and provided feedback and reinforced training. A random number of caregivers were called to receive feedback of the session. The content were modified accordingly.	24 fortnightly home-based session	ECD Curriculum: The curriculum was based on Jamaican curriculum. The intervention includes The curriculum comprised with messages on ECD and health messages. ECD activities based on four types of skills: i. Cognition, ii. Language, iii. Motor and iv. Social-emotional skills. Age appropriate nutrition and health message includes: <ul style="list-style-type: none"> Feeding practices, Dietary diversity, Meal frequency, Nutritional supplementation Immunization Hygiene Healthy eating Sleeping behavior. 	Home visit Session duration: unknown The CHWs had a copy of full curriculum consisting instructions on interactive play and an ECD toolkit (including a growth chart, development checklist, counseling materials and user handbook).Two new activities were given to mothers to practice with their children in each session.	Primary Outcomes: <i>Bayley Scales of Infant and Toddler Development III</i> Intervention vs control: <ul style="list-style-type: none"> Summery index of skill development: ES=0.17, P=0.04 Cognitive development: ES=0.24, P=0.01 Secondary outcome variables : <ul style="list-style-type: none"> <i>Measures of parenting practices and parental beliefs related to child psychosocial stimulation</i> 	Primary Outcomes <i>Bayley Scales of Infant and Toddler Development III</i> Intervention vs control: <ul style="list-style-type: none"> Summery index of skill development: ES=0.17, P=0.04 Cognitive development: ES=0.24, P=0.01 No effect was found on Receptive language (ES=-0.01, P=0.89), Expressive language (ES=0.14, P=0.09), gross motor (ES=-0.14, P=0.12), fine motor (ES=0.13, P=0.09), and socio-emotional scores (ES=0.10, P=0.24). Secondary outcomes: <i>Measures of parenting practices and parental beliefs related to child psychosocial stimulation</i> Intervention vs control : Improved overall caregiver-reported <ul style="list-style-type: none"> Caregiver beliefs towards psychosocial stimulation (ES=0.25 SD, (95% CI: 0.07 to 0.44) and Stimulating parenting practices (ES= 0.35, (95% CI : 0.18 to 0.52) is also improved

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Bangladesh Jena D Hamadani, 2019	Cluster- randomized controlled trial 90 Community Clinics (CC) randomized into 2 groups: i. Intervention (n=859 children) ii. Control (n=878 children)	5-24 months Duration: 12 months	130 Community clinic staff with Education: educational qualification ranging 12 th grade – graduation degree	Training: 8 days training -1 day refresher training in every 3 months Supervision: Each supervisor monitored around 10-12 HWs of 4 CCs and each CC staff monitored once in a month Supervisor filled a checklist rated a health worker's performance using 4 rating scale. The supervisors provided feedback to the HWs at the end of the session.	25 fortnightly session	Adapted version of Jamaican Reach Up & Learn curriculum Curriculum comprised with 6 contents: i. Feedback of previous session, ii. Song, iii. Toy, iv. Book, v. Language activity, vi. Nutrition message vii. Review of the current session. Emphasis on mother-child interaction, demonstration of activities according to age, praising	Pair session: Two mother-child dyads participated in the session. Duration: 30-40 minutes Toy and book materials were given to mother to practice at home and were exchanged with a new set of toys in the subsequent session. Attendance: Mean attendance is 19 (sd= 9). 46% (n=394) of the mothers and their children attended all session	Primary outcomes: <i>Bayley Scale of Toddler & Infant Development III</i> : Cognition Language and Motor <i>Wolke's Behavior Rating Scale:</i> Response to Examiner Emotional tone Cooperation Activity and Vocalization <i>Anthropometric measurement:</i> Weight for age, Height for age Head circumference Secondary outcomes: <i>Family Care Indicator:</i> Quality of stimulation using <i>Maternal knowledge and Maternal depression</i>	Primary Outcomes: Intervention vs control: <i>Bayley Scale of Infant & Toddler Development III:</i> Cognition: ES=1.3, P=0.006) Language: ES=1.1, P=0.01, and Motor: ES=1.2, P=0.006 <i>Wolke's Behavior Rating Scale:</i> Intervention vs control: Responsive to the examiner: ES=1.1, P=0.007, Happier emotional tone : ES=0.9, P=0.01 Cooperativeness: ES=1.0, P=0.008 Vocalization: ES=0.7, P=0.02 No group difference had been found in the growth of the children Secondary outcome: Intervention vs control: i. Maternal knowledge: ES=1.7, P=0.005 ii. Home stimulation: ES=0.8, P=0.03 There is no treatment effect had been found between the groups by age, sex and maternal education and wealth.

