DIR/Floortime® Parent Training Intervention for Children with Developmental Disabilities: a Randomized Controlled Trial

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ABSTRACT

Objective: To determine whether adding a parent training program utilizing the Developmental Individual-difference Relationship-based (DIR/Floortime®) approach for children with developmental disabilities can improve their capacities for attention and initiation.

Methods: Forty-eight pairs of parents and their preschool children with developmental disabilities were randomly assigned to three 1-hour one on one DIR/Floortime® parent training sessions during a 4-month period or to a control group.

Results: Between-group comparison demonstrated a significant difference in favor of the intervention group for attention ($F(1, 46) = 34.52$, $p = .031$, $ph^2 = .099$) and initiation composite scores ($F(1, 46) = 6.55$, $p = .014$, $ph^2 = .127$). Effect sizes were medium to large for the attention composite score (Cohen's $d = .526$) and initiation composite score (Cohen's $d = .653$) respectively.

Conclusion: Adding a modest home-based DIR/Floortime® parent training approach may yield clinically meaningful improvements in attention and initiation for children with a range of developmental challenges.

Keywords: Child development; developmental disability; parent training; DIR/Floortime® (Siriraj Med J 2019; 71: 331-338)

INTRODUCTION

Children with non-autistic developmental disabilities typically exhibit challenging limitations in self-care and are at high risk of developing emotional and behavioral problems compared to typically developing children.[1-3] Studies of parent training for children with developmental disabilities are promising.[4-7] There is good evidence that parent training can yield increased positive parenting and reduction in problematic behaviors in children. These approaches utilize contingency management, planned activities, compliance training, or a combination of these. Some emphasize the importance of fostering more positive relationships between parents and children.[8-13] These strategies, however, are designed to be applied in a generalized manner without explicitly taking into account the neurological and developmental capacities of individual children.

The Developmental Individual-differences Relationship-based (DIR)/Floortime® model[14] focuses on the child's developmental capacity for relating and communicating, taking in, regulating, responding, understanding sensations and information, and planning actions. It is a developmental intervention involving meeting a child at his or her current developmental level, in which the parent or therapist

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follows the child's lead, with playful positive attention while tuning into the child's interests. Once the child connects with the adult, specific techniques are used to challenge and entice the child to move toward ever more complex developmental milestones outlined in the DIR model. In DIR/Floortime® relationships are the pivotal force that nurtures and optimizes development. DIR/Floortime® parent training can improve the core challenges of autism, including relating, interacting, and communicating.[15-17]

Prior to this study, most research on DIR has focused on investigating the effectiveness of DIR/Floortime® in the children with ASD. It has been less clear whether DIR might help children with developmental disabilities who generally have better social abilities than children with ASD.[18-20] It would, therefore, be helpful to learn whether DIR might help other vulnerable populations.

This study seeks to determine whether DIR/Floortime® parent training program for children with development disabilities confers benefit beyond treatment as usual (TAU).

MATERIALS AND METHODS

Study design and participants

After the Institutional Review Board of Faculty of Medicine Siriraj Hospital, Mahidol University approved this study (Si 089/2013), caregivers (parents, or an adult in a caregiving role) were recruited through posters and paper advertising from February 2013 to December 2016. One of the researchers who was a developmental pediatrician confirmed the diagnosis. Inclusion criteria included: patient: diagnosed with a developmental disability, global developmental delay, or a cerebral palsy; age 2 to 6 years; and living with the caregiver for at least 6 months. Children with co-occurring ASD, significant impairments in hearing or vision serious medical problems, intractable seizures, and those whose caregivers were illiterate were excluded.

After the participants agreed and signed informed consent and had undergone a baseline assessment, the children were sorted into 2 strata according to age (24-47 or 48-72 months).

The study is a single-blind, parallel design clinical trial with an allocation ratio of 1: 1. A research assistant who was not directly involved with the study used a random number table to randomly allocate participants to either the DIR/Floortime® parent training group or a waitlist control group. Opaque envelopes were used to conceal the allocation sequence.

