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Effects of integrated psychosocial stimulation (PS) and Unconditional Cash Transfer (UCT) on Children's development in rural Bangladesh: A cluster randomized controlled trial

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ABSTRACT

Background: There is evidence on benefits of psychosocial stimulation (PS) and cash transfer programmes in low- and middle-income countries on children's development. We integrated PS into an unconditional cash transfer (UCT) programme for poor Bangladeshi mothers to examine the effects on children's development.

Methods: This cluster randomized controlled trial was conducted in rural Bangladesh from July 2017 to December 2018 in 33 clusters, with 11 clusters randomly assigned to each of the three arms, namely i) PS + UCT ii) UCT-only and iii) Comparison. We enrolled poor mothers and child (6–16 months) dyads eligible to receive maternity allowance by the Government of Bangladesh. Trained local women imparted training to mothers to provide psychosocial stimulation to their children for one year. Children's cognitive, language and motor development were measured with Bayley-III, behaviour with Wolke's ratings and maternal self-esteem with Rosenberg self-esteem scale. The analysis was intention-to-treat.

Results: Of the 594 mother-child dyads, 40 (6·8%) were lost to follow-up. Compared to UCT-only, children in the PS + UCT had significant improvement in cognitive (B = 2.96, 95% CI: 0.46–5.47, Effect Size [ES] 0.24SD) and language (2.73, 0.39–5.00, ES 0.21SD) scores and were more responsive to examiner (0.30, 0.06–0.52, ES 0.27SD), while compared to comparison group, they had significantly higher cognitive (3.37, 1.27–6.19, ES 0.32SD), language (2.82, 0.53–5.10, ES 0.24SD) and motor (2.65, 0.24–5.06, ES 0.22SD) scores and were more responsive to examiner (0.30, 0.08–0.52, ES 0.26 SD). The mothers' self-esteem was significantly higher in PS + UCT (2.46, 0.94–3.98, ES 0.48 SD) and UCT-only (1.67, 0.02–3.20, ES 0.32 SD) compared to the comparison group.

Conclusion: PS integrated into an UCT programme benefited children's neurodevelopment and UCT improved mother's self-esteem. UCT programme may be an important platform for child stimulation programmes for rural poor populations.

1. Background

Although early years (0–3 years) are very important for brain development of a child, some factors including extreme poverty, stunting, lack of psychosocial stimulation and safety net are barriers for their smooth development (Britto et al., 2017). The early intervention e.g. psychosocial stimulation returns maximum of investment at this age (0–3 years) because the stimulation and interaction with caregivers increases neuronal connections in children's brains (Lagercrantz, 2016). Investment in health and education has been documented as a way to improve human capital and rapid economic growth (Lim et al., 2018). Intervention in early age has the highest returns in adult life (Heckman and Masterov, 2007). Indeed, early years investment in children is a unique window of opportunity to improve individual, community, and societal outcomes as a whole (Denboba et al., 2015).

Based on proxy indicators of poverty and stunting, an estimated 250

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million children do not reach their developmental potential in low- and middle-income countries (LMIC). Children living under the poverty line have lower cognitive and language development score compared to their better-off counterpart (Black et al., 2017). Researchers, programmers and policy makers around the world, especially in LMIC are working for children's maximum potential development. One important intervention of psychosocial stimulation (PS)/parenting programme, 3 decades earlier, reported to be beneficial for children's cognitive and language development. The study was conducted among malnourished children in Jamaica. The intervention consisted of 1-h weekly visits from community health workers over a 2-year period that taught parenting skills and encouraged mothers to interact and play with their children in ways that would develop their children's cognitive and personality skills (Grantham-McGregor et al., 1991). In the last couple of decades, a number of studies designed in many forms (e.g. less frequent sessions, different play materials, varying intervention workers and their training) of parenting/PS intervention using health, nutrition and early childhood education platforms were implemented to see the effect on children's cognitive and language development. Most PS programmes have found a positive effect on children's neurocognitive development and behaviour in LMICs (Grantham-McGregor et al., 1991; Fernald et al., 2008; Yousafzai et al., 2014; Andrew et al., 2020). In Pakistan, PS interventions were provided using health system and found positive effect on children's development (Yousafzai et al., 2014). In India, the interventions were delivered using early childhood education platforms and it was also a successful study to improve children's development (Andrew et al., 2020). We also found from our small randomized controlled trials that the psychosocial stimulation integration or using it in health and nutrition platforms improved children's development in Bangladesh (Hamadani et al., 2006; Tofail et al., 2013) (Hamadani et al., 2019). A recent study in Madagascar failed to report a positive effect of the intervention on children's development. The researchers speculated the lack of compliance to the intervention might be a cause for not reaching the expected impact (Galasso et al., 2019).