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China Zhou et al., 2019	Quasi experimental Design i. Intervention (IECD program running) village=40 ii. Comparison (no IECD) village=43 Pre and post-test on 2953 children Evaluation of Early Childhood Development (IECD) program	0-35 months Duration :1 year	Full time village volunteer Education: 8 years Experience: working experience in ECD centre	Training: No information on training Supervision: Two health professional with expertise on child protection and early stimulation visited parenting session bi-weekly to each village	Weekly 3-4 days session	ECD program includes: <ul style="list-style-type: none">Child health,NutritionResponsive careProtection andEarly learning support Intervention also includes messages on: <ul style="list-style-type: none">Child health,NutritionResponsive care,Protection andEarly learning support Nutritional supplementation: A daily intake package of soybean based micronutrient fortified powders	Group session: Session duration: unknown In each intervention village, an ECD centre was open to all children aged below 3 years, was set up to provide early stimulation interventions by age-appropriate group sessions of caregiver-child play activities and reading to children 3-4 days a week. The center was equipped with toys, story books, touch screens for the young children to play with their caregivers. Attendance: 14% (n=110) children went to ECD Center 3 to 4 times a week 28% (n=210) children went to ECD Center 1 to 2 times a week 27% (n=204) children went to ECD Center 1 to 2 times a month.	Primary outcomes: <i>Suspected developmentally delay (SDD) was detected using Ages and Stages Questionnaire Version III ASQ includes subscales:</i> <ul style="list-style-type: none">Problem solvingPersonal social skillCommunicationFine motorGross motor <i>Anthropometric measurements:</i> Weight for age Length for age Secondary outcomes: <i>Caregiver's engagement in following activities:</i> <ol style="list-style-type: none">Read books to or looked at picture books with child,Told stories to childSang songs to or with child, including lullabies;Took child outside of the home, compound, yard or enclosure,Played with child; andNamed, counted or drew things to or with child.	Primary outcomes: <i>Ages and Stages Questionnaire Version III ASQ includes subscales:</i> Intervention vs comparison: <ul style="list-style-type: none">Over all Suspected Developmental Delay (SDD) decreased from 37% to 19%)SDD decreased in communication (OR= 0.69, P=0.049)SDD decreased in gross motor (Or=0.65, P=0.035)SDD decreased in fine motor (OR=0.40, P<0.001)SDD decreased in Problem solving (OR=0.50, P<0.001)SDD decreased in personal-social (OR=0.58, P=0.017).ASQ Overall score: (OR=0.69, P=0.005). Intervention effect on ASQ score: ES=0.21, P < 0.001 <i>Anthropometric measurements:</i> Length for age Z score: ES=0.13, P < 0.001 Secondary outcomes: Intervention vs comparison: Positive discipline: ES=0.19, P < 0.001

