

Parenting Skills and Emotional Availability: An RCT

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abstract

OBJECTIVE: To investigate whether a responsive stimulation intervention delivered to caregivers of young children either alone or integrated with nutrition interventions would benefit parenting skills and emotional availability to promote children's development and growth compared with either a nutrition intervention alone or the usual standard of care.

METHODS: A cluster randomized factorial effectiveness trial was implemented in an impoverished community in Pakistan. The 4 trial arms were control (usual standard of care), responsive stimulation (responsive care and stimulation), enhanced nutrition (education and multiple micronutrients), and a combination of both enriched interventions. The 4 intervention packages were delivered by community health workers to 1489 mother–infant dyads in the first 2 years of life. Parenting skills and emotional availability indexed by mother–child interaction, caregiving environment, knowledge and practices pertaining to early childhood care and feeding, and maternal depressive symptoms were assessed at multiple intervals. An intention-to-treat factorial analysis was conducted.

RESULTS: Intervention groups were comparable at baseline. Responsive stimulation significantly benefitted parenting skills with large effect sizes on mother–child interaction (Cohen's *d* 0.8), caregiving environment (Cohen's *d* 0.9–1.0), and knowledge and practices (Cohen's *d* 0.7–1.1) compared with small-modest significant effects as a result of nutrition intervention on mother–child interaction and caregiving environment only (Cohen's *d* 0.4 and 0.2, respectively). The combined intervention had a small significant effect on decreasing maternal depressive symptoms over time (Cohen's *d* 0–0.2).

CONCLUSIONS: A responsive stimulation intervention can promote positive caregiving behaviors among impoverished families. Additional research is needed on interventions to reduce maternal depressive symptoms.



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Dr Yousafzai conceptualized the study; developed the protocol, study design, and data collection instruments; coordinated the implementation of the study and oversaw training of the research team; planned analysis; interpreted findings; and drafted the manuscript; Ms Rasheed trained the Community-based Child Development Assessors, oversaw quality assurance of the psychosocial evaluations, contributed to the review of literature, contributed to the interpretation of findings, and critically reviewed drafts of the manuscripts; Ms Rizvi was the statistician for the study and participated in the study design, data analysis, and data interpretation and critically reviewed drafts of the manuscript; Dr Armstrong provided input to the study design and critically reviewed drafts of the manuscripts; and Dr Bhutta conceptualized the study with Dr Yousafzai, provided input to the study design, and critically reviewed drafts of the manuscript.

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WHAT'S KNOWN ON THIS SUBJECT: Early parenting programs benefit children's development in low- and middle-income countries. However, the extent to which these interventions have a positive impact on parenting skills and their emotional availability is less studied.

WHAT THIS STUDY ADDS: An early child development intervention using play and communication activities to promote caregivers' responsiveness can improve mother–child interactions, caregiving environment, caregiving practices pertaining to development and feeding, and, in combination with a nutrition intervention, support maternal emotional well-being.

Parenting programs provide families with information and support to enable their child's survival, development, and well-being.¹ Domains of parenting to support children's health, hygiene and nutrition, stimulation, responsiveness, protection, and socialization may be addressed.² In addition to health and nutrition information, early child development (ECD) programs emphasize promoting stimulation. Low stimulation is a risk for poor child development, particularly for children in low- and middle-income countries.^{3,4} Inadequate resources limit availability of learning materials provided to children,⁵ but interventions using homemade toys or libraries help overcome these barriers.⁶

Responsive parenting (the ability to be aware of a child's signals and provide a timely and developmentally appropriate response)⁷ is a fundamental parenting skill to support children's survival and development. Promoting responsive caregiving behaviors through training^{8,9} or using contexts such as shared book reading¹⁰ or play⁶ have demonstrated improvements in children's development,⁶ maternal mood,⁹ secure infant attachment,⁹ and quality of mother-child interactions.⁸⁻¹⁰ Responsive feeding has shown improvements in maternal verbal responsiveness,^{11,12} child's acceptance of foods,¹² mouthfuls eaten,¹¹ and dietary intake.¹³

A parent's emotional availability influences parenting capacity. Maternal depression is associated with early cessation of breastfeeding,¹⁴ poor ECD,¹⁵ growth,¹⁶ and health outcomes.¹⁷ Interventions addressing maternal depression may improve emotional availability, and participation in parenting programs in low- and middle-income countries shows mixed effects on maternal depression.^{9,18,19}

Although there are many approaches to parenting programs, it is recognized that information sharing alone may be insufficient to promote changes in parenting behaviors. The identification of which behavioral change techniques and social support strategies support early childhood care and development needs to be explored further.²⁰

There is evidence to show ECD programs in low- and middle-income countries promote children's development,²¹ but theories of change in parenting programs and effects on intended parenting outcomes are reported less frequently. We implemented an ECD and nutrition trial in Pakistan. The intervention effects on child outcomes, published in the *Lancet*, reported that the ECD intervention improved children's cognition, language, and motor development.²² In this component of the study, we sought to address whether these same interventions also changed intended parenting outcomes. We

hypothesized that the ECD intervention delivered to caregivers of children in the first 2 years of life either alone or integrated with nutrition interventions would benefit parenting skills and emotional availability.

