Effect of parenting intervention through “Care for Child Development guideline” on early child development and behaviors: A randomized controlled trial

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Abstract

Background

Several studies showed that parenting intervention programs play a core component in early child development. Considering the limited healthcare resources in developing countries, a group design intervention might be cost-effective.

Methods

This randomized controlled trial was conducted from February 2020 to February 2021 at an outpatient public Pediatrics clinic in Isfahan, Iran. We included 210 pregnant women aged 18-45 years in their third trimester and followed their children for 18 months. The intervention group underwent 5 educational group sessions, each lasting for almost 45 minutes. The main outcomes were the children's development and behaviors based on Bayley Scales of Infant and Toddler Development-III (BSCID-III) at 12 months and Children Behavior Checklist (CBCL) at 18-month of age.

Results

Overall, data of 181 children were included in the current study, including 80 in the intervention group and 101 controls. The adjusted median differences were significantly lower in the intervention group than in controls for attention problems (-3.38; SE=1.59; P=0.035), anxiety problems (-2.28; SE=1.03; P=0.007) and pervasive developmental problems (-5; SE= 1.16; P<0.001) based on CBCL results. However, the difference of proportions was not significant in none of the BSCID-III domains in the intervention and control groups.

Conclusion

In this study, parenting interventions through CCD group sessions were significantly effective on several child's behavior domains, but not on children's development. Although CCD is known to improve children's development and behaviors, the feasible method of its delivery to a large population, especially in developing countries, remains to be determined.

Trial Registration

IRCT20190128042533N2, Date of registration: 16/01/2020, www.irct.ir

Introduction

It is estimated that 250 million children aged under five are at risk of not reaching their full developmental potential all around the world (1–3). The term "nurturing care" was coined as a core component of what is required to achieve optimal development in the early years of life, when the brain is developing and the child is more responsive to interventions(4). Parents need to be supported by educational health services

to have the necessary knowledge and skills, as they are at the forefront of providing nurturing care for promoting early child development (ECD). The WHO/UNICEF intervention on Care for Child Development (CCD) made broad, evidence-based recommendations for how to improve ECD (5). Several studies revealed the effect of parenting interventions on different child's developmental domains such as cognitive, language, socio-emotional, and motor development (6–10) as well as child's behavior such as externalizing and internalising behaviors (11–14). However, the majority of studies, specifically on the child's behavior, were conducted in high-income countries. Evidence showed that parents and children in low-middle income countries or middle-income countries are more susceptible to be exposed to additional risk factors that affect nurturing care and ECD. Low parental education, malnutrition, and fewer early learning opportunities are its commonest determinants. Thus, such support for parenting may be more beneficial in low or middle- resource contexts(3, 15). Considering the limited healthcare resources in developing countries, we tried to assess the effect of parenting interventions in a cost-effective setting through CCD interventions on children's development and behaviors to scale up action on child's mental health in Iran as a country located in the Eastern Mediterranean Region.

Methods

Study Participants

This randomized controlled trial was approved by the ethics committee of Isfahan University of Medical Sciences (ID: IR.MUI.RESEARCH.REC.1397.092), registered in the Iranian Registry of Clinical Trials (IRCT20190128042533N2, Date of registration: 16/01/2020) and has therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. It was conducted from February 2020 to February 2021 at an outpatient public Pediatrics clinic in Isfahan, Iran. To calculate the sample size, we used the equation for comparing two means with type I error of 1.96 and power of 0.90. Assumptions in two groups (including effect size equal to 0.40) were pre-specified on the basis of previously published data and the expected effect was hypothesized as a clinically meaningful effect. We hypothesized that an equivalent outcome will be observed in both groups. The sample size was calculated as at least 133 patients in each group. However, due to COVID-19 pandemic and social restriction, we stopped the study when 228 participants had enrolled. We included Iranian pregnant women aged 18–45 years in their third trimester (days 196 to 280 of pregnancy) who had a healthy fetus based on clinical and ultrasound evaluations, then we followed their children for 18 months. We excluded participants who were absent for more than 2 educational sessions, refused to continue the study, as well as those who had a child with congenital anomaly, birth asphyxia, seizure, or with known metabolic or neurological disorders after birth.

Study Design

The study protocol was explained to participants and written informed consent were obtained from participants. Overall, 210 pregnant women were included. Random numbers were generated by random allocation software in binary blocks, and the pediatric neurologist assigned participants into intervention or control groups of equal numbers. The intervention group underwent 5 educational group sessions,

each lasting for almost 45 minutes. The sessions were held during the third trimester of pregnancy (the first session), and then 2–6 weeks, 2–6 months, 6–9 months, and 9–12 months after delivery. The educational content of each session was adopted from the Persian version of the Care for Child Development (CCD)-2012 manual (Table 1) (16). In the intervention group, mothers were trained on how to play and communicate with their children based on the children's age. We used training materials including educational slides and toys for better education of mothers. Parents should engage in play and communication activities to encourage their children's learning, according to CCD recommendations. They also learn how to be sensitive to the needs of children and respond appropriately to address their needs through play and communication. Children 's survival, as well as their healthy growth and development, are enhanced by these basic caregiving skills. The training sessions were held by a Pediatric neurologist. The control group underwent routine education on child care, suggested by WHO, which is currently implemented in most of the primary health care centers in the country by using pamphlets, as well as general skills training sessions such as sessions on breastfeeding encouragement.

Table 1
Topics of parent training sessions based on Care for Child Development (CCD) manual

Sessions	Elements of nurturing care	Session contents
Session 1	Health	Family planning, prevention, and cessation of smoking, alcohol and substance use, antenatal care, childbirth care, prevention of mother to child transmission of HIV, essential newborn care with extra care for small and sick babies, postnatal care contact, kangaroo mother care for low birth weight babies, maternal immunization, childhood immunization, care for children living with developmental difficulties and disabilities, support for parental mental health, early detection of illness or disabling conditions (e.g., sight, hearing), timely, appropriate care-seeking for sick children, integrated management of child illness
Session 2	Nutrition	Maternal nutrition, early initiation, and exclusive breastfeeding, complementary feeding and transition to the family healthy diet, micronutrients as needed, deworming, growth monitoring and intervention when indicated, management of all forms of malnutrition
Session 3	Safety and security	Safe water, sanitation, prevention of child abuse and neglect, prevention and reduction of indoor and outdoor pollution, environments healthy, green, free of toxins, prevention of intimate partner and family violence, prevention of harsh punishment of children, safe play spaces in urban and rural areas
Session 4	Responsive care	Skin-to-skin contact immediately after birth, affectionate and secure adult caregiving in a family environment, guidance for children in daily activities and relationships with others, daily feeding and sleep routines, involvement of fathers, extended family and other partners, social support by families, community groups and faith communities
Session 5	Early learning	Responding to children's communication through vocalizations, facial expressions and gestures, language stimulation through talking and singing, encouragement to explore objects with guidance from caregivers, caregiver-child play and reading and story-telling groups, mobile toy and book libraries, quality daycare, and pre-primary education

Outcome measures

The main outcome of the present study was the children's development at 12 months of age. Moreover, based on our literature review, after the trial registration, we decided to follow up the children's behavior at 18 months of age. We examined children's development in 3 key developmental domains of cognition, language, and motor by Bayley Scales Of Infant and Toddler Development-III (BSCID-III) test. It was validated in Persian and the reliability was assessed using Cronbach's alpha for internal consistency (cognition ($r = 0.79$), language (receptive communication ($r = 0.76$), expressive communication ($r = 0.81$)), motor (fine motor ($r = 0.80$), and gross motor scales ($r = 0.81$))). The standardized Persian version of this questionnaire did not include the other 2 domains of social-emotional and adaptive of the English version of BSCID-III (17). The lower scores in each domain show delayed development in that field. Scores of ≥ 85 show normal developmental status. Scores of 70–84 show mild developmental delay, 55–69 show moderate developmental delay, and < 55 show severe developmental delay(18). In our study, the test was

performed by a certified healthcare provider, who was trained by the Iranian Ministry of Health and Medical Education as one of the staff for performing the BSID-III test in Iran. We also assessed children's behaviors by CBCL/1½–5, which was developed by Achenbach (19). It consists of 99 closed items and one open-ended item. Mothers completed the Persian version of CBCL (20, 21), normalized and translated by Mohammad Esmaeel (22). In addition to a total problem score, CBCL contains 2 broadband scales (externalizing problems and internalising problems) and 8 narrowband syndrome scales including emotionally reactive, anxiety/depression, somatic complaints, withdrawal, sleep problems, attention problems, aggressive behavior, and other problems. The latter involves a range of heterogeneous problems including jealousy, disobedience, food refusal, overeating, being overweight, nail-biting, nightmares, etc. DSM-V scales include affective problems, anxiety problems, pervasive developmental problems, attention-deficit/ hyperactivity problems, and oppositional defiant problems.

Good test-retest reliability was found with correlation coefficients ranging from 0.37 to 0.91 for each item. The average test-retest reliability coefficients for the total competence score and the total problems score were 0.80 and 0.79, respectively (23). In the test re-test analyses conducted by Achenbach et al. (24) with a two-week interval, a test-retest coefficient of 0.87 was reported for behavioral problems.

Sociodemographic data were collected from the mothers in both groups at the time of enrollment. The number of children, educational level of parents, parental ages, and their income, history of paternal smoking, infant's gender, Apgar scores, gestational age, and delivery type were collected.

Statistical analysis

Continuous variables were expressed as means $\pm$ standard deviation (SD), and categorical data as number (percentage). We assessed the normality of data by the Kolmogorov–Smirnov test. Comparisons between means of continuous variables in the intervention and control groups were performed using independent Student t-test for variables with normal distributions, and the Mann-Whitney test for those with non-normal distributions. We used the Chi-square test to assess the difference in the distribution of the categorical variables between intervention and control groups. We calculated the adjusted median difference between the intervention and control groups by median regression models. The models were adjusted with maternal and paternal age and educational levels, paternal cigarette smoking, preterm labor, type of delivery, and child's gender. All analyses followed intention-to-treat (ITT) principles with participants analyzed in the group to which they were originally randomized, regardless of what treatment they received.

Data analyses were performed using the statistical software STATA 12.0 (STATA Corp, College Station, Texas, USA). P-values of less than 0.05 were considered statistically significant.

Results

Among 210 participants, data of 181 children were complete and used in the present study (80 children in the intervention group and 101 children in the control group). We lost 23 participants in the intervention

group because of the COVID-19 outbreak and social distance. Moreover, we lost to follow-up 2 and 4 children in the intervention and control group, respectively (Fig. 1). In total, 51.9% of them were boys. Table 2 shows the maternal, parental, and child characteristics by the group. Maternal and paternal age in the control group was significantly lower than intervention group ($P < 0.05$). The Kolmogorov–Smirnov test for the cognitive score, language score, and motor score, and all CBCL scales were significant ($P < 0.05$), thus the distribution of these variables was not normal. The frequencies of children with normal (score ≥ 85), mild (score = 70–84), and moderate (score = 55–69) neurodevelopmental delay, measured by the BSID-III, are presented in Table 3. The majority of children had scores ≥ 85 in all domains (cognitive, language, and motor domains). The difference of proportions in the two groups of intervention and control was not significant in all domains ($P > 0.05$). The median for all scores was more than 100 in both intervention and control groups. The adjusted median differences between intervention and control groups using median regression were not significant for all domains (Table 3). Table 4 shows the results of CBCL in intervention and control groups at 18 months of age. The median of CBCL scales in the intervention group was significantly lower than the control group for anxiety/depression, attention problems, internalising behaviors and, the total score in the syndrome scale, as well as anxiety problems, and oppositional defiant problems in DSM-oriented scales ($P < 0.05$). The adjusted median differences were significantly lower for intervention group than control group for attention problems (-3.38; SE = 1.59; $P = 0.035$), anxiety problems (-2.28; SE = 1.03; $P = 0.007$) and pervasive developmental problems (-5; SE = 1.16; $P < 0.001$).

Table 2
Parents and children's characteristics

		Intervention	Control	P-value
Parents				
Maternal age, mean(SD)		31.99(4.72)	29.48(5.17)	0.001
Paternal age, mean(SD)		37.23 (8.49)	34.07(5.09)	0.002
Maternal education	n(%)			
	Secondary school and less	8 (10.1%)	13(12.9%)	0.847
	High school or diploma	35(44.3%)	44(43.6%)	
	University education	36(45.6%)	44(43.6%)	
Paternal education	n(%)			
	Secondary school and less	25 (31.6%)	33(33.7%)	0.740
	High school or diploma	34(43%)	45(45.9%)	
	University education	20 (25.3%)	20(20.4%)	
Income, n(%)				
	low	14 (17.5%)	28 (27.7%)	0.090
	moderate	54 (67.5%)	66 (65.3%)	
	high	12 (15%)	7 (6.9%)	
Paternal smoking				
	No	68 (85%)	85(84.2%)	0.876
	Yes	12 (15%)	16 (15.8%)	
Children				
Gender, n(%)	girl	41 (51.3%)	53 (52.5%)	0.870
Gestational age, n(%)	< 37 week	1 (1.3%)	5(5%)	0.167
Delivery Type, n(%)	Cesarean	41(51.3%)	56(55.4%)	0.268

Table 3
Results of BCID-III in intervention and control groups at 12 month of age

		Intervention	Control	Adjusted median differences			
		(n = 80)	(n = 101)	P	coefficient	SE	p ^a
Cognitive score	Median (IQR)	105 (100–115)	110 (100–120)	0.099	-4.22	2.51	0.095
	70–84	1 (1.3%)	3 (3%)	0.423			
	≥ 85	79 (98.8%)	96 (97%)				
Language score	Median (IQR)	112(103–118)	112(103–118)	0.444	-1.92	2.52	0.446
	70–84	1 (1.3%)	0 (0%)	0.982			
	≥ 85	79 (98.8%)	100 (100%)				
Motor score	Median (IQR)	103(97–110)	107(91–112)	0.957	-1.09	2.41	0.652
	55–69	0 (0%)	1 (1%)	0.480			
	70–84	7 (8.9%)	8 (8.1%)				
	≥ 85	72 (91.1%)	90 (90.9%)				
^a Adjusted by maternal and paternal age and educational levels, gestational age, types of delivery, paternal smoking (cigarette), and gender. BCID-III : Bayley Scales Of Infant and Toddler Development-III							

Table 4
Results of CBCL in intervention and control groups at 18 months of age

	Intervention	Control	Adjusted median differences			
	Median (IQR)	Median (IQR)	P	coefficient	SE	p ^a
CBCL syndrome scales						
Emotionally reactive	42(35–46)	42(35–46)	0.120	0	1.23	1
Anxiety/depression	42(38–53)	46(42–53)	0.011	-2.47	2.04	0.227
Somatic complaints	35(35–44)	40(35–44)	0.182	-1.61	1.63	0.326
Withdrawn	40(40–40)	40(40–40)	0.162	-	-	-
Sleep problems	48(48–52)	52(44–57)	0.182	-1.47	1.00	0.145
Attention problems	35(35–41)	41(35–46)	0.043	-3.38	1.59	0.035
Aggressive behavior	40(37–43)	40(37–46)	0.343	-0.96	1.23	0.436
Other problems	42(40–48)	44(41–51)	0.074	-1.81	1.56	0.247
Internalising behaviors	38(36–41)	40(37–43)	0.003	-1.87	0.96	0.052
Externalizing behaviors	38(35–43)	39(37–48)	0.077	-0.97	1.46	0.508
Total score	43(39–51)	47(41–56)	0.009	-3.63	2.17	0.097
CBCL DSM-oriented scales						
Affective problems	42(35–42)	42(35–46)	0.655	0.41	1.80	0.818
Anxiety problems	43(40–46)	46(40–50)	0.012	-2.82	1.03	0.007
Pervasive developmental problems	35(35–40)	40(35–40)	0.110	-5.00	1.16	< 0.001
Attention deficit/ hyperactivity problems	41(35–47)	41(37–47)	0.280	-0.73	1.94	0.707

	Intervention	Control	Adjusted median differences			
Oppositional defiant problems	41(35–44)	41	0.012	0	1.15	1
^a Adjusted by maternal and paternal age and educational levels, preterm labor, types of delivery, paternal smoking (cigarette), and gender.						
CBCL: Child Behavior Checklist						

Discussion

In the present study, educating mothers about the CCD recommendations in a group setting did not lead to the better developmental status of children in the intervention group compared to the control group. There were some significant differences between groups in the children's behavior subscale, including attention problems in the syndrome-oriented scale, as well as anxiety problems and pervasive developmental problems on the DSM-V-oriented scale. However, no statistically significant difference was observed between the intervention and control group in BSID-III scores.

To the best of our knowledge, this is the first study in a developing country in a group setting, focusing on the behavior as well as developmental domains in children in a parenting intervention program. Most studies in low or middle-income countries have merely assessed the developmental outcomes, not the children's behaviors (8, 25–29). As noted above, we conducted CCD sessions for parents in a group setting. Only one recently published cluster randomized clinical trial specifically compared the effectiveness of weekly home visits to weekly mother-child group sessions in rural India (14). Although we found no significant differences in cognitive, language, and motor development between intervention and control groups, Grantham-McGregor et al. revealed that group sessions were as effective as home visits in improving children's cognition and language, while both delivery models similarly had null impacts on children's motor, socioemotional, and behavior development in 1449 participants in India(14). This finding might be because of the program duration, cultural context, risk profiles of the population, and the available resources in the health care system. Since cost analysis revealed that the group-based model required a quarter of the costs compared to home visiting (30, 31), further studies are needed in this regard to discover the efficacy of parenting interventions through group sessions on the children's development and behaviors, particularly in low or middle-income countries.

Our finding on the association of children's behaviors to parenting interventions is consistent with the pooled results of a meta-analysis that showed parenting interventions reduce behavior problems (SMD = -0.13, 95% CI: -0.18, -0.08, $P < 0.001$; $I^2 = 53\%$, $P < 0.001$) (31). We did not find significant impacts of parenting interventions on ECD, however Jeong et al. indicated positive benefits of parenting interventions on children's cognitive development (SMD = 0.32, 95% CI: 0.23, 0.40, $p < 0.001$), language development (SMD = 0.28, 95% CI: 0.18 to 0.37, $p < 0.001$), and motor development (SMD = 0.24, 95% CI: 0.15 to 0.32, $p < 0.001$) (31). The effect sizes are between 0.1 to 0.3, which indicate small effect sizes (32). The inconsistent results might arise from the small sample size in our study.

Identifying primary preventative interventions that would be effective and feasibly- delivered at these levels is helpful to decision-makers in the pursuit of reducing the burden of neurodevelopmental disorders and behavioral problems in low- and middle-income countries as it highlights where resources should be allocated (15). We speculate that CCD recommendations may be more effective for children > 18 months as the mean age of children in our study was lower compared to some previous studies. A long-term follow-up is needed to figure this out. Moreover, we assume that educational group sessions may not be very effective among the Iranian population due to low teamwork ability in Iranians. However, the result of our study is not conclusive and further studies are needed in this regard.

There are some limitations to the present study that may have affected our findings. First, although the recruitment was randomized, mean maternal and paternal age at the time of child delivery were statistically significantly lower in the control group compared to the group that received the intervention. We speculate the older age of both parents in the intervention group might have affected our findings, as older parents may have less time and energy to spend and play with the child and may not be as responsive as younger parents to the child (33). Second, the number of children in the intervention and control groups was not equal. Although we approached an equal number of participants in each group, we lost a considerable number due to the COVID-19 outbreak. Many mothers in the intervention group were not willing to participate in the sessions anymore because of social distancing rules. Third, we were not able to assess parents' knowledge before and after the intervention, and their adherence to CCD instructions due to the limited resources. Fourth, in this study, we just involved mothers in group sessions. Despite the observational evidence that fathers are critically important for ECD (34), we could not involve fathers in our parenting program due to their work time as well as low compliance for the study. Despite these limitations, this study has focused on children's behavior during infancy and early childhood. Most parenting programs for behavioral development to date have been commonly delivered to preschool-aged children rather than young children during the earliest years of life and our information in early childhood was scarce (15, 35–37). Moreover, we represented the child's behavior through a valid and reliable tool, while several previous studies reported no details regarding the reliability or validity of the measurement tool for behavioral problems (31). Another strength of the current study is its novelty in developing countries and the first study of its kind in the region.

Conclusion

In the present trial, delivering parenting interventions through CCD group sessions had significant effects on several child's behavior domains, but not on their development. Although CCD is known to improve children's development and behaviors, the feasible method of its delivery to a large population, especially in developing countries, remains to be determined. Longitudinal studies on a large sample of children are necessary in this regard.

Abbreviations

BSCID-III: Bayley scales of infant and toddler development-III

CBCL: Children behavior checklist

CCD: Care for child development

ECD: Early child development

SD: Standard deviation

SE: Standard error

ITT: Intention-to-treat

Declarations

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

O.Y and R.K designed the study SS.D, N.H, M.A, M.P and M.B contributed to data collection. M.Kh performed the statistical analysis. M.B, N.B, and Sh.B wrote the first draft of the manuscript. O.Y and R.K edited it. All authors reviewed the manuscript.

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Ethical statement (approval ,guideline ,informed consent)

This randomized controlled trial was approved by the ethics committee of Isfahan University of Medical Sciences (ID: IR.MUI.RESEARCH.REC.1397.092), and has therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. The study protocol was explained to participants and written informed consent were obtained from participants.

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Figures

Figure 1

Flow diagram of the trial