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Madagascar Galasso et al., 2019	<p>Cluster Randomized Controlled trial</p> <p>125 Nutrition program running site were randomly allocated into 5 groups:</p> <p>i). Standard-of-care programme with monthly growth monitoring and nutrition education (T0, n=497)</p> <p>ii). T1=T0+Home visit for nutrition counseling (T1,n=500),</p> <p>iii. T2=T1+LNS for 6-18 months old children (T2, n=494)</p> <p>iv) T3= T2+LNS for pregnant or lactating mothers(T3, n=499)</p> <p>v. T4= T1+Home visiting program (T4,n= 500) on early</p> <p>Integration with Community based Nutrition Program</p>	<p>0-11 months at enrollment</p> <p>Duration : 2 years</p>	<p>The existing Community Health Workers were responsible for delivering Standard-to-Care program. An additional number of CHWs were recruited for home visiting session.</p> <p>Education: minimum secondary educational level</p>	<p>Training: 10 days extensive training.</p> <p>Training comprised with theoretical and practical session</p> <p>Refresher training: in every 6 months.</p> <p>In addition a team of early child development trainers provided support in the program session for 1 week at the beginning and 6 months of implementation.</p> <p>Supervision: One local NGO was involved in program supervision.</p>	48 fortnightly home visiting session on nutrition counseling and stimulation	<p>The curriculum was adapted from Jamaican Reach up Learn Jamaican home visiting program. The curriculum consists of activities focusing cognitive, language and motor development.</p>	<p>Home visiting session</p> <p>Session duration: unknown</p> <p>CHWs provided stimulation messages to the mothers. No toys were provided in the home visiting sessions. A set of toy and books were given to participants.</p>	<p>Primary outcome: <i>Ages and Stages Questionnaire (ASQ I)</i></p> <ul style="list-style-type: none"> • Problem solving, • Personal-social skill • Communication, • Fine motor and • Gross motor <p><i>Anthropometric Measurement:</i> Height-for-age and weight-for-age Z score.</p> <p>Secondary outcome:</p> <ul style="list-style-type: none"> • <i>Dietary diversity,</i> • <i>Caregiver knowledge on child development, Care, feeding practice, hygiene,</i> • <i>Home stimulation: assessed by UNICEF Family Care Indicator (number of books, play objects, and play activities with any adult in the household in the previous 3 days).</i> • <i>Household food security.</i> 	<p>Primary outcome: <i>Ages and Stages Questionnaire (ASQ I)</i> Findings of 2-year follow up: No difference had been found SQ domains: Gross motor: T1group:ES=0.08, P=0.63, T2:ES=0.269, P=0.12, T3:ES=0.032, P=0.84, T4:ES =0.199, P=0.24 Fine motor T1;ES=0.104,P=0.47, T2: ES=0.235, P=0.14, T3 :ES=0.045, P=0.77 T4: ES=0.163, P=0.31 Problem solving: T1: ES=0.158, P=0.36 T2 : ES=0.158, P=0.36 T3 : ES=0.074, P=0.67 T4:ES=0.157, P=0.35 Personal-social: T1:ES=0.151, P=0.27, T2: ES=0.107, P=0.48, T3 : ES=-0.083, P=0.58 T4:ES=0.086, P=0.55 Communication : T1: ES=0.098, P=0.46, T2: ES=0.136, P=0.31, T3 : ES=-0.089, P=0.48, T4:ES =0.122, P=0.34) and Total ASQ score: T1: ES =0.151, P=0.35, T2: ES=0.220, P=0.22, T3 : ES=-0.01, P=0.95, T4: ES =0.178, P=0.31</p>	<p>Nutritional outcome: T2 : ES= 0.210 (95% CI -0.004 to 0.424) T3 : ES= 0.216 (95% CI 0.043 to 0.389) lower stunting prevalence T2: ES=-9.0 (95% CI -16.7 to -1.2) T3:ES=-8.0% [95% CI -15.6 to -0.7)</p> <p>Secondary outcome: No difference among the groups Parental stimulation activity at home T1:ES =0.00, P=0.96, T2:ES=0.026, P=0.76 T3:ES=0.147, P=0.15 T4:ES =0.152, P=0.10 Maternal knowledge: T1;ES =-0.266, P=0.06 T2:ES=-0.141, P=0.33 T3:ES=0.254, P=0.11 T4:ES =-0.046, P=0.78</p> <p>Differential effect by maternal education and child sex were inconclusive.</p>