Previous studies documented that conditional cash transfer (CCT) programmes have an impact on maternal and child health (Fiszbein and Schady, 2009) and development (Fernald et al., 2008). Unconditional Cash Transfer (UCT) to families also was found to be effective on child and adolescent's physical and mental health outcomes (Li and Mora, 2016, Angeles et al., 2019) and language development in rural settings (Fernald and Hidrobo, 2011). One randomized controlled trial in Niger integrating parenting programme into UCT found no impact on child cognitive, language and motor development but the emotional development of the children was improved (Barry et al., 2017).

Systematic review and meta-analysis documented that cash transfers alone have had limited impact on distal outcomes for child well-being e. g on nutritional status and health (Manley et al., 2020; Siddiqi et al., 2018). But there is strong evidence that cash transfers can improve more proximal outcomes, such as improving access to food (Bastagi et al., 2019). Indeed, cash transfer to the poor families can improve the family's purchase capacity of their daily necessities which ultimately may be helpful for them and their children's health and development. Cash receipt was associated with enhanced children's verbal working memory, general cognitive functioning, and learning. Furthermore, cash plus good parenting provided an additive effect, although the study did not follow a robust methodology (Sherr et al., 2017). PS interventions by themselves might be more cost effective than combining them with cash transfers but targeting poor families is a big challenge. The utilization of health services by poor families are low in the LMICs. So, to cover maximum families for PS intervention, in the absence of a well--functioning health system in LMICs, other means must be targeted. UCT platform may seem a good option to help economically disadvantaged families.

The Sustainable Development Goals (SDGs) by 2030, directly incorporate early childhood development (ECD) under Target 4.2 to have access to "quality early childhood development, care and pre-primary education for all children aged less than 8 years". But there are very few integrated child development programmes that target most children in low resource settings like Bangladesh. The coverage of ECD programme for all children especially for the children aged less than three years remains a big challenge. It is strongly recommended by experts in early child development to integrate promotion of responsive and nurturing caregiving, supporting maternal mental health, and social protection programmes (e.g. cash transfer programme) into health and nutrition programmes (Daelmans et al., 2015). Social safety net programmes including cash transfer programme and the psychosocial stimulation have been suggested for improving ECD (Britto et al., 2017). De Hoop and Rosati reported that UCT is less costly and less difficult to handle compared to CCT programmes (De Hoop and Rosati, 2014).

However, there is limited information on integration of child stimulation programmes with unconditional cash for the poor on children's neurodevelopment. Our objective was to measure the impact of integrated ECD activities into unconditional cash transfer programme on children's development.

2. Methods

2.1. Study design and participants

It was a cluster randomized controlled trial with three arms: i) Psychosocial stimulation (PS) and UCT ii) Only UCT and iii) Standard care (Comparison arms). We selected *Ullapara* sub-district for this study because this sub-district had sufficient number of *wards* (a clearly demarked area) for cluster randomization. The study area was only 180 km from Dhaka, therefore regular visit by the research staff based in Dhaka could be made easily. We did baseline assessments between August and December 2017 and end line assessment between September and November 2018. The intervention programme took place between August 2017 and November 2018.

In the study area, most women were housewives and men were involved with agriculture activities for their livelihood. The participants of this study were the rural poor women in Bangladesh and were all eligible for the maternity allowance of the Bangladesh government (Hossain et al., 2019). The children were 6–16 months old at enrolment. The children with severe acute malnutrition, suffering from known chronic diseases or twins were excluded. The children having developmental delay or other illness were referred to the nearest sub-district health facility. The village health workers (VHWs) with at least completed secondary school education conducted the psychosocial stimulation sessions for one year. All the VHWs were females and permanent residence of the study area.

Ethical approval

We got permission from the Government of Bangladesh prior to conducting this study. We obtained written consent from the parents of the children at enrolment. The proposal (Protocol number: PR 17065) was approved by the Institutional Review Board of the International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b).

2.2. Randomization and masking

Eleven *Unions* (each *Union* consist of three *Wards*) out of 14 were randomly selected from this sub district by use of a computerized random selection process. Within each *Union*, the three *Wards* were randomized to the three treatment arms resulting in total 33 clusters. Each *Ward* was considered a cluster. We followed this process so that the study population for the treatment arms were comparable. Randomization was conducted by a third person who was not involved with the intervention. In each arm around 200 and in total 594 mother child dyads were enrolled in the study. The enrolment flow chart is provided in Fig. 1. The assessors were masked to study groups but due to