Intervention

Treatment was carried out using the DIR/Floortime®[14] approach. The first author was an experienced clinician who had her expert training leader certification from the Interdisciplinary Council on Developmental and Learning Disorders. Caregivers in the intervention group viewed a 2-hour DVD about DIR/Floortime® and received an accompanying book, an approach previously utilized to study the method with parents of children with ASD.[16,21]

Caregivers were trained for 1 hour on how to observe their children's cues and responses. Caregivers were coached to join the children in pleasurable activities, maintain engagement, and to sustain reciprocal interactions. For children with symbolic capacity, pretend play was encouraged. Controlling and intrusive responses on the part of caregivers were identified, discouraged, and substituted with two-way emotional gestural communication.

Caregivers in the intervention group were asked to spend a minimum of 15 hours per week utilizing DIR/Floortime® techniques throughout the study period. Parents of the children in both groups were asked to continue their other usual treatment interventions such as physical therapy or speech therapy throughout the study period. At the end of the first and third months, the researcher observed and gave feedback to parents in the intervention group about how well they were related to their children. The assessment was based on the child and caregiver's functional emotional capacities.[22] Controlling and intrusive responses were again identified and discouraged and substituted with responses aimed at facilitating two-way emotional signaling and communication between parents and their children. Modeling and coaching were used to improve caregiver performance. The goals, method, and techniques of home program were adjusted to meet the child's current needs. Both groups were reassessed at the end of the fourth month.

Measurements

Baseline measurement included assessment of the children's development and family demographic characteristics.

Child Behavior Rating Scale (CRBS)

The CBRS[23] was the primary outcome measurement, rating the children's interactions with their caregivers. The caregiver and child were video-recorded while playing together in any manner they chose. The assessors were two developmental psychologists who were blinded to the group status. They rated Attention (attention to activity, persistence, involvement, and compliance or cooperation subscales), and Initiation (initiation of activity, joint attention, and affect). The assessors rated each of the items on a 5-point Likert scale. The two

assessors' scores were averaged and subscale scores were averaged for composite scores. Cronbach's alpha for the two assessors was 0.94 for the attention composite score and 0.77 for initiation.

Functional Emotional Developmental Questionnaire (FEDQ)

The FEDQ[24] is a questionnaire for the parent to assess Greenspan's six Functional Emotional Developmental Levels (FEDLs): (1) shared attention and regulation, (2) engagement and relating, (3) purposeful emotional interaction, (4) social problem-solving, (5) creating ideas, and (6) logical use of symbolic ideas in social problem solving. All are scored on a 7-point scale. The Thai version of the FEDQ has a satisfactory internal consistency (Cronbach's alpha = 0.83) with an ICC of 0.89.[25]

Mullen Scales of Early Learning (MSEL)

The MSEL[26] is a developmental test for children from birth to 68 months of age. Four cognitive domains of the MSEL were used: visual reception, fine motor skills, receptive language, and expressive language. This instrument was administered by a developmental pediatrician who was blinded to intervention status. Subscale scores are compared against age equivalents and summarized as the Early Learning Composite (ELC). Higher scores reflect more intact development.

Parenting Stress Index-Short Form (PSI-SF)

The PSI –SF[27] is a 36-item questionnaire designed to measure stress in the parent-child system on three subscales: parental distress, parent-child dysfunctional interaction, and difficult child. Higher scores indicate greater stress. The ICC of the total Parenting Stress Index score in the current study was 0.82.

Compliance and co-interventions

Parents kept logs of hours per week they used DIR/Floortime® technique as well as other interventions.

Sample size calculation

A prior study found a mean CBRS score (initiation) of 2.8 [standard deviation (SD), 0.9] for a population of children with developmental disorders other than autism.[23] In the present study, we sought to detect a minimum clinically important between-group difference of 0.8. A sample size of 40 was needed to provide 80% power to detect this difference at a two-tailed significance level of 0.05. If the estimated drop-out rate was 20%, the number of subjects to be recruited was 48.