METHODS

Study Design

This trial was conducted with the Lady Health Worker (LHW) Program, a national community-based health service addressing family planning, health, and nutrition, particularly for women and children, living in disadvantaged communities through monthly home visits and community meetings.²³ A cluster randomized effectiveness trial with a 2 × 2 factorial design tested the effectiveness and feasibility of integrating new interventions with routine services to improve ECD and growth outcomes. The 4 trial arms were as follows: (1) control ($n = 368$),

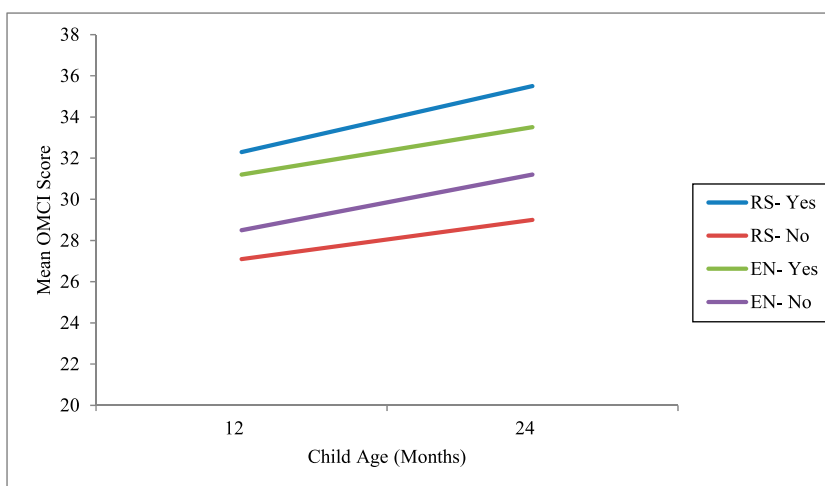


FIGURE 1

Mean scores for mother and child interaction at 12 and 24 months of child age. Twelve months: RS, $n = 698$; no RS, $n = 665$; EN, $n = 661$; no EN, $n = 702$. Twenty-four months: RS, $n = 708$; no RS, $n = 682$; EN, $n = 679$; no EN, $n = 711$. The linear mixed-model analysis is adjusted for clustering and controlled for covariates of SES, household food security, maternal education, number of siblings, and child gender. Significant differences at each time point between responsive stimulation and no responsive stimulation ($P < .001$) and between enhanced nutrition and no enhanced nutrition ($P < .001$) were observed. There were significant interactions between the 2 interventions at each time point ($P < .001$). Repeated-measures analysis, controlled for covariates of SES, household food security, maternal education, number of siblings, and child gender showed over time from 12 to 24 months: RS, β 8.0 (SE 0.6), 95% confidence interval (CI) 6.9–9.2; EN β 5.3 (SE 0.7), 95% CI 4.0–6.7; interaction β 5.8 (SE 0.9), 95% CI 4.0–7.5.

(2) responsive stimulation (RS, $n = 383$), (3) enhanced nutrition (EN, $n = 364$), and (4) combined (RS & EN, $n = 374$). All 4 trial arms continued to receive the standard health care services provided by LHWs. The LHW was responsible for delivering the intervention package (standard care with or without 1 of the enriched intervention packages) to every child in her catchment aged <2 years from June 2009 through March 2012.

Identified by an independent surveillance team, every infant born in the study area in the first year of the trial roll out was eligible for enrolment for the in-depth outcome evaluations when infants were 6, 12, 18, and 24 months old. A total of 1489 mother–infant dyads were enrolled at birth (up to the first 2.5

months of life) and followed for assessment to 2 years of age (with 7% attrition). The primary outcomes were child development and child growth.²²

The trial was implemented in a predominantly rural and impoverished community. Among enrolled children, 40% came from the poorest households, 32% lived in households with food insecurity, 68% had mothers who were illiterate, and 27% were stunted by 1 year of age. Ethical approval was granted by the Ethics Review Committee of the Aga Khan University. Details on the study design, subjects, trial profile, intervention monitoring and compliance, data collection procedures, and findings on intervention effects on child

outcomes and cost-effectiveness are reported elsewhere.^{22,24}

Interventions

The RS intervention was an adaptation of the Care for Child Development (CCD) approach developed by the United Nations Children's Fund (UNICEF) and the World Health Organization,²⁵ which uses play and communication activities to promote responsive care. The approach has 2 goals: (1) to help caregivers provide stimulation opportunities to promote children's cognitive, language, motor, and social-emotional skills and (2) using techniques based on Homan's interaction theory,²⁶ to enhance responsive care by helping caregivers observe and respond to their child's

TABLE 1 Mean (SD), 95% Confidence Interval of HOME Inventory Scores for Quality of the Caregiving Environment at 6 and 18 Months of Age