Author Country	Study design & Sample size	Child age and duration	Staffing	Training and supervision	Number of sessions	Intervention Content	Intervention Process	Outcomes	Findings and size of effect
Caribbean Chang et al., 2015	Randomized Controlled Trial Fifteen Public Health Centers were randomly allocated to: i. Intervention (n=251 mother-child pairs) ii. Control (n=250 mother-child pairs) Integrated with Government Health Center	3-18 months Duration: 15 months	Community Health Workers are government staff. Education: minimum 3 years of secondary education Government nurse of the health centres	Training: 3 days training. Training contains viewing of films and role play. Supervision: A supervisor visited the clinic, reviewed topics and provided feedback in discussion and practice. Supervisor conducted monitoring visit in every 6 weeks and used a 3-point checklist. The checklist consists ratings on how well the CHW demonstrated and involved with mothers and praised them.	Five sessions Each session consists of 5 visits at 3, 6, 9, 12 and 18 months of age.	Five 3 minutes short films on parental stimulation were developed to promote development of children. The film consists of 9 modules: i. Love, responding and comforting ii. Talking to children iii. Praise\ iv. Using bath time to play and learn v. Looking at books vi. Simple toys to make vii. Drawing viii. Games ix. Puzzle Nurses provided message cards to the mothers. The cards include information on the topic of the films. Book reading encouraged to increase mother-child interaction. Concepts such as in/out and big/little and the shapes circle and square were taught to mothers.	Group session Group size: Median=37 Range: 26 to 50 Duration: Median duration was 16 minutes Range: 14 to 20 minutes Nurses give 2-3 minutes per mother. The CHW discussed the topics and demonstrated with mothers in the waiting area. The CHWs were given manual before each health visits containing step of the session. Nurses conducted discussed session. They gives picture books at 9 and 12 months of age and puzzle at 18 months of age. Mother attendance: At 3 months visits: 97.9% At 18 months visit: 89.4% All sessions: 83.1% Cost: Group session:yearly 197.1 USD per child Home visits: 245.1USD	Primary outcomes: <i>Griffith Mental Development scales:</i> - Cognition - Language - Motor - Eye-Hand coordination <i>MacArthur-Bates Short Form of the Communicative Development Inventory (CDI):</i> Language assessment <i>Anthropometric measurement:</i> - Weight for Age - Length for Age -Head Circumference Secondary outcomes: <i>Home Observation for Measurement:</i> Subscales: -Involvement -Responsivity - Acceptance - Learning materials - Practice <i>Center for Epidemiological Studies- Depression Scale (CES-D):</i> Maternal depression	Primary outcomes: <i>Griffith Mental Development scales:</i> Intervention vs control group: Cognition: ES=0.3, P=0.007 No treatment effect was found in language, motor and eye-hand coordination and CDI scores and child growth between the groups. Secondary outcomes: <i>Parental knowledge:</i> ES=0.4, P<0.001 No difference had been found in home stimulation and maternal depressive symptoms between the groups.