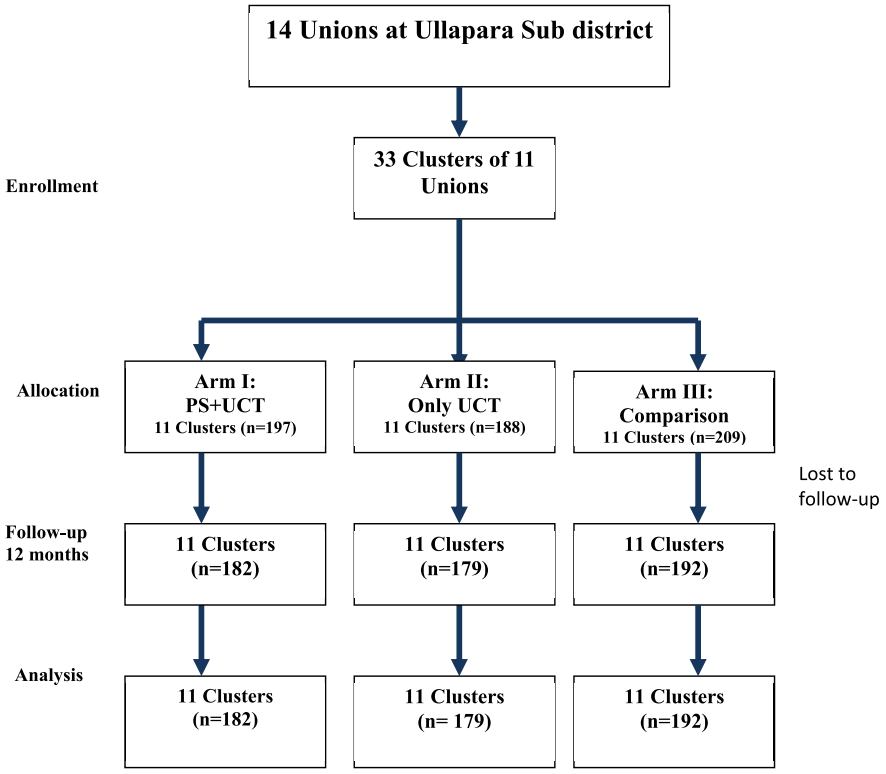

Fig. 1. Participant's enrolment and follow-up flow chart in the trial.

characteristics of the intervention the study participants and the VHWs were not masked.

A sample size of 11 clusters per intervention group and 18 mother child dyads per cluster was estimated to be sufficient to detect an effect size of 0.3 SD on Bayley cognitive composite scores (Nahar et al., 2009) assuming an intra cluster correlation of 0·05, $\alpha = 0{\cdot}05$, and statistical power of 80%. This resulted in 200 mother child dyads in each arm.

2.3. Procedures

The curriculum used for psychosocial stimulation was adapted from Reach Up (Grantham-McGregor and Smith, 2016) which was first used in Jamaica and has been already tested and used in several studies in Bangladesh (Hamadani et al., 2006; Nahar et al., 2009; Nahar et al., 2012; Tofail et al., 2013) among malnourished and anaemic children. The curriculum is mainly based on improving caregiver and child interaction and providing age specific developmentally appropriate activities for the child. It also included nutritional and personal hygiene messages appropriate for mothers and children. The curriculum was translated to Bangla language and minor modifications were made for use in this study. Six VHWs were locally recruited with the help of community leaders considering that they should have easy access to the participants' houses in the villages.

The VHWs were trained for 10 days on the sessions in the study area using a training curriculum by a female supervisor with master in psychology who later supervised the VHWs to ensure quality of intervention. The sessions were conducted domiciliary for approximately 40–60 min every fortnight for one year. Each VHW conducted three to four sessions every day for six days a week. The VHWs were instructed and encouraged to follow the sequences of every session that included rapport building with child and mother, feedback from the mothers on previous session, rhymes or songs, playing with age specific toys and picture books and general and nutritional messages. One male field supervisor was deployed with a motor bike to monitor the field every day to ensure the coverage of the VHWs as per pre planned sessions, availability of age specific play materials as per curriculum, check session conduction forms or to solve any other field related problem.

The VHWs visited the homes and demonstrated play activities to the mothers using toys made from recycled materials and they encouraged mothers to play with the child at home as often as they could and were also instructed to make other toys at home. The toys were left in the homes and exchanged with new toys on the following visit. The mother and child dyads of PS + UCT received the intervention.

The mothers in the PS + UCT and UCT only groups received taka 500 (US$6.25) as maternity allowance from government of Bangladesh (GoB) through banking channel under safety net programme of the ministry of women and children affairs, GoB. The eligibility criteria for getting UCT are: i) mother's age $\geq$20 years; ii) mother is pregnant during UCT enrolment iii) the mother has no child or one child; iv) monthly income of the mother is less than Taka 1500 (US$ 18.75); v) the family owns a residence only or lives in residence of others; vi) the mother or the family do not have agricultural land or pond for fish culture and vii) poor and disabled women will have priority to receive UCT. We excluded to evaluate children of disabled mothers. The mothers who received cash were also invited to attend basic health education (HE) orientation programme on issues such as disaster management, child marriage and dowry by designated local non-government organizations (LNGOs)/community-based organizations (CBOs) through GoB funding. Usually, many poor people are out of any formal health system in Bangladesh. Most poor families seek health care from informal practitioners e.g. quacks, traditional healers, homeo medicine practitioners, Kabiraj and Ayurveda practitioners. They rarely visit health facilities. But, the children of poor families need to bring under the quality ECD programme as per SDG goals. So, it is difficult to catch those people using health system for psychosocial stimulation. Safety net programme especially the UCT programme for rural mother could be a readymade platform to provide home based PS services for maximum coverage of quality ECD programme for the children aged less than three years since there is few platforms to provide ECD services in low- and middle-income countries. This integrated form of UCT and PS

could be sustainable and scalable for poor people in rural low resource settings. However, further research can be done to find cost effective integration of PS services into UCT.

2.4. Outcomes

The main outcomes of the study, fixed before analysis, were children's cognitive, language and motor composite scores using the Bayley Scales of Infant and Toddler Development third edition (Bayley, 2006). We rated the children's behaviour as secondary outcomes during the assessment on five Wolke scales: response to the assessor in the first 10 min, emotional tone, cooperation with the assessor, vocalization, and activity level throughout the test. These ratings have been used on Bangladeshi children (Hamadani et al., 2006; Hamadani et al., 2019). The secondary outcomes also included children and mothers' anthropometric measurements (height and weight) using WHO indices, quality of home stimulation for the children using the family care indicators (FCI) (Hamadani et al., 2010), mothers' self-esteem using Rosenberg self-esteem scale (Dey et al., 2012), household food security using Household Food Insecurity Access Scale (HFIAS) (Hasan et al., 2017), maternal depressive symptoms using validated Bengali version of WHO's Self-reported Questionnaire-20 (SRQ-20) (Chowdhury et al., 2003). Information about violence against women and socioeconomic status were also collected. All these tools were used in our settings previously. The details of these outcomes and its definition and rational to consider in this study has been described in the supplementary tables (S1).

Baseline data was collected between August to October 2017 by seven assessors who were blind to study arms. The assessors conducted the assessment at the community clinics/schools near the children's residence.

Table 1
Background characteristics of the participants by groups (n = 554).

Characteristics	PS + UCT n = 182 Mean (SD)/n(%)	UCT Only n = 179 Mean (SD)/n(%)	Comparison n = 192 Mean (SD)/n(%)
Age at end line (Months)	22.3 (2.1)	22.1 (2.0)	22.1 (2.6)
Sex (female)	94 (47.7%)	104 (55.3%)	90 (43.1)
Asset index (range: 1 = low-5 = high)	2.9 (1.4)	3.0 (1.4)	3.0 (1.4)
Crowding index[a]	3.3 (1.2)	3.1 (1.3)	3.3 (1.4)
Maternal education, *years*	5.7 (3.0)	6.0 (3.3)	5.6 (3.2)
Cognitive composite score	97.5 (10.8)	99.0 (13.1)	97.9 (11.3)
Language composite score	89.7 (10.9)	89.4 (12.7)	90.7 (11.7)
Motor composite score	94.9 (13.7)	95.20 (12.1)	93.6 (12.9)
Response to examiner[b]	5.3 (0.7)	5.4 (0.8)	5.3 (0.7)
Emotional tone[b]	4.9 (0.7)	5.0 (0.77)	5.0 (0.69)
Activity[b]	4.7 (0.8)	4.8 (0.8)	4.7 (0.8)
Cooperativeness[b]	5.0 (0.8)	5.13 (0.9)	5.0 (0.8)
Vocalization[b]	3.7 (1.3)	3.3 (1.2)	3.5 (1.3)
Length for Age Z (LAZ) score	−0.9 (1.4)	−1.2 (1.4)	−0.8 (1.3)
Weight for Age Z (WAZ) score	−0.7 (1.4)	−0.9 (1.4)	−0.5 (1.3)
Family care indicators[c]	5.8 (3.5)	6.6 (4.4)	5.9 (3.1)
Maternal depression[d]	8.1 (4.7)	7.5 (4.6)	8.1 (4.7)
Maternal self esteem[e]	25.6 (4.1)	24.9 (5.0)	25.4 (4.8)
Maternal BMI[f], *kg/m*[b]	21.3 (3.4)	21.0 (3.3)	21.5 (3.5)
Violence against the mothers[g] (yes)	43 (21.8%)	41 (21.8%)	44 (21.1%)
Food security (yes)[h]	95 (48.2%)	105 (55.9%)	99 (47.4%)

[a] Number of members/number of living rooms in the household.
[b] Behaviors are all 9 point ratings.
[c] Family care indicator (FCI) includes subgroup of varieties of play materials, source of play materials, play activities with child done by any adult in the family in the last one week and were scored as Yes = 1 and No = 0.
[d] A continuous scale (SRQ-20) in 20-point ratings, with higher scores indicating more depression.
[e] Rosenberg self-esteem scale 0–30 points with higher scores indication higher self-esteem.
[f] Body Mass Index.
[g] Any of three types of violence: physical, mental or sexual violence.
[h] According to Food and Agriculture Organization (FAO) of United Nations, household food insecurity access scale (HFIAS) is an ordinal variable ranging 1–4 indicating 1 = Food Secure, 2 = Mildly Food Insecure Access, 3 = Moderately Food Insecure Access, 4 = Severely Food Insecure Access. Binary variable is computed as 1 = food secure and 0 = mild, moderate or severe food insecure.

