European Journal of Clinical Nutrition (2012) 66, 701–709

0954-3007/12
www.nature.com/ejcn

ORIGINAL ARTICLE

Effects of a community-based approach of food and psychosocial stimulation on growth and development of severely malnourished children in Bangladesh: a randomised trial

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Background/Objective: Psychosocial stimulation (PS) and food supplementation (FS) improve development of malnourished children. This study evaluates the effects of a community-based approach of PS and FS on growth and development of severely malnourished children.
Subjects/Methods: Severely underweight hospitalised children aged 6–24 months ($n = 507$) were randomly allocated on discharge to five groups: (i) PS, (ii) FS, (iii) PS + FS, (iv) clinic-control and (v) hospital-control. PS included play sessions and parental counselling on child development. This was done at each fortnightly follow-up visit, that is, every second week, for 6 months at community clinics. FS included distribution of cereal-based food packets (150–300 kcal/day) for 3 months. All groups received medical care, micronutrient supplementation, health-education and growth monitoring. Children's development was assessed using revised version of Bayley Scales of Infant Development at baseline and after 3 and 6 months of intervention. Anthropometry was measured using standard procedure.
Results: Comparing groups with any stimulation with those with no stimulation there was a significant effect of stimulation on children's mental development index (group*session interaction $P = 0.037$, effect size = 0.37 s.d.) and weight-for-age Z-score (group*session interaction $P = 0.02$, effect size = 0.26 s.d.). Poor levels of development and nutritional status were sustained, however, due to their initial very severe malnutrition. There was no effect on motor development and linear growth.
Conclusion: Children receiving any stimulation showed a significant benefit to mental development and growth in weight. More intensive intervention with longer duration is needed to correct their poor developmental levels and nutritional status.
European Journal of Clinical Nutrition (2012) **66,** 701–709; doi:10.1038/ejcn.2012.13; published online 22 February 2012

Keywords: malnutrition; community-based intervention; psychosocial stimulation; food supplementation; Bangladesh; children

Introduction

It is estimated that over 200 million children under 5 years in developing countries fail to reach their developmental potential (Grantham-McGregor, 2007). Malnutrition is a major contributor to children's delayed cognition, behavioural problems and later poor school achievement that persist till adulthood (Grantham-McGregor, 1995; Chang *et al*., 2002; Grantham-McGregor, 2007; Walker *et al*., 2007, 2011; Dewey and Begum, 2011; Gandhi *et al*., 2011).

In Bangladesh, 41% of children under 5 years are underweight (−3 s.d.) (UNICEF, 2010) and in need of rehabilitation. Dhaka Hospital of ICDDR,B treats more than 400 severely underweight children with Weight-for age Z-score (WAZ) <-4 s.d. and/or weight-for-length Z-score (WLZ)

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Received 13 September 2011; revised 30 December 2011; accepted 8 January 2012; published online 22 February 2012

<-3 s.d. in the Nutrition Rehabilitation Unit (NRU) yearly after recovery from acute illnesses. Children with >-4 WAZ<-3 and whose caregivers are unable to stay at NRU are advised to attend the hospital's nutrition follow-up unit (HNFU). However, follow-up attendance is poor and home or community-based management of these severely malnourished children is more feasible and less expensive in a low-income country like Bangladesh.

Reports on community-based management of undernourished children in low-income countries including Bangladesh have mostly focused on food and micronutrient supplementation, medical care and growth monitoring (WHO, WFP, UNSCN, UNICEF, 2007; IPHN, 2008). Evaluation of such management has reported positive impact on weight gain and reduction in the mortality of the children (Ashworth, 2006; Sadler *et al.*, 2007, 2011). Few attempts have been made to incorporate psychosocial stimulation (PS) in the routine management of undernourished children, and child development issues are rarely addressed.

Home visiting with food supplementation (FS) and PS for 2 years has resulted in sustained benefits to moderately malnourished children (Waber *et al.*, 1981; Grantham-McGregor *et al.*, 1991; Walker *et al.*, 2005, 2011), whereas PS lasting 1 year in rural Bangladesh also benefitted the development of moderately and severely underweight children (Hamadani *et al.*, 2006). Recently, a hospital-based non-randomised trial of PS with very severely malnourished children showed improvement in children's growth and development (Nahar *et al.*, 2009).

The present study evaluates the effectiveness of a community-based randomised trial of FS and PS on growth and development of severely malnourished children. After 3 months of intervention, the children who had received food and PS had significantly higher follow-up attendance than the controls, and those who received FS had higher weight gain compared with the other groups (Hossain *et al.*, 2011). In this paper, we present the findings at the end of study, that is, after 6 months of intervention.