Authors/co untry	Study design & Sample size	Child age & Duration	Staffing	Training and Supervision	Number of sessions	Intervention Content	Interventio n Process	Outcomes	Findings and size of effect
Pakistan Yousafzai et al., 2014	Community-based Cluster- Randomized Effectiveness Trial 1489 Children randomly allocated into 4 groups: i. Enhanced Nutrition (n=364) ii. Responsive Stimulation (n=383) iii. EN+RS (n= 374) iv. Control (n=368) Integrated with Govt. Lady Health Worker Program Follow-up study: The children were followed up 2 years after the intervention	6 - 24 months Duration: 2 years Age at Follow- up: 4 years	Government Lady Health Worker Education: 8 years education	Training of LHW EN group: 2 days training RS group: 3 days training on responsive stimulation curriculum For combined group: 5 days training Refresher training: 1 day refresher training in every 6 months. 15 days were allocated for refresher training in each year. Supervision: 6 supervisors supervised intervention sessions. Each supervisor supervised 25 LHWs and used a checklist to evaluate the quality of the session. The checklist includes information on: • Frequency, of LHW visits • Information about the last LHW visit; e.g. duration and purpose • Recall about advice provided pertaining to basic curriculum and enriched interventions	24 monthly home visit & group session.	ECD curriculum: Adapted curriculum of UNICEF and WHO Care for child development package was used to promote sensitivity and responsively of the mothers using developmentally appropriate toys. The curriculum includes messages on care for development and problem solving. Nutritional supplementation: Sprinkles (multiple micronutrient powder)	Group session + Home visit: Group size: unknown Duration: 1.20 hours. The curriculum provided through monthly group meeting Home visit: The Care for developme nt package was integrated regular routine home visits, lasted for 30 minutes.	Primary outcomes: <u>At 12 and 24 months</u> <i>Bayley Scale of Infant and Toddler Development III:</i> - Cognitive, - Language and - Motor - Socio-emotional development <u>At 12 months of age:</u> Social-emotional scores <i>Anthropometric Measurement:</i> - Weight for age and - Length for age Z score Secondary outcomes: Household food security At Follow-up: Primary outcomes: <i>Wechsler Preschool and Primary Scale of Intelligence (WPPSI):</i> - Block design, - Information, - Matrix reasoning, - Vocabulary, - Picture concepts, - Symbol search, and - Word reasoning.	Primary outcomes: <i>Bayley Scale of Infant and Toddler Development III:</i> At 24 months age RS vs Control group: Cognition: ES=0.6, (95% CI;0.5 to 0.8) Language: : ES=0.7, (95% CI; 0.5 to 0.8) Motor: : ES=0.5 (95% CI; 0.4 to 0.7) RS+EN vs control group: _____Cognition: ES=0.5 (95% CI; 0.3 to 0.6), Language: ES=0.6 (95% CI; 0.4 to 0.7) Motor: ES=0.4 (95% CI; 0.2 to 0.6) EN vs control group: Cognition: ES=0.2 (95% CI; 0.0 to 0.4), Language: ES=0.4 (95% CI; 0.3–0.6) Motor: ES=0.2 (95% CI;0.0–0.4) Combined intervention group (RS & RS+EN) vs Control group: Cognition: ES=0.36 (95% CI:0.12 to –0.59) Receptive language: ES=0.27 (95% CI:0.03 to –0.50) <i>Anthropometric Measurement:</i> EN group had significantly better height for age Z score than other 3 groups –2.4 [1.1], P=0.02. Weight for age not differed among the groups. At Follow-up: Primary outcomes

								<p><i>Executive functioning tests</i></p> <p><i>Bracken School Readiness Assessment, 3rd ed</i></p> <p><i>Strength and difficulties Questionnaire:</i> Behavior difficulties</p> <p><i>Motor Proficiency test: Bruininks-Oseretsky Test , Version 2</i></p> <p>Secondary outcomes: - <i>Home Observation for the Measurement of the Environment, Early Childhood version (HOME-EC):</i> Home stimulation - <i>Parenting knowledge</i> - <i>Observation for Mother-Child Interactions</i> - <i>Self-Reporting Questionnaire (SRQ-20):</i> Maternal depressive symptom</p>	<p>Responsive e stimulation + enhanced nutrition group vs no stimulation group:</p> <ul style="list-style-type: none">• IQ: ES=0.1• Executive functioning : ES= 0.3,• Pre-academic skills: ES=0.5 and• Pro-social behavior : ES= 0.2 <p>Only responsive group vs no stimulation group:</p> <ul style="list-style-type: none">• IQ was: ES=0.1,• Executive functioning : ES= 0.3,• Pre-academic skill : ES= 0.2• Pro-social behavior : ES= 0.2 <p>Enhanced nutrition plus responsive stimulation and only enhanced nutrition group improved motor skill with the ES=0</p> <p>Secondary outcomes</p> <p>Combined responsive stimulation vs no stimulation group:</p> <ul style="list-style-type: none">• Responsive care giving behavior : ES= 0.3 and• Home stimulation: ES= 0.3 <p>Responsive stimulation plus enhanced nutrition group vs no stimulation group:</p> <ul style="list-style-type: none">• Responsive care giving behavior : ES= 0.2 and• Home stimulation: ES= 0.3 <p>No significant difference had been found in maternal depressive symptoms among the groups.</p>
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Appendix: 8.3