2.5. Statistical analysis

A wealth factor was computed using principle component analysis from a list of assets that the family owned (Hamadani et al., 2006) and a crowding index was calculated based on the number of household member per living room. Anthropometric information of the children was converted to Length/height-for-age Z score (L/HAZ), weight-for-age Z score (WAZ) and body mass index-for-age Z score (BAZ) using the WHO Anthro software (version 1.0.4) and compared with reference data according to WHO 2006 population. Mothers' Body Mass Index (BMI) was calculated using the formula 'weight in kilograms divided by height in meters squared'. We assessed similarity across groups at baseline by the magnitude of imbalance (Altman and Doré, 1990).

The study design suggests a multilevel mixed effect model where cluster plays as a random effect variable. Here, child-mother dyads are nested to clusters (wards) and the clusters are nested to unions. This hierarchical structure is adapted to the regression models so that the results are free from false inferences. It also helpful for substantive interest in cluster effects and inference to a population of clusters. Theoretically, multilevel models may be of random intercepts, random slopes or of both random intercepts and slopes. Since, our data was collected by clusters which were drawn randomly, a random intercept multilevel regression model is a best fit for the analysis.

So, for intention to treat analysis mixed effect regression model was used to compare the outcome variables between the groups, using a random effect for clusters. Age and sex of the children, dummy variables for assessors and cluster effect were controlled in the analysis. Moreover, a sensitivity analysis was done controlling child stimulation environment score (Family care indicator), wealth factors, LAZ score of the children and mental health (self-esteem) and education status of the mothers. We considered variables in the model having biological and scientific plausibility with main outcome. Effect size was measure based on Cohen's d calculation to represent the magnitude of differences between groups (LeCroy and Krysik, 2007).

This study was funded by Grand Challenges Canada, Saving Brains Programme (SB-1707-09401).

3. Results

Between September 29, 2017, and December 30, 2018, 594 mother child dyads were enrolled in the study at baseline. At the end of the one-year intervention, 554 mother child dyads were available for follow-up. The groups seemed generally well balanced along baseline background characteristics and outcomes, except that the comparison group had better LAZ and WAZ scores at baseline than the other groups (Table 1).

Of the 594 mother child dyads enrolled at baseline, 40 (6·8%) were lost to follow-up. Two children were dead due to drowning, 36 families moved outside the study catchment area to bigger cities for better livelihood, one family fled away at night due to huge financial debt in the community, and one divorced mother migrated with her child to outside of the study area (Fig. 1).

Table 2
Multiple regression analysis of the effects of intervention on outcome measures.

Outcomes after intervention	(PS + UCT) Vs UCT only[a]		(PS + UCT) Vs Comparison[a]		UCT only Vs Comparison[a]	
	B (95% CI), P-value	Effect Size[j]	B (95% CI), P-value	Effect Size[j]	B (95% CI), P-value	Effect size[j]
Cognition	2.96 (0.46, 5.47) 0.021	0.24 (0.04, 0.45)	3.73 (1.27, 6.19) 0.003	0.32 (0.12, 0.53)	0.77 (−1.70, 3.24) 0.542	0.10 (−0.10, 0.31)
Language	2.73 (0.39, 5.08) 0.022	0.21 (0.00, 0.41)	2.82 (0.53, 5.10) 0.016	0.24 (0.04, 0.42)	0.09 (−2.21, 2.39) 0.942	0.04 (−0.16, 0.24)
Motor	2.02 (−0.44, 4.48) 0.107	0.12 (−0.08, 0.33)	2.65 (0.24, 5.06) 0.031	0.22 (0.02, 0.42)	0.63 (−1.80, 3.05) 0.612	0.10 (−0.11, 0.30)
Response to examiner[b]	0.30 (0.06, 0.52) .012	0.27 (0.06, 0.47)	0.30 (0.08, 0.52) 0.007	0.26 (0.06, 0.46)	0.01 (−0.21, 0.23) 0.909	0.003 (−0.21, 0.20)
Emotional tone[b]	0.20 (−0.05, 0.45) 0.130	0.14 (−0.07, 0.34)	0.09 (−0.16, 0.35) 0.453	0.04 (−0.15, 0.25)	−0.10 (−0.36, 0.15) 0.426	0.09 (−0.12, 0.29)
Activity[b]	0.17 (−0.03, 0.38), 0.099	0.18 (−0.03, 0.38)	0.17 (−0.03,0.37), 0.093	0.11 (−0.10, 0.31)	−0.001 (−0.20,0.20), 0.991	0.07 (−0.13, 0.27)
Cooperativeness[b]	0.02 (−0.23, 0.28), 0.871	0.04 (−0.17, 0.24)	0.03 (−0.21, 0.28), 0.792	0.06 (−0.14, 0.26)	0.01 (−0.24, 0.26), 0.923	0.02 (−0.18, 0.22)
Vocalization[b]	0.16 (−1.52, 1.84), 0.854	0.02 (−0.18, 0.23)	−0.91 (−2.54, 0.73), 0.277	0.08 (−0.13, 0.28)	−1.07 (−2.71, 0.58), 0.205	0.09 (−0.11, 0.29)
Height for age Z score (HAZ)	0.12 (−0.10, 0.34), 0.273	0.06 (−0.15, 0.26)	−0.01 (−0.22, 0.20), 0.893	0.04 (−0.11, 0.29)	−0.14 (−0.35, 0.08), 0.210	0.10 (−0.10, 0.31)
Weight for age Z score (WAZ)	0.04 (−0.17, 0.25), 0.685	0.02 (−0.18, 0.23)	−0.06 (−0.26, 0.14) 0.563	0.09 (−0.11, 0.29)	−0.10 (−0.31, 0.10), 0.323	0.11 (−0.09, 0.31)
BMI[c] for age Z score (BAZ)	−0.04 (−0.27, 0.20), 0.760	0.00 (−0.20, 0.21)	−0.07 (−0.30, 0.16), 0.547	0.08 (−0.12, 0.28)	−0.03 (−0.27, 0.20), 0.773	0.07 (−0.13, 0.28)
Family care indicator[d]	2.28 (1.50, 3.06), <0.001	0.81 (0.60, 1.02)	3.02 (2.25, 3.78), <0.001	1.04 (0.82, 1.25)	0.73 (−0.03, 1.50), 0.061	0.26 (0.06, 0.47)
Maternal self esteem[e]	0.79 (−0.76, 2.33), 0.318	0.14 (−0.06, 0.35)	2.46 (0.94, 3.98), 0.002	0.48 (0.28, 0.69)	1.67 (0.015, 3.20), 0.032	0.32 (0.12, 0.53)
Maternal depression[f]	−0.70 (−2.28, 0.88), 0.385	0.16 (−0.04, 0.37)	−1.23 (−2.49, 0.52), 0.192	0.19 (−0.01, 0.39)	−0.34 (−1.90, 1.23), 0.672	0.04 (−0.16, 0.25)
Mother's BMI, *kg/m*[b]	0.71 (−0.15, 1.58), 0.106	0.18 (−0.03, 0.38)	0.08 (−0.77, 0.92), 0.860	0.02 (−0.18, 0.22)	−0.64 (−1.49, 0.21), 0.141	0.14 (−0.07, 0.34)
Violence against women[g,i,k]	OR (95% CI), P-value		OR (95% CI), P-value		OR (95% CI), P-value	
No	Ref.		Ref.		Ref.	
Yes	0.60 (0.13, 2.74), 0.510	−0.40 (−0.87, 1.74)	0.56 (0.13, 2.45), 0.445	−0.54 (−0.87, 1.45)	0.94 (0.23, 3.79), 0.933	−0.06 (−0.77, 2.79)
HFIAS[h,*,i,k]						
Secure	Ref.		Ref.		Ref.	
Mild insecure	1.50 (0.45, 4.96), 0.507	0.50 (−0.55, 3.96)	0.78 (0.25, 2.42), 0.670	−0.22 (−0.75, 1.42)	0.52 (0.16, 1.70), 0.279	−0.48 (−0.84, 0.70)
Moderate insecure	0.49 (0.09, 2.53), 0.394	−0.51 (−0.91, 1.53)	0.29 (0.06, 1.46), 0.133	0.50 (−0.55, 3.96)	0.59 (0.13, 2.77), 0.506	−0.41 (−0.87, 1.77)
Severe insecure	8.34 (1.61, 43.14), 0.011	7.34 (0.61, 42.14)	2.81 (0.68, 11.61), 0.153	0.50 (−0.55, 3.96)	0.34 (0.06, 1.96), 0.226	−0.66 (−0.94, 0.96)

[a] All models (except *&** are logistic regression) are random-effects multilevel regression model of intervention (Cash + PS, Cash only and Comparison) on the outcomes, adjusted by child's age, sex, union, tester and cluster (as random effect).
[b] Behaviors are all 9 point ratings.
[c] Body Mass Index.
[d] Family care indicators (FCI) includes the subgroup of varieties of play materials, source of play materials, play activities with child done by any adult in the families in the last one week and were scored as Yes = 1 and No = 0.
[e] Rosenberg self-esteem scale 0–30 points with higher scores indication higher self-esteem.
[f] A continuous scale in 20-point with higher scores indicating more depression (Self Reporting Questionnaires-20).
[g] Three types of binary variables of violence: physical, mental and sexual violence were accumulated to binary variable-violence against women (yes or no).
[h] According to Food and Agriculture Organization (FAO) of United Nations, household food insecurity access scale (HFIAS) is an ordinal variable ranging 1–4 indicating 1 = Food Secure, 2 = Mildly Food Insecure Access, 3 = Moderately Food Insecure Access, 4 = Severely Food Insecure Access.
[i] Random-effects multilevel logistic regression model with similar settings to other models; values are presented as n (%) and adjusted odds ratio with 95% CI and p-value.
[j] Effect size was calculated as Cohen's d (except [$]).
[k] Effect size was calculated as *(1-OR)*.