Methods

Participants

Hospitalised children without acute infections at ICDDR,B, aged 6–24 months, of either sex, with a WAZ<-3 s.d., residing in one of the four selected slums of Dhaka city were eligible to participate. The following exclusion criteria were used: children with WLZ<-3 s.d., oedema, persistent anorexia, fever, congenital disorders, diseases affecting growth or requiring hospitalisation, no fixed residence or primary caregiver not capable of providing stimulation. We identified the areas from where most malnourished children attended Dhaka hospital of ICDDR,B and established community nutrition follow-up units (CNFU) in four primary health clinics near those areas.

Randomisation

Upon discharge and after obtaining parental informed consent, the eligible children were randomly assigned to five groups as follows: (i) PS, (ii) FS, (iii) PS along with FS (PS + FS), (iv) clinic-control (CC): fortnightly, that is, every second week follow-up care at CNFU and received growth monitoring, health education, micronutrient supplementation but no additional FS or PS and (v) hospital-control (CH): fortnightly follow-up care at HNFU of ICDDR,B and received the same management as CH group. Randomisation was done by a colleague not involved in the study. Four sets of separate randomisation were prepared for each CNFU, using computer-generated, block-randomisation scheme, with permuted block lengths of 5 and 10. The group assignment was kept in closed envelopes with sequential numbers in accordance to the order of enrollment and CNFU.

Interventions

Psychosocial stimulation. The PS comprised of play sessions and parental education for 1 h using a semi-structured curriculum (Hamadani *et al.*, 2006). This was conducted by trained female health workers (play leaders) with 8–10 years of schooling, at community-clinics for 6 months.

Play sessions were carried out with every child and mother using low cost, culturally appropriate homemade toys. Mothers were fully engaged in the activities. They were lent the toys and simple picture books to take home and exchanged the toys with new ones at every visit. The mothers were encouraged to play with their children at home between the visits. During the parenting sessions, the play leaders discussed matters of early child development, the importance of play, chatting and praising the child. They demonstrated how to incorporate play into daily activities. The sessions were conducted with one mother/child pair but occasionally if more than one pair attended at the same time two or three mother/child pairs were combined.

Food supplementation. Children assigned to FS and PS + FS groups received food packets when leaving the hospital and at each of the follow-up visits at CNFU for the first 3 months. One and two packets/day was offered to children aged 6–11 and 12–24 months, respectively. The mothers/caregivers were taught about preparation of the packets. Food packets were also provided to other under-five sibling(s) to minimise food sharing. Each of the packets (known as '*Pushti Packet*' in Bangladesh) contained: roasted rice powder 20 g, roasted lentil powder 10 g, molasses 5 g and soya oil 3 g, to provide 150 kcal (~630 kjoules) of energy with 11% of the energy derived from protein (Karim *et al.*, 2005).

Routine clinical management. All children received the following services at each visit according to standard practice at ICDDR,B (Ahmed *et al.*, 2001).

Growth monitoring and promotion. Children's weight, length/height, mid-upper arm and head circumferences were measured using standard procedures (WHO, 1995).

Health education. Structured lessons on primary health care were provided by the play leaders.

Micronutrient supplementation. During the first 3 months, multivitamin drops with a daily dose of 1 ml providing vitamin-A, vitamin-D, thiamin, riboflavin, pyridoxine, nicotinamide, calcium, ascorbic acid and zinc sulphate, and from weeks 2–12, iron and folic acid were provided as standard treatment of severe malnutrition (WHO, 1999).

Others. All study children were immunised according to the Expanded Programme of Immunization guidelines, and children $\geqslant$1 year were dewormed if they had not received the treatment in the previous 6 months.

Follow up
Mothers/caregivers were asked to bring their children to CNFU or HNFU, fortnightly for the first 3 months and then monthly for the next 3 months, that is, nine visits over 6 months. During the later part of the project, we were concerned that the number of visits may be inadequate to significantly impact children's development and thus increased the visits in all groups to fortnightly in the last 3 months, that is, 12 visits over 6 months ($n=179$, 35% of total sample).

Measurements
The following measurements were made at enrollment and after 3 and 6 months of interventions at HNFU:

Development. Children were assessed with the revised version of Bayley Scales of Infant Development (BSID-II) (Bayley, 1993) at HNFU by a trained tester, blind to the children's group. The test has not been validated in Bangladesh but has been used previously (Hamadani *et al*., 2001, 2006; Black *et al*., 2004; Tofail *et al*., 2008; Nahar *et al*., 2009) and demonstrated theoretically expected associations with nutritional and socio-economic status and home environment, and has acceptable test-retest reliability. The BSID-II includes mental development index (MDI) and psychomotor development index (PDI).

Anthropometry. The children's weight, length/height and head circumference were measured using standard procedure (WHO, 1995). Children's WAZ, WLZ and length-for-age *Z*-score (LAZ) were calculated based on WHO growth standards (WHO, 2006). Mother's weight and height were recorded to calculate their body mass index.

Maternal depression. Maternal depressive symptoms were assessed using a questionnaire based on the modified version of the Centre for Epidemiologic Studies-Depression Scale (CES-D) (Radloff, 1977) that was used in previous studies in Bangladesh (Black *et al*., 2007, 2009) and in Jamaica (Baker-Henningham *et al*., 2003, 2005). The scale was designed to assess the frequency of depressive symptoms expressed in number of days with these symptoms. Mothers were asked to recall how many days in the past week they experienced depressive symptoms and the number of days (0–7) was recorded. Responses were summed to make a total depression score. Greater scores indicated higher level of depression. Inter observer reliability between trainer and tester on 10 children was good ($r=0.98$).

Socio-economic status. On enrollment a research assistant collected information on the families' wealth, standard of housing, family structure and parental characteristics. Asset score was calculated based on household possessions (for example, chair, bed, radio, television, cassette player, rickshaw, bicycle and others) giving a score of '1' if they had any of the items and '0' if not. These were then summed to make a possible maximum score of 15. A crowding index was made by calculating the number of persons per room, and housing index was made by rating condition of the roof, floor and wall of the house, type of latrine and availability of water supply. The method was previously used in Bangladesh (Hamadani *et al*., 2006; Nahar *et al*., 2009).

Outcomes
The primary outcomes were MDI and PDI after 3 and 6 months of intervention. Secondary outcomes were children's growth in weight and length.

Sample size
A sample size of 60 in each group was estimated to demonstrate five points difference in MDI based on a previous study in Bangladesh (Hamadani *et al*., 2006), which had an s.d. of 12, a significance level of 5% and power of 90% considering five treatment groups.

Statistical analysis
Data were analysed using SPSS version 18 (SPSS Inc., Chicago, IL, USA). Differences among the groups in baseline characteristics (that is, maternal depression) and between those lost to follow-up and tested (that is, maternal depression, education and father's occupation) were examined using ANOVA for continuous variables and χ^2-test for dichotomous variables.

For intention to treat analyses of five randomised groups, we used a longitudinal approach including assessments at baseline, 3 and 6 months (GLM repeated measures), controlling for age at final test session that was related to outcome measures and maternal depression, education and father's occupation.

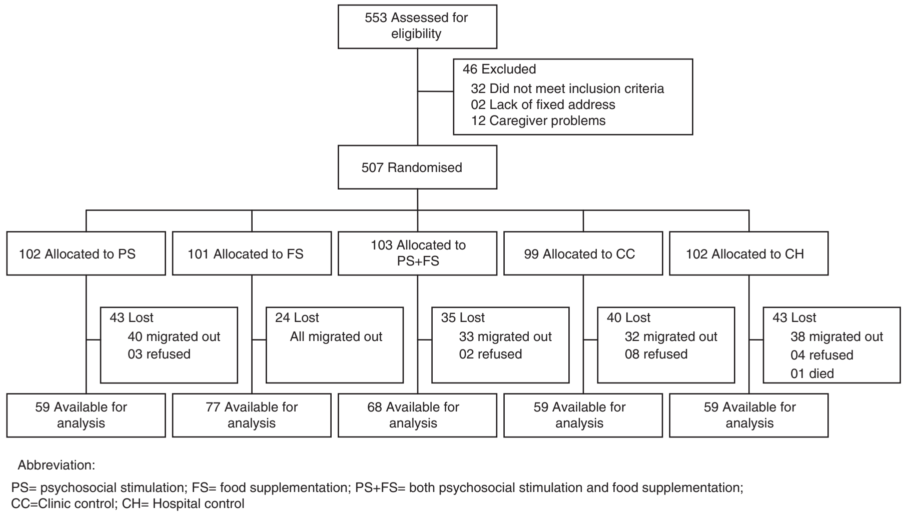

Figure 1 Study profile.

A *P*-value less than 0.05 was considered statistically significant.

Ethics

The proposal was approved by the Institutional Review Board of ICDDR,B. Written consent was also obtained from mothers at the time of enrolling of the children. Children who were not responding to the treatment and had any major illness during the study were treated or referred to health facilities.

Result

We screened a total of 553 children for eligibility and enrolled 507 children in the randomised trial. Figure 1 provides the flow chart of the sample enrolled. A total of 185 children (36%) were lost before the final assessment. The reason for loss to follow-up was mostly leaving the residential area (90% of total loss), refusal to make follow-up visits (9%) and death (single child).

There was significantly less attrition in children receiving FS compared with other groups ($P=0.029$). Children tested and lost did not differ in background characteristics except for mothers' depression, education and fathers' occupation.

Children of mothers with higher education were more frequently lost in PS + FS group ($P=0.003$) and children with lower educated mothers were more frequently lost in CH group (0.057). There were no significant differences of mothers' education between lost and tested children in other groups. The overall group difference was significant (ANOVA $P=0.011$).

In the PS group, there were significantly higher loss in children of fathers with unstable jobs ($P=0.053$) but overall group difference was not significant.

Children of less depressed mothers were more frequently lost in the PS group (0.004) but there were no overall significant group differences.

Baseline characteristics

Children and families' characteristics did not significantly differ among groups except for maternal depression score, where mothers of children of CH group were less depressed mothers than those in the other groups ($P=0.014$) (Table 1).

Adherence to interventions

The attendance at follow-up visits differed significantly among the groups. The mean (s.d.) of total attendance were as follows: PS + FS (9.5 (1.9)), PS (9.1 (2.1)), FS (7.5 (1.7)), CC (6.3 (2.5)) and CH (4.4 (2.1)) (ANOVA $P<0.001$). There was no significant difference in children's attendance among the two stimulation groups (median (inter quartile range): PS + FS group 9 (9–12) and PS group 9 (8–11), ($P=1.0$)) and they each attended significantly more frequently than FS and either control groups (all $P<0.001$). The CH attended significantly less frequently than the CC ($P<0.001$).

Out of intended 9 visits, the median number of total attendance was 8 (inter-quartile range 6–9) and out of intended 12 visits, the median number of total attendance was 8 (inter-quartile range 5–12).

The mean (s.d.) number of food packets received was significantly greater in the PS + FS group (123.0 (39.0)) than the FS group (115.0 (45.0)) ($P<0.001$).

Development and nutritional status

The children had very poor developmental scores and nutritional status at baseline. Using one-way analysis of co-variance (ANCOVA) there was no significant difference in the developmental and anthropometric indices after 6 months of intervention controlling for age at final assessment, baseline scores and maternal depression scores at

Table 1 Baseline family characteristics of all children showing mean (s.d.), 95% CI or % of variables ($N=322$)

	PS, N = 59		*FS, N = 77*		*PS + FS, N = 68*		*CC, N = 59*		*CH, N = 59*	
	Mean (s.d.)	*95% CI*	*Mean (s.d.)*	*95% CI*	*Mean (s.d.)*	*95% CI*	*Mean (s.d.)*	*95% CI*	*Mean (s.d.)*	*95% CI*
Socio economic										
Asset score[a]	6.1 (2.1)	5.5, 6.6	6.2 (2.3)	5.7, 6.7	6.6 (2.3)	6.1, 7.2	6.3 (2.4)	6.0, 7.0	6.6 (2.5)	6.1, 7.2
Crowding index (person/room)	4.1 (1.3)	3.7, 4.6	4.6 (2)	4.3, 5.0	4.7 (1.6)	4.3, 5.1	4.6 (1.7)	4.2, 5.0	4.4 (1.5)	4.0, 4.8
Housing score[b]	14.0 (2.1)	13.4, 15.0	14.2 (2)	13.7, 14.6	14.2 (2.1)	13.7, 14.7	14.1 (2.2)	13.6, 14.7	14.2 (2.3)	13.6, 14.7
Parental characteristics										
Mothers' age	23.7 (4.5)	22.3, 25.2	23.4 (5.8)	22.2, 24.7	24.6 (6.5)	22.3, 25.2	24.4 (6.1)	23.0, 25.8	23.6 (4.8)	22.1, 25.0
Mothers' BMI (enrollment)	19.5 (3.1)	18.7, 20.3	19.8 (3.3)	19.1, 20.5	19.2 (2.6)	18.4, 20.0	19.8 (3.2)	19.0, 20.5	19.6 (2.6)	18.8, 20.4
Mothers' schooling (years)	3.6 (3.6)	2.7, 4.5	3.4 (3.3)	2.6, 4.2	3.1 (3.2)	2.3, 4.0	3.9 (3.8)	3.0, 4.8	4.0 (3.5)	3.1, 4.9
Fathers' schooling (years)	3.9 (4.0)	2.8, 5.0	4.2 (4.0)	3.2, 5.1	4.7 (3.9)	3.7, 5.7	5.4 (4.8)	4.3, 6.4	5.0 (3.9)	3.9, 6.0
[c]Mother unemployed (%)	86.4		82.0		82.4		80.0		76.3	
[c]Father with unstable job (%)	42.4		54.0		55.2		39.0		51.0	
Total maternal depression[d] (symptoms in days)	60.2 (22.4)	54.4, 66.0	58.0 (23.1)	53.0, 63.1	54.9 (20.1)	50.0, 60.4	62.6 (24.6)	57.0, 68.6	49.1 (22.9)	43.3, 55.0
Total hospital stay (days)	3.5 (3.0)	2.9, 4.2	3.3 (2.2)	2.7, 3.9	3.6 (2.5)	3.0, 4.3	3.6 (3.0)	3.0, 4.2	3.0 (1.6)	2.3, 3.6

Abbreviations: BMI, body mass index (weight in kg/height in meter^2); CC, clinic-control; CH, hospital-control; FS, food supplementation; PS, psychosocial stimulation; PS + FS = combined food supplementation.
[a]Score was calculated on the presence of 15 common household possessions giving a score of '1' for having any of these items and '0' for not having and summed.
[b]Condition of roof, floor and wall of the house, type of latrine and availability of water supply was rated and summed.
[c]χ^2-test.
[d]In relation to the modified version of Centre for Epidemiologic Studies Depression Scale (CES-D). Mother experiencing depressive symptoms in the past week and the number of days (0–7) was recorded and summed. Higher the score, higher was the depression level.
ANOVA.
No significant differences by treatment groups for any other variables except maternal depression ($P=0.01$).

baseline that were significantly different between lost and tested and among the five groups (Table 2).

Treatment effect. Repeated measures analyses of the MDI, PDI and anthropometric measures (LAZ and WLZ) controlling for age at 6-month assessment, maternal depression score at baseline mothers' education and fathers' occupation showed no significant treatment effect (group*test session interactions all $P>0.05$).

There were significant group differences in the developmental and anthropometric indices when we compared PS + FS group with other groups. The PS + FS group had higher MDI compared with CH (mean difference (MD) = 4.5, 95% CI: 8.3, 0.6, $P=0.022$) and CC (MD = 3.4, 95% CI: 7.4, 0.6, $P=0.092$). They also had higher PDI than CH (MD = 4.8, 95% CI: 9.2, 0.4, $P=0.031$), CC (MD = 4.6, 95% CI: 9.1, 0.06, $P=0.047$) and FS (MD = 6.3, 95% CI: 10.3, 2.2, $P=0.003$).

The PS + FS group had a 0.3 unit higher WAZ (95% CI: 0.1, 0.5, $P=0.011$) and LAZ (95% CI: 0.7, 0.004, $P=0.048$) compared with CH. However, all the groups deteriorated throughout the study period and there was a significant within group test session effect ($P=0.022$). Figure 2 shows MDI, PDI, WAZ and LAZ by treatment groups at three measurements. Results are not shown in table.

Using the same GLM analysis controlling for frequency of visits offered to the children, there were no changes in the means of outcome variables after 6 months of intervention, and the children who received additional visits did not benefit more than children who received less.

Effect of PS with or without food
Inspection of the graph of adjusted MDI scores (Figure 2) shows that the two groups that received stimulation (PS and PS + FS) declined less than the other groups. We therefore combined them into 'any stimulation group' and the remaining three groups (FS, CC and CH) into a 'no stimulation group'. We then reran the GLM repeated measures of MDI with two groups and the interaction between group and test session was significant ($P=0.037$) with the 'any stimulation group' gaining more than the no-stimulation group (regression coefficient = 5.4, $P=0.017$, 95% CI: 9.9, 1.0, effect size = 0.37).

Stimulation also had a significant benefit on WAZ (regression coefficient = 0.3, $P=0.078$, 95% CI: 0.6, 0.03, effect size = 0.26 s.d.) and the group difference and group*session interaction was significant ($P=0.002$ and 0.02, respectively).

Unfavourable events
No adverse events were reported. A total of 21 children were readmitted to the hospital because of diarrhoea, pneumonia or urinary tract infection, and there were no significant differences in hospitalisation by groups. One child in CH group died of measles at home.

Table 2 Characteristics of all children who completed 6 months intervention showing mean (s.d.), 95% CI and % of variables ($N=322$)

	PS, N=59		FS, N=77		PS+FS, N=68		CC, N=59		CH, N=59	
	Mean (s.d.)	95% CI	Mean (s.d.)	95% CI	Mean (s.d.)	95% CI	Mean (s.d.)	95% CI	Mean (s.d.)	95% CI
Age in months	12.3 (3.8)	11.2, 13.3	12.9 (4.5)	12.0, 13.8	12.8 (4.1)	11.2, 13.3	13.1 (3.9)	12.1, 14.2	12.4 (3.9)	11.3, 11.4
Sex (male) (%)[a]	59.3		55.8		52.2		51.7		64.4	
*At Baseline**,[b]										
MDI	69.5 (14.9)	66.0, 73.0	69.3 (13.7)	66.3, 72.3	71.3 (11.7)	68.1, 75.0	69.7 (13.5)	66.2, 73.2	68.3 (13.7)	64.9, 71.8
PDI	66.4 (14.7)	62.3, 70.4	66.2 (15.2)	62.7, 69.8	71.5 (16.4)	67.7, 75.3	67.4 (16.2)	63.3, 71.5	68.4 (16.4)	64.3, 72.4
LAZ[c]	−3.4 (0.9)	−3.6, −3.1	−3.6 (1.0)	−3.9, −3.4	−3.5 (1.1)	−3.7, −3.2	−3.6 (1.1)	−3.8, −3.3	−3.6 (1.0)	−3.8, −3.3
WAZ[c]	−3.8 (0.7)	−4.0, −3.6	−3.9 (0.6)	−4.1, −3.8	−3.8 (0.7)	−4.0, −3.9	−3.8 (0.6)	−4.0, −3.7	−3.9 (0.6)	−4.05, −3.7
WLZ[c]	−2.7 (0.8)	−2.9, −2.5	−2.7 (0.7)	−2.9, −2.5	−2.7 (0.9)	−2.9, −2.5	−2.6 (0.7)	−2.8, −2.4	−2.7 (0.8)	−2.9, −2.5
*After 6 months of intervention***,[d]										
MDI	71.3 (15.1)	67.3, 74.6	67.9 (14.4)	65.0,71.4	72.3 (15.3)	68.9, 75.7	66.6 (14.4)	63.5, 70.9	66.7 (13.6)	62.4, 69.7
PDI	66.4 (14.7)	62.4, 70.5	66.2 (15.2)	62.8, 70.0	71.5 (16.5)	67.6, 75.2	67.4 (16.2)	63.6,71.8	69.4 (16.4)	63.9, 72.1
LAZ[c]	−3.7 (0.9)	−4.0, −3.5	−3.9 (1.1)	−4.1, −3.7	−3.7 (1.0)	−4.0,−3.5	−3.9 (1.0)	−4.1, −3.6	−4.1 (1.0)	−4.4, −3.9
WAZ[c]	−3.0 (1.2)	−3.3, −2.8	−3.4 (0.8)	−3.6, −3.1	−3.0 (1.2)	−3.3,−2.8	−3.3 (0.8)	−3.5, −3.0	−3.2 (1.1)	−3.5,−3.0
WLZ[c]	−1.7 (1.0)	−1.9, −1.4	−1.8 (0.8)	−2.0, −1.6	−1.7 (0.8)	−1.9, −1.5	−1.8 (1.0)	−2.0, −1.5	−1.6 (1.0)	−1.8, −1.4

Abbreviations: CC, clinic-control; CH, hospital-control; FS, food supplementation; LAZ, Length-for age *Z*-score; MDI, mental development index; PDI, psychomotor development index; PS, psychosocial stimulation; PS + FS, combined food supplementation; WAZ, Weight-for age *Z*-score; WLZ, Weight-for length *Z*-score.
[a] χ^2-test.
[b] ANOVA.
[c] In relation to the WHO 2006 standard.
[d] ANCOVA controlling for baseline score, age at final test session, maternal depression score at baseline.
**P*-value for MDI = 0.7, PDI = 0.09, LAZ = 0.7, WAZ = 0.7, WLZ = 1.0
***P*-value for MDI = 0.1, PDI = 0.5, LAZ = 0.09, WAZ = 0.4, WLZ = 0.2

Discussion

None of the individual treatment groups; food alone, stimulation alone or both showed a significant benefit in development or growth; however, with 37% loss of the children, the power to find an effect was reduced. We therefore combined the stimulation groups and compared them with all other children, and there was a significant treatment effect of stimulation on MDI and WAZ. The effect size was moderate in MDI (0.37 s.d.) and small in WAZ (0.26 s.d.), however, the children still had poor levels of development due to the initial very low levels.

The present study reported both the planned intention-to-treat analysis as well as *post hoc* analysis with regrouping. There are few studies in low-income countries to which we could compare our results. In a previous study with undernourished community children in Bangladesh, the effect size of MDI was one-third of a standard score (Hamadani *et al.*, 2006). The other Bangladeshi study with severely malnourished children in hospital had slightly greater effect sizes (0.52 s.d. in mental development and 0.37 s.d. in motor development), but the children and their mothers had daily intervention while in hospital (Nahar *et al.*, 2009). Larger effects (effect size 0.8 s.d.) were found on mental development in several Jamaican studies with undernourished children (Powell *et al.*, 2004), low birth weight infant (effect size 0.38 s.d. in performance IQ and 0.53 s.d. in visual spatial memory) (Walker *et al.*, 2004, 2010) and with moderately stunted children (effect size 0.4 to 0.6 s.d.) (Walker *et al.*, 2006, 2007). But all of these studies involved home visiting for as long as 1–2 years and the children were less malnourished compared to our study.

The duration of the present intervention was very short, only 6 months, compared with other intervention studies, which lasted 1 year (Hamadani *et al.*, 2006) or more (Waber *et al.*, 1981; Grantham-McGregor *et al.*, 1991), and the intervention sessions were less frequent than other studies with malnourished children. In addition, food supplements were provided only to the study children and their siblings under 5 years for 3 months, whereas in Jamaica (Grantham-McGregor *et al.*, 1991) and Colombia ((Waber *et al.*, 1981) food supplement for the child was provided weekly for at least 2 years and some food was given to other family members (Waber *et al.*, 1981).

The poor developmental scores and nutritional status of the participating children is alarming, and is probably due to long-term and severe malnutrition as well as extremely disadvantaged backgrounds. We are unaware of any study that included children with such severe degree of stunting and developmental delay except our previous hospital-based study where children were even more stunted and developmentally delayed (Nahar *et al.*, 2009). There is considerable evidence that stunting in early childhood can have long-term negative effects on cognitive development, school achievement, behaviour, economic productivity in adulthood and maternal reproductive outcomes

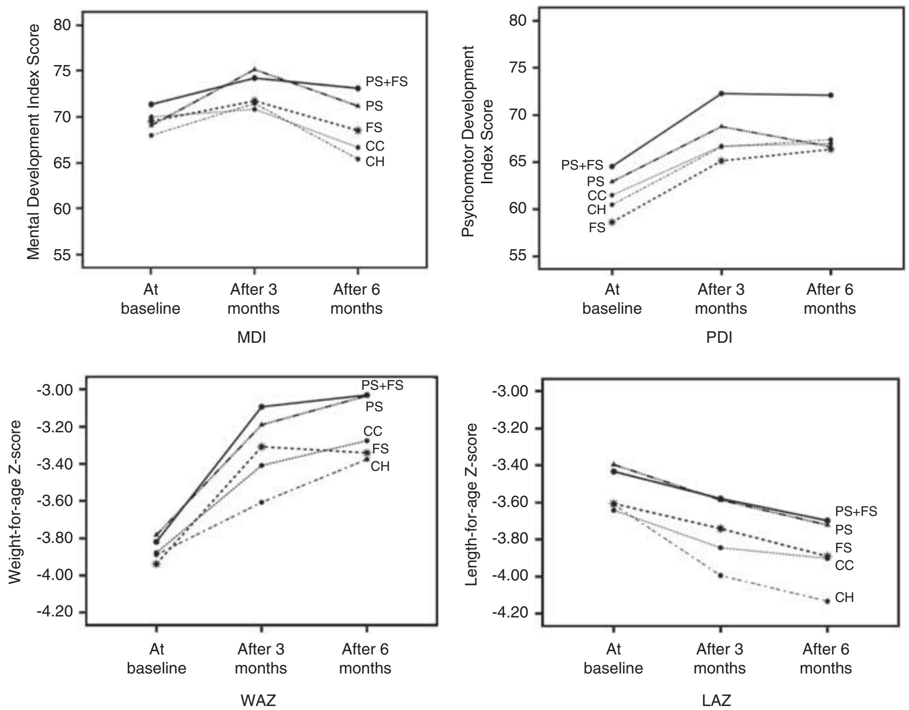

Figure 2 ANCOVA using GLM repeated measures analysis showing mean developmental and anthropometric indices by groups at baseline and after 3 and 6 months of intervention controlling for age at final test, maternal depression score at baseline, mothers' education and fathers' occupation.

(Grantham-McGregor, 2007; Walker *et al.*, 2007; Dewey and Begum, 2011; Gandhi *et al.*, 2011). Follow-up studies in Jamaica have shown that stunted children significantly had more anxiety and depressive symptoms and lower self-esteem in late adolescence (effect size 0.4–0.5 s.d.) than non-stunted participants and effects are reduced by psychosocial intervention (Walker *et al.*, 2007, 2011).

In the present study, the interventions benefit growth in weight but not the length, which is similar to the result of our previous hospital-based study (Nahar *et al.*, 2009). However, all groups remained severely underweight and stunted after 6 months of intervention. For supplementing children with food, we adhered to the National Food Supplementation Programme. The National Nutrition Programme of Bangladesh had been delivering a supplementary feeding program through community-based initiatives, which provided two packets/day of a dry food ration for 3 months to 6–24 months old severely malnourished children. However, the supplementary food provided was probably insufficient for these very severely stunted children and it may also have replaced other food at home that was not measured in the study. In Guatemala, FS alone benefitted growth and development (Freeman *et al.*, 1977). In Bogota, FS produced a beneficial effect on growth of children that was sustained even 3 years after the termination of intervention and at this point children who received both FS and home visits had better length and weight compared with the controls (Super *et al.*, 1990).

The protocol was changed in later part of the study by increasing the frequency of visits. The number of visits was, however, not associated with the overall result. The attendance at scheduled follow-up visits were highest in the group receiving combined intervention group and lowest in the CH group, hence indicate a positive impact of intervention and follow-up care at community-clinics. On average the children in the stimulation groups (PS + FS and PS) received 9.3 play sessions, which was less intensive compared with other intervention studies (Waber *et al.*, 1981; Grantham-McGregor *et al.*, 1991; Hamadani *et al.*, 2006; Nahar *et al.*, 2009). The play leaders met with the supervisor weekly to review the visits and the children's progress. The supervisor accompanied the play leaders on monthly visits to ensure that the activities were at an appropriate level. We did not assess the quality of stimulation visits. However, close monitoring of the intervention activities might have influenced the result of this short-term, less intensive trial.

There are strong justifications for establishing community-based management of malnourished children. In the present study, we found one community-based approach of delivering food and PS through existing primary health care services in the local communities. The intervention was provided among the slum dwellers, living in an environmentally hazardous area coupled with inadequate facilities. But in other settings like rural community, it could be more feasible and relevant where the structure of home environment is different and more support could be given to the child. In the present study, the stimulation program was run by low-paid health workers, but it should also be possible to train staff members who already run the primary health clinics. More community-based approaches in different settings are required to identify a feasible intervention programme on a larger scale in Bangladesh.

Limitation and weakness
There are few weaknesses in this study. First, there was considerable attrition rate of the children. Although we tried to reduce the loss by collecting cell phone numbers, village home address, fathers' working address and motivating parents and other family members to continue the intervention, more than one third of the children were lost to follow-up. Many faced very difficult financial situations for which they left the area without leaving the new address with us. Receiving food packets may have been attractive for these poor families, hence less losses in FS groups. More frequently children with higher educated mothers were lost in PS + FS group and with lower educated mother lost in CH group. Both losses may have contributed to decrease the size of the effect of intervention. Children of fathers with unstable jobs were higher in PS group but there was no association between fathers' occupation and children's outcome. We therefore, employed a conservative analysis controlling for the group differences. Second, the protocol was changed by increasing the frequency of visits for 35% sample, although it was not associated with the overall outcomes. Third, differing the length of intervention, that is, FS for 3 months and stimulation for 6 months is a fault of the design, and in a true sense the 6-month evaluation was concurrent for the stimulation group and follow-up for the supplementation group.

Conclusion

PS with or without supplementation significantly benefitted the mental development (effect size 0.37. s.d.) and weight (effect size 0.26 s.d.) of severely malnourished children. Moreover, community-based follow-up services increased the adherence to the follow-up. This was a less intense and shorter intervention than most other studies, so the small improvement in MDI is encouraging and of public health importance. But lack of improvement in the overall nutritional status in spite of FS is disappointing and the little effect on WAZ has no clinical importance. However, more intensive PS and more FS for a longer period are needed to correct these children's poor levels of nutritional status and development. More studies are needed with different community-based approaches to scale-up the community-based rehabilitation of greater numbers of malnourished children.

The illumina raw data generated using the B-CLL samples are available on request from the corresponding author.

Conflict of interest

The authors declare no conflict of interest.

Acknowledgements

The study was funded by Sida/SAREC, Sweden and supported by ICDDR,B and its donors, which provide unrestricted support to the Centre for its operations and research. Current donors providing unrestricted support include: the Australian Agency for International Development (AusAID), Government of the People's Republic of Bangladesh, Canadian International Development Agency (CIDA), Embassy of the Kingdom of the Netherlands (EKN), Swedish International Development Cooperation Agency (Sida), Swiss Agency for Development and Cooperation (SDC) and Department for International Development (DFID), UK. We sincerely appreciate these donors for their support and commitment to the Centre's research efforts. The study was also supported by the International Maternal and Child Health (IMCH), Department of Women's and Children's Health, Uppsala University, Sweden. We sincerely appreciate the secretarial assistance of IMCH staffs. We gratefully acknowledge the study participants, their parents and family members and all the staff of research team.

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Supplementary Information accompanies the paper on European Journal of Clinical Nutrition website (http://www.nature.com/ejcn)