Study title: Integrating a Group-Based, Early Childhood Parenting Intervention into Primary Health Care Services in Rural Bangladesh: A Cluster-Randomized Controlled Trial

Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	P a g e	
Title and abstract					
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1	Impact of integrated early childhood development program and primary health care service on the development of malnourished children- a cluster-randomized controlled trial
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) ^{i,ii}	See table 2	1	
Introduction					
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	3	Aiming at sustainability, we involved the Bangladesh Government's primary health services through rural community clinics (CC) in the present study using a cluster randomized controlled trial. CC is a ground breaking program of Bangladesh Government in rural areas, through public-private partnership providing primary health services to large number of population with low cost.
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	3	The aims of the intervention were to improve the cognitive, language and motor development of undernourished children, to enhance knowledge of the mothers on child rearing practices

					and to test the feasibility of using the CCs for this intervention.
Methods					
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	4	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		4	We randomly interviewed few mothers and found long distance is the main cause for not attending sessions regularly. Therefore we restricted inclusion into the study to those living within 20-30 minutes walking distance. Based on the findings of pilot study we fixed maximum sample size to 25 for each CC. Our initial plan was to include children with weight-for-age z score (WAZ) of <-2SD. However, we could not find adequate number of children with that criteria and therefore extended the inclusion criteria to children with WAZ <-1.5SD.
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	4	WAZ more than <-1.5SD and living close (within 20 min walking distance) to Community Clinic
	4b	Settings and locations where the data were collected		4	We recruited children from catchment areas of CCs in Kishorganj district located at about 100 km from Dhaka City. We selected 2 Sub-districts of Kishorganj that had a total of 74 CCs and we randomly selected 20 CCs from each sub-district. Half of the clinics in each sub-district were randomly assigned to intervention.
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	5	The intervention was started concurrently in both sub-districts. Mothers and their children attended session together every fortnight at Community Clinic and the average duration of the session was 40 to 50 minutes. On average, CHCPs conducted 1 session/week, while FWAs and HAs ran 1 session every 2 weeks.

Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	8-9	The primary outcomes were cognition, language and motor composite score, behaviour and growth of children. All children (n=785) were assessed using Bayley Scale of Infants and Toddler Development third edition ²⁵ before and after the intervention. Children were assessed at CC. The secondary outcome variables include- home stimulation, play materials, maternal mental health and knowledge on child caring practice. The interview had been conducted at child's home.
	6b	Any changes to trial outcomes after the trial commenced, with reasons		N A	
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or <i>k</i>), and an indication of its uncertainty	??	
	7b	When applicable, explanation of any interim analyses and stopping guidelines		N A	
Randomisation:					
Sequence generation	8a	Method used to generate the random allocation sequence		??	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	4	We selected 2 Sub-districts of Kishorganj that had a total of 74 CCs and we randomly selected 20 CCs from each sub-district. Half of the clinics in each sub-district were randomly assigned to intervention. We found more than 25 eligible children in five CCs and 25 children were randomly selected from amongst them.
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	3	We selected 2 Sub-districts of Kishorganj that had a total of 74 CCs and we randomly selected 20 CCs from each sub-district. Half of the clinics in each sub-district were randomly assigned to intervention. A researcher was not directly involved with the study performed the randomization procedure using a computer generated code.