We measured interobserver agreement for all assessors with the trainer before assessment using intraclass correlation coefficient (ICC) and the ICC for Bayley (cognitive, language and motor) composite score was more than r = 0.90 for each tester and the ICC for behaviour ratings was more than r = 0.80, except for two assessors whose ICC for behaviour ratings of children's activity and response to examiner was r = 0.75 and received additional training. We also measured agreement between the assessor and trainer during the study in 70 (12%) tests, and inter-observer reliabilities for each assessor was more than r = 0·90 for all Bayley composite scores and ranged between r = 0·71 to1.0 for all behaviour ratings.

Intention to treat analysis showed that the children in the PS + UCT had significant improvement in their cognitive (Regression coefficient [B] = 2.96, 95% confidence interval [CI]: 0.46 to 5.47, p = 0.021, Effect size [ES] = 0.24, CI: 0.04 to 0.45), and language (B = 2.73, CI:0.39 to 5.08, p = 0.021, ES = 0.21, CI: 0.00 to0.41) composite scores compared to the children of only UCT group.

The intervention effect was even larger when we compared the outcomes between PS + UCT and comparison group. The children of PS + UCT also had significantly higher cognitive (B = 3.73 CI: 1.27 to 6.19, p = 0.003, ES = 0.32, CI: 0.12 to 0.53), language (B = 2.82, CI: 0.53 to 5.10, p = 0.016, ES = 0.24, CI: 0.04 to 0.42) and motor (B = 2.65, CI:

0.24 to 5.06, p = 0.031, ES = 0.22, CI: 0.02 to 0.42) composite scores than the comparison group.

The mean cognitive, language and motor composite score in the children of only UCT group were larger compared to the comparison group but the difference was not statistically significant (Table 2).

There was no apparent intervention effect on children's growth and mothers' BMI. The children of PS + UCT were more responsive to examiner compared to both the children of only UCT and the comparison groups (ES = 0.30, CI: 0.06 to 0.52 and ES = 0.30, CI: 0.08 to 0.52 than the only UCT and comparison group respectively.

The mother's self-esteem was higher in PS + UCT (B = 2.46, CI: 0.94 to 3.98, p = 0.002, ES = 0.48, CI: 0.28 to 0.69) and in only UCT (B = 1.67, CI: 0.015 to 3.20, p = 0.032, ES = 0.32, CI: 0.12 to 0.53) compared to the comparison group. Home stimulation was also significantly higher in PS + UCT and compared to only UCT (B = 2.28, CI: 1.50 to 3.06, ES = 1.04) and comparison (B = 3.02, CI: 2.25 to 3.78, ES = 0.26) groups (Table 2).

Further sensitivity analyses adjusting for LAZ-score, wealth factor, family care indicators, mothers' mental health (self-esteem) and education status showed similar findings (Table S2).

Estimated ICCs for cognitive, language and motor scores were 0.032, <0.001 and 0.022 respectively.

4. Discussions

We found that the integrated PS + UCT significantly improved the Bayley cognitive and language composite score compared to the children of only UCT group. We also found significantly higher score of the children of PS + UCT in the cognitive, language and motor composite score compared to the children of comparison group. Analysis of secondary outcomes found that children's response to examiner were significantly better in the PS + UCT than the only UCT group. We found significant improvement of mother's self-esteem of PS + UCT and Only UCT compared to the comparison group. Our above findings are important since we integrated PS into UCT and we reported for the first time that PS + UCT works for economically disadvantageous children's development.

The Bayley test is a robust assessment tool for children of this age, it has been validated and used in several studies in Bangladeshi population, showing sensitivity to interventions and nutritional status (Nahar et al., 2012; Tofail et al., 2013; Hamadani et al., 2019) as well as discrimination between poor and rich population (Hamadani 2014). The testers were also trained appropriately and had showed high agreement with the trainers before and during the study. The results can therefore be considered reliable.

One cRCT that integrated UNICEF's Care for Child Development curriculum with monthly home visit into UCT to measure effects on children's development in Niger, reported benefits to socioemotional outcomes but none on child development (Barry et al., 2017). The children were economically disadvantaged and the authors recommended access to proper water and hygiene practice along with more intensive psychosocial stimulation and UCT intervention for better child development outcome in this setting.