HOME Subdomain and Total Scores	RS Intervention			EN Intervention			P Interaction
	Yes	No	P	Yes	No	P	
Age 6 mo							
Responsiveness	7.2 (1.8) 7.0–7.3	6.8 (1.6) 6.7–6.9	.15	7.1 (1.7) 6.9–7.2	6.9 (1.7) 6.8–7.1	.88	.23
Acceptance	6.9 (1.0) 6.8–6.9	6.8 (0.9) 6.8–6.9	.64	6.8 (1.1) 6.7–6.9	6.9 (0.8) 6.9–7.0	.004	.32
Organization	3.5 (1.2) 3.3–3.6	3.3 (1.2) 3.1–3.4	.93	3.6 (1.2) 3.4–3.7	3.2 (1.2) 3.0–3.3	.18	.01
Learning materials	2.7 (1.6) 2.5–2.9	2.3 (1.4) 2.2–2.5	<.0001	2.5 (1.4) 2.4–2.6	2.6 (1.6) 2.3–2.8	.18	<.0001
Involvement	5.9 (1.1) 5.8–6.0	5.5 (1.1) 5.4–5.6	.05	5.7 (1.2) 5.5–5.8	5.8 (1.1) 5.6–5.9	<.0001	.004
Variety	2.9 (0.9) 2.8–3.0	2.8 (0.8) 2.7–2.9	.02	2.6 (0.8) 2.6–2.7	3.1 (0.8) 3.0–3.2	<.0001	.05
Total	29.0 (4.4) 28.5–29.5	27.6 (3.7) 27.2–28.0	.002	28.2 (4.1) 27.8–28.6	28.4 (4.2) 27.9–29.0	.03	.58
Age 18 mo							
Responsiveness	8.4 (1.8) 8.3–8.6	7.5 (1.6) 7.3–7.6	<.001	8.1 (1.7) 7.9–8.3	7.9 (1.8) 7.6–8.1	.08	.42
Acceptance	6.5 (0.8) 6.4–6.6	6.3 (0.8) 6.2–6.4	.01	6.5 (0.8) 6.5–6.6	6.3 (0.8) 6.2–6.4	.002	.96
Organization	3.7 (1.2) 3.5–0.8	3.6 (1.1) 3.4–3.7	.12	3.7 (1.1) 3.6–3.9	3.5 (1.1) 3.4–3.7	.03	.32
Learning materials	5.0 (1.8) 4.7–5.2	3.3 (1.8) 3.1–3.5	<.0001	4.3 (2.0) 4.0–4.6	4.0 (2.0) 3.6–4.4	.16	.49
Involvement	6.0 (1.4) 5.9–6.2	5.0 (1.6) 4.8–5.1	<.0001	5.6 (1.6) 5.4–5.8	5.4 (1.6) 5.2–5.6	.25	.99
Variety	3.2 (0.6) 3.2–3.3	3.0 (0.7) 2.9–3.0	<.0001	3.1 (0.7) 3.0–3.2	3.1 (0.7) 3.0–3.2	.78	.86
Total	32.8 (5.1) 32.1–33.5	28.0 (5.0) 28.0–29.2	<.0001	31.4 (5.5) 30.5–32.2	30.2 (5.4) 29.2–31.1	.02	.46

Six months: RS, $n = 699$; no RS, $n = 666$; EN, $n = 658$; no EN, $n = 707$. Eighteen months: RS, $n = 702$; no RS, $n = 661$; EN, $n = 668$; no EN, $n = 695$. The linear mixed-model analysis is adjusted for clustering and controlled for covariates of SES, household food security, maternal education, and number of siblings. Child gender was not a significant covariate for the HOME Inventory scores. Repeated-measures analysis, controlled for covariates of SES, household food security, maternal education, and number of siblings showed over time from 6 to 18 months: RS, β 1.42 (SE 0.36), 95% confidence interval (CI) 0.71 to 2.13; EN β -0.53 (SE 0.29), 95% CI -1.1 to 0.04; interaction β -0.09 (SE 0.47), 95% CI -1.01 to 0.83.

signals through play and communication interactions, leading to changes in sentiments that promote caregiver-child interactions. The LHW suggested developmentally appropriate activities for caregivers to try with their child and then proceeded to coach caregivers by helping them to observe their child's signals and respond appropriately to experience a successful interaction (see the Supplemental Information for details on adaptation).

The EN intervention enriched the existing nutrition education curriculum in the LHW program. This was achieved by the addition of responsive feeding messages (including recognizing and responding to early cues of hunger, communication, encouragement, and patience during feeding and independent feeding), distribution of a multiple micronutrient powder (MNP) for children aged 6–24 months to address the prevalent micronutrient deficiencies in the population,²⁷ helping LHWs to link

nutrition and health messages, and training LHWs to move away from a didactic approach of delivering nutrition education to one whereby she seeks to understand the situation of the child and family, and responds appropriately. The MNP distribution included instruction on how to mix the powder in the prepared semi-solid food for the case child.

The CCD approach was delivered through monthly group meetings and home visits. The EN intervention supplemented the nutrition education service delivered by LHWs in routine monthly home visits. The combined trial arm received a combination of both interventions (see theory of change in Supplemental Fig 6).

Measures and Procedures

Data were collected by trained data collectors, independent of the intervention implementation team, and masked to intervention assignment. All data collectors had completed secondary education, and the specialist team collecting child

development-related data (Community-based Child Development Assessors [CCDAs]) had work experience in either teaching or community development or held a bachelor's degree in psychology. After baseline training, refresher training was provided every 6 months, and each assessor received a monthly supervisory visit with feedback.

Household demographic and socioeconomic status (SES) information was collected from each enrolled household.²² For this component of the study, secondary outcomes related to parenting skills and emotional availability were mother-child interaction (an indicator of maternal responsive caregiving behaviors), the quality of the caregiving environment, maternal caregiving knowledge and practices pertaining to development and feeding, and maternal depressive symptoms. Uniform questionnaires were administered in each arm of the trial in Sindhi. Language translation

TABLE 2 Mean (SD), 95% Confidence Interval of Maternal Knowledge and Practices on Care for Child Development at 12 and 24 Months of Age

Maternal Knowledge and Practice	RS Intervention			EN Intervention			P Interaction
	Yes	No	P	Yes	No	P	
Baseline							
Knowledge	9.1 (2.8) 8.9–9.3	8.9 (3.2) 8.7–9.2	.46	8.9 (2.9) 8.7–9.1	9.2 (3.1) 8.9–9.4	.003	.034
Practice	8.1 (4.9) 7.7–8.5	9.3 (5.2) 8.8–9.8	<.0001	8.2 (4.9) 7.8–8.6	9.2 (5.3) 8.7–9.7	<.0001	.001
Total	17.2 (6.5) 16.7–17.7	18.3 (6.9) 17.7–18.9	<.0001	17.2 (6.4) 16.6–17.6	18.4 (6.9) 17.7–19.0	<.0001	.001
12 mo							
Knowledge	11.3 (2.2) 11.1–11.5	10.7 (2.4) 10.5–10.9	<.0001	11.0 (2.0) 10.9–11.2	10.9 (2.4) 10.7–11.2	.04	.008
Practice	13.1 (2.3) 12.9–13.3	12.3 (3.0) 11.9–12.6	.14	12.2 (2.4) 12.0–12.5	13.1 (2.0) 12.9–13.3	<.0001	.004
Total	24.4 (3.6) 24.0–24.7	22.9 (4.3) 22.5–23.3	<.0001	23.3 (3.4) 22.9–23.7	24.0 (3.3) 23.6–24.4	.002	.625
24 mo							
Knowledge	12.3 (2.2) 12.1–12.5	10.8 (2.6) 10.6–11.0	<.0001	11.3 (2.6) 11.0–11.6	11.8 (2.5) 11.5–12.2	.11	.05
Practice	13.8 (1.9) 13.5–14.0	12.4 (2.1) 12.2–12.6	<.0001	13.0 (2.8) 12.8–13.2	13.2 (2.2) 12.8–13.5	.03	<.0001
Total	26.1 (3.3) 25.7–26.4	23.2 (3.5) 22.9–23.5	<.0001	24.3 (4.5) 23.9–24.7	25.0 (4.0) 24.3–25.7	.65	<.0001

Baseline: RS, *n* = 757; no RS, *n* = 732; EN, *n* = 737; no EN, *n* = 752. Twelve months: RS, *n* = 701; no RS, *n* = 665; EN, *n* = 661; no EN, *n* = 705. Twenty-four months: RS, *n* = 708; no RS, *n* = 682; EN, *n* = 679; no EN, *n* = 711. The linear mixed model analysis is adjusted for clustering and controlled for covariates of SES, maternal education, number of siblings, and child gender (however, child gender is not a significant covariate for knowledge scores and total scores, and number of siblings is not a significant covariate for practice scores). Repeated-measures analysis, controlled for covariates of SES, household food security, maternal education, number of siblings, and child gender, showed over time from 12 to 24 months: RS, β 1.7 (SE 0.3), 95% confidence interval (CI) 1.1 to 2.3; EN, β -0.6 (SE 0.3), 95% CI -1.3 to 0.02; interaction β -0.7 (SE 0.3), 95% CI -1.3 to 0.003.

and cultural modification protocols were followed to ensure retention of the conceptual integrity of items.²⁸

Maternal responsive caregiving behaviors were assessed when children were 12 and 24 months old using the Observation of Mother and Child Interaction (OMCI) tool.²⁹ The CCDAs observed a live 5-minute interaction while mother and child played together with a picture book. The tool comprises 19 items covering maternal affect, maternal touch, maternal verbalization, sensitivity and contingent responses, scaffolding, language stimulation, focus, child affect, child focus, child's communication efforts, and mutual enjoyment. The OMCI items were identified from a framework on responsive parenting proposed by Landry and colleagues.³⁰ The scoring format is based on the frequency of the occurrence of behaviors with higher scores indicating more responsive interactions.

Interobserver agreement between CCDAs and the supervisor using the Bland-Altman test was moderate to high (at 12 months for the mother, $n = 81$, $r = 0.82$, $P < .001$, and for the child, $n = 81$, $r = 0.82$, $P < .001$; at 24 months for the mother, $n = 154$, $r = 0.58$, $P < .001$, and for the child, $n = 154$, $r = 0.77$, $P < .001$).

The Home Observation for the Measurement of the Environment (HOME) Inventory assessed the caregiving environment of children at 6 and 18 months old. The HOME Inventory is a measure of the quality and quantity of stimulation and support in the child's home.³¹ In this study, the original 45 items were retained with some cultural modifications determined after extensive piloting. Interobserver agreement between CCDAs and the supervisor using the Bland-Altman test was high ($n = 96$, $r = 0.99$, $P < .001$).

Maternal knowledge and practices about children's development were collected by using structured

questionnaires when children were 12 and 24 months old. Questions included a key item from the ECD module of the UNICEF Multiple Cluster Index Surveys (In the past 3 days, did you or any household member over 15 years of age engage in any of the following activities with your child: read books or looked at pictures together, told stories, sang songs, took child outside of the home compound, play with child, named or

counted or drew things to or with child).³² In a separate questionnaire, information on infant and young child feeding indicators was collected by maternal report at baseline, and when infants and young children were 6, 12, 18, and 24 months old.³³

Maternal depressive symptoms were assessed using the self-reporting questionnaire (SRQ-20). The SRQ-20 was administered to mothers at

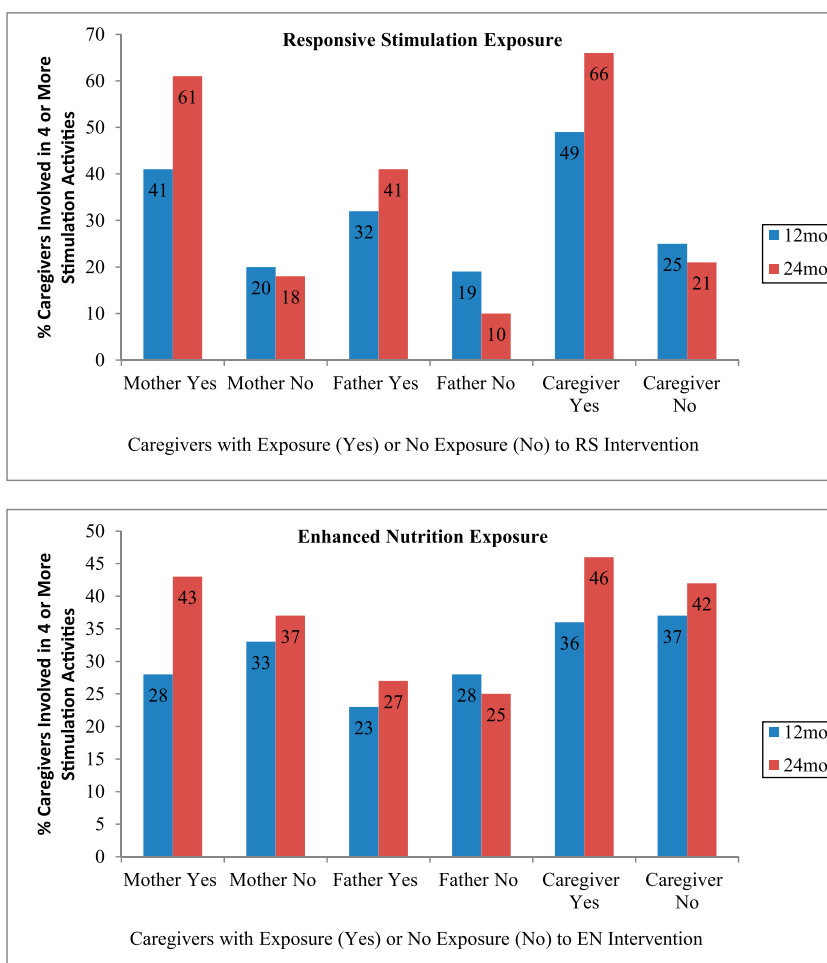


FIGURE 2

Prevalence of caregivers involved in ≥ 4 stimulation activities (early learning activities) with their young children in the previous 3 days. Source: Maternal Knowledge and Practices Questionnaire, UNICEF Multiple Indicator Cluster Surveys item. Caregiver is another adult caregiver apart from the parent. Cluster adjusted generalized estimating equation analysis controlling for SES, household food security, maternal education, number of siblings, and child gender indicate the following: (1) Mothers were significantly more involved over time (12–24 months) in RS versus no RS exposure ($P < .0001$) and in EN versus no EN exposure ($P = .002$), and there was significant interaction between the 2 interventions ($P = .001$). (2) Fathers were significantly more involved over time (12–24 months) in RS versus no RS exposure ($P < .0001$) and in EN versus no EN exposure ($P < .0001$), and there was significant interaction between the 2 interventions ($P = .0001$). (3) Caregivers were significantly more involved over time (12–24 months) in RS versus no RS exposure ($P < .0001$) but not in EN versus no EN exposure ($P = .08$), and there was significant interaction between the 2 interventions ($P = .02$).

baseline and when children were 6, 12, 18, and 24 months old. The SRQ-20 comprises 20 items designed to identify mental distress, including depression and anxiety-related symptoms.³⁴ Validity and reliability for postnatal depression for the Urdu version have been evaluated in Pakistan, and a score ≥ 9 indicates risk of postnatal depression.^{35,36} In this study, the Urdu version was translated to Sindhi. Interobserver agreement between CCDAs and the supervisor using the Bland-Altman test was high ($n = 51, r = 0.99, P < .001$).

Statistical Analysis

Statistical analysis was performed by using the Statistical Product and Services Solution, Version 15.0. All analyses reported are adjusted for clustering effect by using generalized estimating equations. An intention-to-treat analysis to determine the effect of intervention exposure on parenting skills and emotional availability was followed. First, we assessed whether the outcomes were different between the 2 interventions of the factorial design (RS versus no RS, and EN versus no EN) at each measurement interval by using linear mixed models and generalized estimating equations controlling for specified confounding variables. Interactions between the 2 interventions were tested for significance. Second, repeated-measures analyses were conducted to assess the effect of intervention over time compared with the control group controlling for confounding variables. Third, the effect sizes (Cohen's *d*) for the treatment arms were calculated for significant outcomes by taking the difference in adjusted means between treatment and control group over the pooled SD.

RESULTS

Baseline characteristics (household SES, household food security, gender, enrollment age in months, birth order, and growth status at enrollment) were comparable between intervention exposures; however,

significant differences were found in maternal education status, and this is controlled for in the analysis of all intervention effects.²²

Mother-Child Interaction

Mother-child dyads exposed to RS compared with no RS had significantly higher mean scores at 12 months (mean 32.3 [SD 8.3] vs mean 27.1 [SD 8.2], $P < .0001$) and 24 months of age (mean 35.5 [SD 9.1] vs mean 29.0 [SD 9.9], $P < .001$). Similarly, mother-child dyads exposed to EN compared with no EN had significantly higher mean scores at 12 months (mean 31.2 [SD 8.0] vs mean 28.5 [SD 9.7], $P < .0001$) and

24 months of age (mean 33.5 [SD 9.0] vs mean 31.2 [SD 10.3], $P < .001$). A significant interaction was observed between the 2 interventions at each measurement interval, indicating an additive benefit to the combined intervention ($P < .001$; Fig 1). Repeated-measures analysis showed a significant benefit over time on mother-child interaction for RS, EN, and the combined intervention.

Caregiving Environment

At 6 months of child age, mothers exposed to RS had significantly higher total mean HOME score compared with mothers not exposed to RS ($P = .002$). The categories of "learning

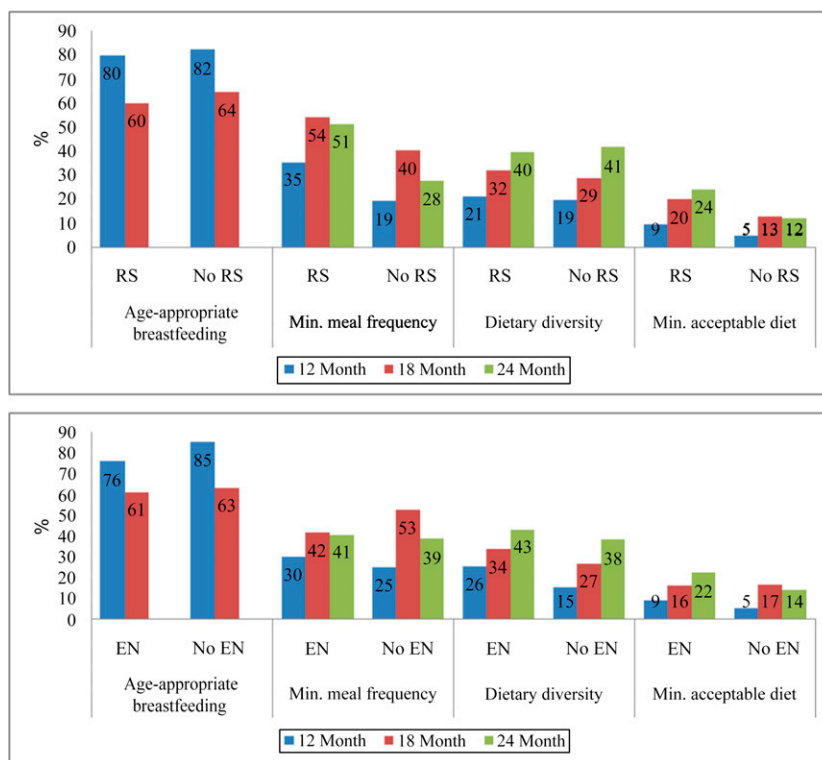


FIGURE 3

Prevalence of age appropriate feeding practices as measured by the World Health Organization infant and young child feeding indicators. Cluster-adjusted generalized estimating equation analysis controlling for SES, household food security, maternal education, number of siblings, and child gender indicate the following: (1) Age-appropriate breastfeeding over time in RS versus no RS exposure was not significant ($P < .91$); in EN versus no EN exposure, it was significant ($P < .0001$); and interaction between the 2 interventions was not significant ($P = .44$). (2) Minimum meal frequency was significantly more over time in RS versus no RS exposure ($P < .0001$), but not in EN versus no EN ($P = .59$), and there was no significant interaction between the 2 interventions ($P = .21$). (3) Dietary diversity, over time, was not significantly better in RS versus no RS exposure ($P = .52$) but was significantly better in EN versus no EN ($P = .001$), and there was no significant interaction between the 2 interventions ($P = .48$). (4) Minimum acceptable diet over time was significantly better in RS versus no RS exposure ($P < .0001$), but not significant in EN versus no EN ($P = .33$), and there was no significant interaction between the 2 interventions ($P = .29$).

materials” (an indicator of the variety of toys and books accessible to the child), “involvement” (an indicator of mother’s involvement in learning and play), and “variety” (an indicator of the variety of learning opportunities provided to the child) scored significantly higher in the exposed group ($P \leq .05$). By 18 months of child age, mothers exposed to RS had significantly higher mean scores in all categories (except for “organization,” an indicator of routine and safety at home). For the EN intervention, there were significant differences in the total mean HOME score between exposed and not exposed mothers at 6 months ($P = .03$) and 18 months ($P = .02$) of infant and young child age. However, there was no significant interaction effect at either 6 or 18 months of age, indicating no additive benefit to the combined intervention (Table 1). Repeated measures analysis showed a significant benefit on HOME Inventory score from 6 to 18 months for RS alone.

Maternal Knowledge and Practices

Summary scores (knowledge and practice) pertaining to CCD at 12 and 24 months of child age were significantly higher among mothers exposed to RS compared with not exposed mothers ($P < .0001$) and lower among mothers exposed to EN compared with not exposed mothers (12 months, $P < .0001$; 24 months, $P < .002$). Significant interaction was observed between RS and EN interventions by 24 months ($P < .0001$), indicating an additive benefit to the combined intervention (Table 2). Repeated-measures analysis showed a significant benefit from 12 to 24 months for RS alone. Figure 2 shows the number of caregivers (mothers, fathers, and other adult caregivers) involved in ≥ 4 stimulation activities with their child over a 3-day period, over time, was significantly higher among caregivers exposed to RS and EN with additive benefits to the combined intervention.

With respect to infant and young child feeding indicators, exposure to EN showed over time a greater proportion of mothers practicing age-appropriate breastfeeding ($P < .0001$) and providing diverse diets ($P = .001$) compared with no EN. The provision of minimum meal frequency and minimum acceptable diet over time were significantly better among mothers exposed to RS ($P < .0001$). There were no significant interactions observed between the 2 interventions (Fig 3).

Maternal Depressive Symptoms

At baseline, among the 1489 enrolled mothers, 29% had a SRQ-20 score indicative of high depressive symptoms (≥ 9) and 12% expressed

suicide ideation. The prevalence of maternal depressive symptoms increased in the period of follow-up for both interventions (Fig 4). Analysis of intervention effects show at 6 months, mothers exposed to RS compared with no RS and EN compared with no EN had significantly lower mean SRQ-20 scores ($P < .004$ and $P < .05$, respectively), but no significant interaction was observed between the interventions. However, by 24 months of child age, a significant interaction was observed between the interventions indicating an additive benefit to the combined intervention ($P = 0.02$; Table 3). Repeated-measures analyses suggest a significant protective benefit

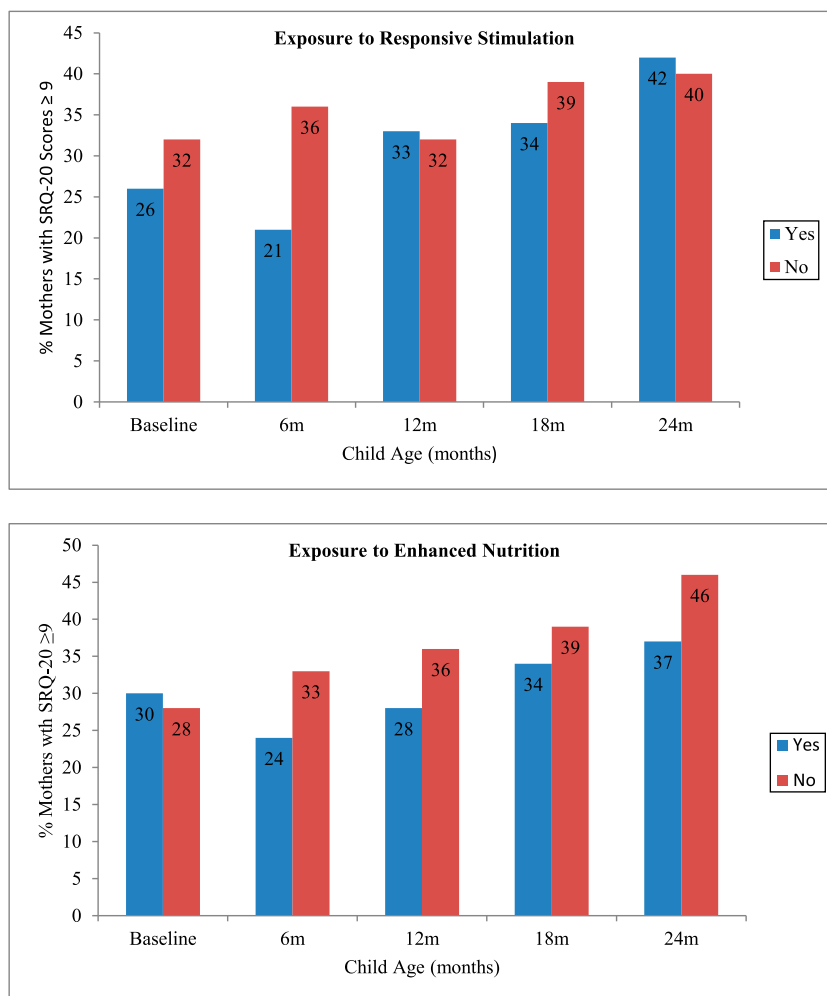


FIGURE 4 Prevalence of maternal depressive symptoms over time in different intervention exposure groups (SRQ-20 score ≥ 9).

(decline in SRQ-20 score) over time for the combined intervention.

Table 4 shows the treatment effect sizes on the significant outcomes at the study end point. Significant effects are large for both trial arms exposed to RS in all caregiving outcomes (Cohen's *d* 0.7–1.1). For maternal depressive symptoms, only the combined intervention has a small significant effect. For EN, small to modest significant effect sizes are observed for care environment and mother–child interaction (Cohen's *d* 0.2–0.4).

DISCUSSION

By 24 months of child age, significant benefits with moderate-large effect sizes were observed as a result of RS exposure on mother–child interaction, care environment, and knowledge and practices pertaining to development; significant benefits with small-modest effect sizes were observed for mother–child interaction and care environment as a result of EN exposure. Although additive benefits were seen on mother–child interaction and knowledge and practices pertaining to development in the combined intervention, there were no

significant differences in the effect sizes with respect to RS alone or RS combined with EN. In agreement with the hypothesis, RS benefitted parenting outcomes with significant impact, and there was no harm in the combination. The added advantage of the combined intervention was a small, significant effect on maternal depressive symptoms.

Benefits on maternal responsive caregiving behaviors were also seen in previous interventions in low- and middle-income countries.^{8,9} Inclusion of responsive care and responsive feeding messages in the RS intervention and responsive feeding in the EN intervention benefited both interventions, which may explain in part some benefits to feeding practices as a result of RS exposure. Caregivers in the EN group did not receive responsive care advice using the same behavioral change technique, which was guided by the developmental literature (ie, rehearsal and feedback on interaction during play and daily care activities), as the RS group received; however, application of this technique for responsive feeding is worth exploring in future research to strengthen the impact of nutrition counseling on

responsive parenting behaviors. Whereas Landry and colleagues found parents were able to demonstrate responsiveness in a shared reading activity by transferring skills learned in other activities,¹⁰ in this population, it might be necessary to ensure adequate rehearsal of skills for responsiveness across a range of specific activities.

Enrichment of home stimulation for children's development was shown in both interventions, but with greater impact as a result of the RS as measured by the HOME Inventory. Specifically in the RS exposure, early benefits were observed at 6 months in categories of provision of stimulation opportunities and learning materials, but by 18 months, caregivers' acceptance, responsiveness, and involvement had also improved, suggesting duration of intervention exposure might benefit various domains of parenting. Paternal involvement in play also increased over time, which may have been the result of family communication about the intervention given that LHWs specifically reached female caregivers.

The group-based delivery strategy and behavior change techniques (eg, problem solving and social support) were intended to support mothers and contribute to the reduction in maternal depressive symptoms. In this study, we found the combined intervention had a small benefit on maternal depression. Data from previous research demonstrate mixed results. In South Africa, early benefits to reducing maternal depressive symptoms were observed, but these were no longer evident at later time points,⁹ whereas in Bangladesh, mothers who participated in twice-monthly groups compared with home or clinic contacts had reduced symptoms of maternal depression.¹⁸ In Jamaica, maternal depressive

TABLE 3 Mean (SD), 95% Confidence Interval of SRQ-20 Scores for Maternal Psychosocial Distress at Baseline, 6, 12, 18, and 24 Months of Age

Age, mo	RS Intervention			EN Intervention			<i>P</i> Interaction
	Yes	No	<i>P</i>	Yes	No	<i>P</i>	
Baseline	6.4 (3.6)	6.8 (4.1)	.91	6.5 (4.1)	6.7 (3.6)	.34	.08
	6.0–6.7	6.4–7.2		6.1–6.9	6.3–7.0		
6	5.6 (4.0)	7.0 (4.6)	.004	5.6 (4.5)	6.8 (4.1)	.05	.27
	5.1–6.1	6.6–7.4		5.1–6.2	6.4–7.3		
12	6.7 (4.6)	6.6 (4.4)	<.0001	6.2 (4.6)	7.0 (4.3)	.26	<.0001
	6.2–7.2	6.2–6.9		5.7–6.7	6.7–7.4		
18	6.9 (4.9)	7.6 (5.3)	.21	6.8 (5.2)	7.6 (5.0)	.35	.51
	6.3–7.4	7.2–8.0		6.3–7.3	7.1–8.1		
24	7.6 (5.1)	7.6 (5.5)	.13	6.9 (5.3)	8.3 (5.2)	.25	.02
	7.0–8.2	7.2–8.1		6.4–7.4	7.9–8.7		

Baseline: RS, *n* = 757; no RS, *n* = 732; EN, *n* = 659; no EN, *n* = 706. Six months: RS, *n* = 700; no RS, *n* = 665; EN, *n* = 659; no EN, *n* = 706. Twelve months: RS, *n* = 701; no RS, *n* = 665; EN, *n* = 661; no EN, *n* = 705. Eighteen months: RS, *n* = 702; no RS, *n* = 661; EN, *n* = 668; no EN, *n* = 695. Twenty-four months: RS, *n* = 708; no RS, *n* = 682; EN, *n* = 679; no EN, *n* = 711. The linear-mixed model analysis is adjusted for clustering and controlled for covariates of SES, household food security, maternal education, and number of siblings. Child gender was not a significant covariate for maternal psychosocial distress outcome. Repeated-measures analyses, controlled for covariates of SES, household food security, maternal education, and number of siblings, showed over time from baseline to 24 months: RS, β 0.10 (SE 0.31), 95% confidence interval (CI) –0.51 to –0.71; EN, β 0.47 (SE 0.37), 95% CI –0.25 to 1.19; interaction β –1.07 (SE 0.49), 95% confidence interval –2.02 to –0.12.

TABLE 4 The Effect Size of the Treatment Arms on Caregiving Capacity at End Time Point

Outcome	Evaluation Tool	End Point Evaluation (Child Age, mo)	Cohen's <i>d</i> (Effect Size) for Each Intervention Group (95% CI)		
			RS + EN	RS	EN
Maternal psychosocial distress	SRQ-20	24	-0.2 (-0.4 to -0.1)	0.1 (0.0 to 0.3)	-0.1 (-0.2 to 0.1)
Mother sensitivity and responsiveness	OMCI	24	0.8 (0.6 to 0.9)	0.8 (0.6 to 0.9)	0.4 (0.2 to 0.5)
Care environment	HOME Inventory	18	1.0 (0.8 to 1.2)	0.9 (0.7 to 1.0)	0.2 (0.0 to 0.3)
Care for child development	Questionnaire (maternal report)	24	0.7 (0.5 to 0.8)	1.1 (0.9 to 1.3)	0.1 (-0.1 to 0.2)

Effect size was calculated as the difference in mean scores between treatment and control arms over the pooled SD score. Analysis was adjusted for clustering and controlled for covariates of SES, household food security, maternal education, and number of siblings by using generalized estimating equations. The 95% confidence intervals (CIs) indicate significance compared with control.

symptoms were reduced as a result of participation in a home visiting stimulation program¹⁹ but not in an earlier ECD intervention study in Pakistan.³⁷ In contexts such as the current study site, the prevalence of maternal depressive symptoms is high and likely to be the result of multiple issues not captured in our data (eg, domestic violence). More research is needed to better understand how to address the needs of both children and mothers in combined packages addressing maternal depression and ECD.

There are measurement limitations in this study. We did not measure responsive feeding behaviors, which would have been informative about whether this message was practiced in both interventions. Furthermore, changes in the household with respect to care for the child and support of the mother relied only on maternal reports rather than data

collected from family members or household observations.

However, the CCD approach, adapted for an impoverished community in Pakistan and delivered by LHWs in an existing community health service, does benefit important components of caregiving capacity associated with healthy ECD and growth. These results might be generalizable to similar populations. The use of multiple behavioral change techniques appeared supportive,²⁰ but future research can explore how specific behavioral change techniques mediate outcomes of care and maternal emotional availability.

CONCLUSIONS

The CCD approach improved maternal responsive caregiving behaviors, mother-child interactions, quality of the home stimulation environment, parental knowledge

and involvement in children's development, and supported improvements in young child feeding practices. We recommend that adaptation of the generic curriculum considers the context of caregivers and includes multiple behavioral change techniques to optimize beneficial caregiving behaviors.

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