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	5	The clinics were then randomized into intervention and control using computer generated code by a researcher who was not involved in the study.
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	4	
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	4	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	5	The surveyors identified the household with children 6-24 months old within 30 minutes walking distance from the clinic. They weighed the children and enrolled those whose parent consented to participate in the study.
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		5	Both mothers of intervention and control clinics were informed about the program and they also informed about the possibility of participating in the intervention. The surveyors also told them about the assessment of their children during enrollment. Throughout the study period the mothers of both arm were unaware about the classification.
	11b	If relevant, description of the similarity of interventions			
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	9	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses			
Results					
Participant flow (a diagram is strongly recommended)		13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome		

	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members		
Recruitment	14a	Dates defining the periods of recruitment and follow-up			
	14b	Why the trial ended or was stopped			
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group		
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis		
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome		
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended			
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory			
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms ⁱⁱⁱ)			
Discussion					
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses			

Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)		
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence			
Other information					
Registration	23	Registration number and name of trial registry			
Protocol	24	Where the full trial protocol can be accessed, if available			
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders			

Appendix 8.4:

Study title: Scaling-Up an Early childhood Parenting Intervention by Integrating into Government Health Care Services in Rural Bangladesh: A Cluster-Randomised Controlled Trial

Table 2: Extension of CONSORT for abstracts to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	Identification of study as cluster randomised
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	Eligibility criteria for clusters
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	Whether objective or hypothesis pertains to the cluster level, the individual participant level or both
Outcome	Clearly defined primary outcome for this report	Whether the primary outcome pertains to the cluster level, the individual participant level or both
Randomization	How participants were allocated to interventions	How clusters were allocated to interventions
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	Number of clusters randomized to each group
Recruitment	Trial status ¹	
Numbers analysed	Number of participants analysed in each group	Number of clusters analysed in each group
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Results at the cluster or individual participant level as applicable for each primary outcome
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

¹ Relevant to Conference Abstracts

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	See table 2	1-2
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	4-5
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	4
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		N/A
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	4-5
	4b	Settings and locations where the data were collected		6 & 8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	Table 1, page 6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Whether outcome measures pertain to the cluster level, the individual participant level or both	6-8
	6b	Any changes to trial outcomes after the trial commenced, with reasons		N/A
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines		N/A
Randomisation:				

Sequence generation	8a	Method used to generate the random allocation sequence		5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	5
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	4
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)	5
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	5-6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		6
	11b	If relevant, description of the similarity of interventions		N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	8-9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		N/A
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after	For each group, losses and exclusions for both clusters and individual cluster members	Figure 1, pg. 9 & 10

		randomisation, together with reasons		
Recruitment	14a	Dates defining the periods of recruitment and follow-up		4
	14b	Why the trial ended or was stopped		N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Baseline characteristics for the individual and cluster levels as applicable for each group	Table 4
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	Figure 1, pg. 10
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	Table 5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		Table 2 & 3
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		N/A
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		10-14
Other information				
Registration	23	Registration number and name of trial registry		6
Protocol	24	Where the full trial protocol can be accessed, if available		N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders		Title page

Appendix 8.5

Supervisor Checklist: Observation of Child Development Parenting Sessions

Supervisor name: _____

DOV: /___/___/./___//___/./___//___/

CC: _____

HW name: _____

Number of children attended the session: /___/ Start time: _____ End time: _____

Appropriate session is conducted: 1= yes 0 = No Session no : /___/

Review of Last Visit (*Please circle the appropriate response*)

1. CHCP/HA/FWA checked with caregivers if they played with their child at home (what they did, how often, if their child enjoyed it)

Very well	Adequately	A little
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Activities and methods

2. CHCP/HA/FWA was prepared for the visit in advance

Yes	No
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3. CHCP/HA/FWA used correct materials and activities as in curriculum

All correct	Some correct	Few correct
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4. CHCP/HA/FWA *explained* the activities and objectives (what the child should achieve) to the caregivers (*i.e. verbally explained the activity*)

Very well	Adequately	A little
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5. CHCP/HA/FWA *demonstrated* the activities to the caregivers and children (*i.e. **showed** them what to do*)

Very well	Adequately	A little
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6. CHCP/HA/FWA *talked about* the activities while demonstrating with the children (*e.g. – ‘I am putting this block on top of that one. Can you put this block on top of that one?’*)