Data analysis

Data were analyzed using SPSS, version 18.0. An intent-to-treat analysis was used. For drop-outs, we used the last-observation-carried-forward method. Paired t-tests compared pre-test and post-test scores. Analysis of covariance was conducted to investigate the impact of the treatment intervention between groups, with follow-up scores as the dependent measure and baseline scores as covariates.

RESULTS

Sixty families were screened: 4 declined to participate, 2 did not respond to the baseline evaluation, and 6 were not eligible because of the children's health problems. Forty-eight families were randomized to either the treatment group (n = 23) or control (n = 25). Six families dropped out, 3 from each group. Reasons included an inability to reach the caregivers, moving away, and 'too busy'. (Fig 1)

The average age of the children was 39.98 months. Sixty-eight percent of the diagnosis was global developmental delay. Most were living in a two-parent household. Seventy-five percent had an ELC of ≤50, indicating moderate to severe developmental delay. Eighty-five percent received usual services averaging 1.14 hours per week. Groups did not significantly differ concerning for average service hours. The parent and child demographic characteristics were not significantly different between groups (Table 1). We used intention to treat analysis and the last-observation-carried-forward method for missing data.

Primary outcome

Control group post-test attention and initiation composite scores of the CRBS were not significantly different from pre-test scores. Intervention group post-test attention and initiation composite scores were significantly higher than pre-test scores ($p < .001$). Between-group comparison demonstrated a significant difference in favor of the intervention group for attention ($F(1, 46) = 34.52$, $p = .031$, $p\eta^2 = .099$) and initiation composite scores ($F(1, 46) = 6.55$, $p = .014$, $p\eta^2 = .127$). Effect size for the difference between groups was medium to large for both the attention composite score (Cohen's $d = .526$) and initiation composite score (Cohen's $d = .653$) (Table 2).

Subscale results demonstrated significantly better outcomes for the persistence, involvement, initiation of activity, and joint attention subscales. There were no significant differences in attention to activity, compliance, or affect (Table 2).

TABLE 1. Demographic information and statistical tests of group differences for participants.

	Control group N=25	Intervention group N=23	*P* value
The children			
Mean (SD) age in months	39.36 (11.4)	40.65 (13.6)	.301
Male	11 (44%)	14 (56%)	.243
Diagnosis			
Down syndrome	2 (8%)	4 (17%)	
Cerebral Palsy	7 (28%)	7 (30%)	.561
Global developmental delay	16 (64%)	12 (52%)	
Mean (SD) CBRS			
Attention composite scores	3.04 (0.90)	2.85 (0.93)	.473
Initiation composite scores	2.91 (0.77)	2.53 (0.77)	.096
Mean (SD) FDQ	32.24 (11.21)	29.61 (11.03)	.564
Early Learning Composite			
More than 85	3 (12%)	2 (9%)	
71-85	4 (16%)	1 (4%)	.538
50-70	7 (28%)	9 (39%)	
Less than 50	11 (44%)	11 (48%)	
History of convulsion	1 (4%)	2 (9%)	.532
Participation in daycare or kindergarten	5 (20%)	7 (30%)	.617
Their families			
Primary caregiver:			
Parent / Grandparent	19 (76%)/ 6 (24%)	15 (65%)/ 8 (35%)	.412
Bachelor degree or higher	11 (44%)	6 (26%)	.195
Two-parent household	22 (88%)	20 (87%)	.195
Worked inside of the home	14 (56%)	11 (48%)	.466
Sibling in family (yes/ no)	19 (76%)	20 (87%)	.571
Mean (*SD*) Total PSI score	87.88 (21.09)	93.52 (27.5)	.390

Secondary outcomes

Intervention group post-test FEDQ scores were significantly higher than the pre-test score ($p = .001$) but not significant in the control group ($p = .099$). Between-group analysis revealed significant differences in favor of the invention ($F(1, 46) = 7.37$, $p = .031$, $p\eta^2 = .141$). The effect size for the difference between groups was medium to large (Cohen's $d = .729$).

For both groups, post-test MSEL subscale scores were significantly higher than the pre-test scores. Between-group analysis showed that the invention group had significantly better scores for the receptive language

TABLE 2. Presents mean (SD) of the outcome measures and the results of the analysis of covariance (ANCOVA) for group analyses.

	Control Group (n=25)		Intervention Group (n=23)		F (1, 46)	*P* value	Cohen's *d*
	Pre-test	Post-test	Pre-test	Post-test			
Child Behavior Rating Scale (CBRS): Attention Domain							
Attention to Activity	3.40 (1.00)	3.44 (1.12)	3.21 (1.08)	3.54 (0.91)	2.12	.153	.421
Persistence	2.80 (0.92)	3.04 (0.97)	2.61 (1.08)	3.19 (1.03)	4.21	.046*	.574
Involvement	3.02 (1.04)	3.24 (1.01)	2.83 (0.94)	3.48 (0.74)	4.95	.031*	.570
Compliance	2.92 (0.98)	3.02 (0.94)	2.74 (0.94)	2.96 (0.94)	0.18	.671	.116
Attention composite scores	3.04 (0.90)	3.18 (3.29)	2.85 (0.93)	3.29 (0.79)	4.94	.031*	.526
Child Behavior Rating Scale (CBRS): Initiation Domain							
Initiation to activity	2.80 (1.00)	2.84 (1.04)	2.26 (0.93)	2.87 (0.98)	11.99	.009	.944
Affect	2.62 (0.83)	2.82 (1.06)	2.43 (0.83)	3.00 (0.87)	3.35	.074	.527
Joint attention	3.30 (0.93)	3.34 (0.85)	2.89 (0.80)	3.30 (0.78)	4.91	.032*	.443
Initiation composite scores	2.91 (0.77)	3.30 (0.86)	2.53 (0.77)	3.06 (0.77)	6.55	.014*	.653
Total FEDQ Score	32.24 (11.21)	33.76 (11.81)	29.61 (11.03)	37.35 (11.37)	7.37	.009*	.729
Mullen Scales of Early Learning (MSEL)							
Visual Reception	23.68 (9.26)	26.04 (9.57)	20.91 (11.9)	25.35 (11.31)	1.97	.167	.648
Fine Motor	21.64 (7.41)	23.80 (8.03)	20.48 (8.12)	22.91 (8.91)	0.079	.780	.170
Receptive Language	21.56 (8.89)	22.92 (9.45)	19.17 (10.33)	23.55 (11.15)	4.33	.043*	.663
Expressive Language	17.64 (10.69)	18.68 (9.45)	15.39 (9.85)	18.90 (9.85)	5.53	.023*	1.11
Parental Stress Index							
Parental Distress	30.08 (8.92)	29.04 (7.20)	31.43 (10.6)	29.09 (9.83)	0.148	.702	.140
Parent-Child Dysfunctional Interaction	29.72 (6.10)	28.64 (6.96)	28.09 (8.28)	32.00 (7.98)	5.27	.026*	.414
Difficult Child	29.16 (8.89)	28.6 (8.16)	30.74 (9.82)	30.09 (9.12)	0.237	.629	.112
Total Parental Stress Index	87.88 (21.09)	85.30 (24.28)	93.52 (23.98)	85.03 (24.29)	1.240	.271	.275

* p value < 0.05

subscale ($F(1, 46) = 1.97$, $p = .043$, $p\eta^2 = .088$) and the expressive language subscale ($F(1, 46) = 1.97$, $p = .043$, $p\eta^2 = .109$). There was no significant difference in the visual reception or fine motor subscales. Mean changes in the ELC score in this study could not be calculated because scores were lower than 49.

Intervention group PSI-SF post-test parent–child dysfunctional interaction score was significantly lower than pre-test ($p = .011$). Parental stress and difficult child scores did not significantly change from baseline. Between-group analysis showed that the parent–child dysfunctional interaction score in the intervention group was the only individual subscale score that was significantly higher than that in the control group when the pre-test score was a covariate ($F(1, 46) = 5.27$, $p = .026$, $p\eta^2 = .033$). No other adverse effects of the intervention were detected.

Moderator analysis

Regression analysis was carried out to determine the moderator effect of baseline variables on the improvements in the attention and initiation composite scores. Age, groups of children classified by ELC, and baseline score demonstrated some association with the improvement in the attention ($R^2 = .284$, $F(3, 44) = 5.83$, $p = .002$) and initiation composite scores ($R^2 = .381$, $F(3, 44) = 5.83$, $p = .001$). Pre-test attention and initiation composite scores had a significant negative weight, indicating the children with higher baseline scores might have a lower chance of improving. Age of the children was significantly associated with the improvement in initiation composite scores, i.e., older children were more likely to show improved initiation. Pre-test ELC did not demonstrate moderator effect on both composite scores.

Compliance and co-interventions

35% of the intervention group reported using DIR/Floortime® techniques an average of 14 hours/week; 52% spent 7 to 14 hours/week; 13% spent <7 hours/week. Children in both the control and intervention groups received additional services (e.g., speech therapy, occupational therapy, or physical therapy) for an average of 1.20 (SD, 0.58) hours/week and 1.08 (SD, 0.73) hours/week, respectively. There were no significant differences in the time spent receiving such services between the two groups ($p = .554$).

DISCUSSION

This study supports the feasibility of studying DIR/Floortime® parent training intervention across groups of children beyond those with autism.[15-17,28] Children with non-autistic developmental disorders in the intervention group showed significantly greater involvement and had better communication with their parents or caregivers. Effect sizes were medium to large. The lack of significance in CBRS changes in compliance or cooperation and attention to activity scores between groups is similar to Casenhiser.[17] However, DIR/Floortime® does not focus on compliance nor activity but on encouraging initiation and interaction.

In this research protocol, we asked parents to spend at least 15 hours per week using the intervention with their children. Parent logs showed that only one-third of parents met the requested time. The studies of parent training programs found that when the programs were implemented with high fidelity, the parenting practices improved significantly, but the effect was much less when implementation fidelity was low.[29-30] Program adherence relates to the content and dose of the intervention. It may be moderated by the quality of training, supporting system, and participant responsiveness. More research is needed to clarify the moderating impact of the components included here in order to encourage the family to practice DIR/Floortime® at home.

Further analysis was conducted to compare gains in attention and initiation composite scores of CBRS between the parents in the invention groups who spent different amounts of time using the DIR intervention. There is no statistical difference in improvements for those children whose parents documented spending more or less time using the intervention with their children. A similar analysis was attempted to look at the effect of the different kinds of developmental disabilities across children, however, no statistical difference was detected. This finding was likely due to the small number of subjects.

Prior studies have noted a concern that parent-mediated interventions might cause increased parental stress.[31] Of additional note, we found a statistically elevated Parent-Child Dysfunctional Interaction Score of PSI. We interpret this finding in the context of both the process of training and the improvement in initiation and attention. On the one hand learning techniques for improving interactions might increase parental awareness of the problematic aspects of the relationship. Further, when a child is more able to attend to what she wants and is more able to initiate, this too may create a feeling in the parent that their relationship is harder. These concerns should be studied in more detail in future studies, particularly in light of no differences between groups in the Parental Distress Score of PSI and total PSI scores. Qualitative assessments might shed further light on the clinical impact of DIR for individual families.

Limitations

The main limitation of the current study were, first, the families in the intervention group used DIR/ Floortime® in addition to their children's routine care, whereas the control group received only their routine care. Improvements with intervention may be attributable to any amount of increase in time spent between caregivers and children.

While the effects of DIR Floortime® parent training are promising at four months, long-term effects of the intervention are unknown. Further study with more diverse caregivers, better stratification of the children regarding their challenges, and longer follow-up are needed.

Summary

Adding parent training intervention and the home-based DIR/Floortime® for 1-2 hours per day for four months produced statistically significant and clinically meaningful improvements. Further research should investigate long-term outcomes and the effects on parents' perception about their child, themselves, and their relationships with their children.

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