The effect size of our intervention is not directly comparable to other ECD interventions since the most other interventions used health and nutrition platform in low- and middle-income countries (LMIC). Due to cultural and similar economic background in South Asian countries our findings were somewhat comparable to that of other studies in this area. Our moderate effect size for cognitive and language development for the poor children is similar to the other studies conducted among malnourished children in Bangladesh. Most previous child stimulation studies were conducted integrating nutrition services using health facilities and found moderate effect size (Hamadani et al., 2006; Nahar et al., 2009; Tofail et al., 2013). But one recent study carried out in the malnourished children involving staff of Community Clinics found strong effect size in rural Bangladesh (Hamadani et al., 2019). The participants of this study were recruited from the adjacent areas of the community clinics. The authors recommended alternative way of catching remaining children through other platforms. The intervention workers for this study were staff of the community clinics who had previous connection and professional trust with the families of the children. But we served our intervention through home visit and the intervention workers were female community paid workers (Community Health Workers) who were not professional health providers. Most of the providers did not have previous contact with the mothers in our study. Besides, our study was conducted in the economically disadvantaged children. We found another important intervention; Pakistan Early Childhood Development (PEDS) programme, which reported similar effect size (Yousafzai et al., 2014). In PEDS study the providers were experienced to deliver health care services for a long time and they recruited healthy children. The effects of our study were also similar to a recent study conducted in urban slums of Odisha, India in the healthy children, which was designed to complement India's Integrated Child Development Services (ICDS) (Andrew et al., 2020).

We did not find any significant improvement of children's cognitive, language and motor development of the only UCT group compared with the comparison group although there were improvements in all the three domains (Table 2). One cRCT in rural Ecuador reported that only UCT significantly improved language development of the children compared to comparison group (Fernald and Hidrobo, 2011). However, in Ecuador; US$20/month, which was approximately 10% of the monthly family income of the participants was provided, whereas, in ours, it was US$6.25/month, which was around 5% of the monthly income. So, further research is important to see the optimum benefits of children's development at different ceiling of UCT. UCTs are usually less costly to implement than CCT programmes due to lesser monitoring involved for the usage of funds (Haushofer and Shapiro, 2016) and our study findings support that psychosocial stimulation integrated into UCT benefited children's cognitive and language development. In Bangladesh, Ministry of Women and Children Affairs (MoWCA) is responsible for child development activities and as per Comprehensive early Childhood Care and Development (ECCD) policy of Bangladesh, period of early child development has been defined from zero to eight years (Ministry of Women and Affairs (2013). Comprehensive early childhood care and development (ECCD) policy. Government of the People's Republic of Bangladesh. Primary and Mass Education Ministry of Bangladesh is working for children aged more than three years to support early learning/school readiness through institutional service delivery. But it is first thousand days when we need to focus our attention and effort with minimum resources to get the maximum outcome of neurocognitive development (Heckman and Masterov, 2007). On the other hand, there is access barriers for the poor on the use of government health system especially for such mothers in developing countries (Arsenault et al., 2018). In Bangladesh health system reforms are required to ensure suitable and equitable health services (Adams et al., 2013). Indeed, the platforms of health and education system alone are not sufficient to serve all the poor people in low- and middle-income countries for delivery of ECD intervention and ensuring maximum utilization for the first three years.

We designed this intervention for the children aged less than three years. Since government of Bangladesh has set priorities for ECD for national development and aims to achieve SDGs related to ECD where all children should get early childhood care, the intervention should be delivered to the homes of the children less than three years along with UCT or any other cash transfer or relevant safety net programme for the poor.

The World Bank also recommends combining cash transfer and parenting programmes together for child development in poor population (Arriagada et al., 2018). They however, emphasized for more evidence through research that is needed to understand the key elements of the optimal combinations, fidelity of implementation, cost-effectiveness

of different design features, replicability, and sustainability of results (Arriagada et al., 2018).

The main strengths of the study include the use of PS into UCT with a cluster randomization and a highly motivated experienced child development research group to conduct the study. There are a number of limitations. The Bayley Scales were adapted but not standardised for Bangladesh although we have previously used this tool in many studies and found it to be discriminative of different conditions and sensitive to pick intervention benefits. Inclusion of another arm with only stimulation (only PS) could bestow more robustness to this study. The cash was very small and might not have been enough to see any change. Moreover, the participants received the cash for six months together. It would be better if the cash is transferred to the mothers in each month. The limitations also include the spill-over effect on outcomes (Truelove et al., 2014). The study is a community-based cluster randomized controlled trial and there may be spill-over effects to some extent. The unit of randomization i.e. the old *Ward* is composed of a big village or two/three adjacent villages, however, two *Wards* are usually separated by a road or a paddy field or a canal which can limit the spill over effect. Though, if the families in the two Wards are related and visit each other frequently, there is a possibility of some spill over effect, that cannot be overlooked when generalizing the findings.

5. Conclusions

In conclusion, this study supports the fact that psychosocial stimulation can be successfully integrated into an unconditional cash transfer programme to improve poor children's development in rural Bangladesh. Further research is required to document maximum benefits from integrated psychosocial stimulation and different amount of unconditional cash transfer programme.

Author contribution

SJH and JDH conceived the study. SJH, JDH, SEA, FT and BRR designed the study. JDH, BRR and SJH led data collection. HMS, SJH and JDH did the statistical analyses. SJH wrote the first draft of the manuscript. All authors critically reviewed the manuscript and approved the final draft.

Declaration of competing interest

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.socscimed.2021.114657.

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