Very well	Adequately	A little
-----------	------------	----------

7. CHCP/HA/FWA encouraged the caregivers to do the activities with the child	Most of the time	Some of the time	None
8. CHCP/HA/FWA asked caregivers to say what they were going to do in the next week	Most topics remembered	Some topics remembered	Few topics remembered
9. CHCP/HA/FWA makes an effort to include all caregivers during the session	All mothers	Some mothers	Few/none of mothers
10. CHCP/HA/FWA ensures all caregivers practice the play activities and helps them	All mothers	Some mothers	Few/none of mothers
11. CHCP/HA/FWA helps caregiver when they practice the play activities	All mothers	Some mothers	Few/none of mothers

Relationship between CHCP/HA/FWA and caregiver

12. CHCP/HA/FWA asked the caregivers' opinion, listened to the caregivers and responded to her comments	Most of the time	Some of the time	Little of the time
13. CHCP/HA/FWA encouraged and positively reinforced the caregivers	Most of the time	Some of the time	Little of the time

Relationship between Visitor and child

14. CHCP/HA/FWA praised the children when they attempted and/or completed an activity	Most of the time	Some of the time	Little of the time
15. CHCP/HA/FWA gave children enough time to explore the materials and to complete the activities with no grabbing toys	Most of the time	Some of the time	Little of the time

Overall visit: Participation

16. Caregivers actively participated in the visit (talking and playing)	Lots of participation of caregivers	Some participation of caregivers	Little participation of caregivers
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17. The overall attitude of the CHCP/HA/FWA during the visit was

Very collaborative / not at all bossy	Sometimes collaborative, sometimes bossy	Not very collaborative, bossy
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18. The overall atmosphere of the visit was

Very happy	Happy	Neutral
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19. How were the different components of the curriculum conducted?

Curriculum's Name	Done very well	Done Moderately Well	Done poorly	Not Done
Feedback from last week				
Song				
Book				
Language				
Toy activity				
Nutritional message				
Review home activities				

20. Session was conducted within window period Yes=1, no=0

21. Record form was filled up completely. Yes=1, no=0

22. Tracking form was filled up completely. Yes=1, no=0

23. Overall feedback, comments and suggestions:

Appendix 8.6

Supervisor Checklist to evaluate the session

1. Supervisor's name: _____ 2. DOV: /___/___/./___//___/./___//___/
3. CC: _____ HW's name & designation: _____
4. Number of children attended the session: /___/ Session no : /___/
5. Were all the children given **toy/book on arrival**? 1= yes to all 0 = No/some /___/
6. Did the Provider take feedback of all steps of previous session's activity from all mothers?
1= yes, all, 0 = none/some N/A=9 /___/

If scored "0" mentioned which section omitted:

Questions	Hardly Ever= 1	Some of the Time= 2	Much of the Time= 3
7. Did the Provider give enough time to the child to explore the materials before starting with the activity?			
8. Did the Provider demonstrate play activities with its objectives to each mother?			
9. Did the CCSP praise/encourage the child during the activity?			
10. Did the Provider let the main caregiver do the activity alone with the child ?			
11. Did the Provider praise all the mothers?			
12. Did the Provider encourage mothers to praise their children?			
13. Did the Provider listen to the caregiver?			
14. Did the Provider ask the mother's opinion ?			
15. Were all the Mothers engaged throughout session?			
16. Did the mothers talk/interact with each other during the session?			
17. Did the Mothers sing with their children?			

18. Did the mothers enjoy the session?			
19. Did the children have fun during the session?			

20. Provider followed the steps accordingly: 1= yes 0 = No /___/

21. Appropriate session is conducted: 1= yes 0 = No /___/

22. How were the different components of the curriculum conducted?

Serial	Step of curriculum	1=poorly	2=moderately well	3=very well	Comments
1	Song				
2	Toy activity				
3	Language				
4	Book				
5	Nutritional message				
6	Review of the session				

23. Children performance:

	Song	Toy activity	Book
% of children enjoyed/doing activity			

24. Overall comments: