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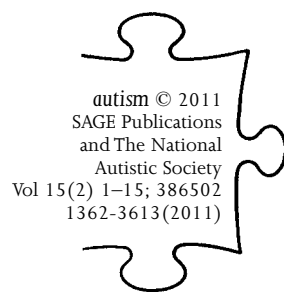
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A pilot randomized controlled trial of DIR/Floortime™ parent training intervention for pre-school children with autistic spectrum disorders



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ABSTRACT This pilot study was designed to test the efficacy of adding home-based Developmental, Individual-Difference, Relationship-Based (DIR)/Floortime™ intervention to the routine care of preschool children with autistic spectrum disorder. Measures of functional emotional development and symptom severity were taken. It was found that after the parents added home-based DIR/Floortime™ intervention at an average of 15.2 hours/week for three months, the intervention group made significantly greater gains in all three measures employed in the study: Functional Emotional Assessment Scale (FEAS) ($F = 5.1$, $p = .031$), Childhood Autism Rating Scale ($F = 2.1$, $p = .002$), and the Functional Emotional Questionnaires ($F = 6.8$, $p = .006$). This study confirms the positive results obtained by a previous DIR pilot study (Solomon et al., 2007).

KEYWORDS
autistic spectrum disorders;
DIR/Floortime™;
home-based intervention;
parent training

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Autistic spectrum disorder (ASD) is a severe developmental disability. Children with ASD typically are diagnosed before age 3. Once considered to be a very rare disorder, occurring in around 3 or 4 children per 10,000, recent epidemiological research indicates that the prevalence rate of ASD is approximately 9.0 per 1,000 population (95% CI 8.6–9.3) (Centers for Disease Control and Prevention, 2006).

Children with ASD have challenges at two levels. At one level, they are compromised in the basic foundations of relating, communicating, and

thinking, such as having difficulty with reciprocal social communication as part of a relationship. At a second level, they frequently show superficial symptoms such as repetitive behavior, self-stimulation, and self-absorption (Richler et al., 2007; Watt et al., 2008).

Children with ASD need a lot of help in developing early skills in establishing joint attention, imitation of caregivers, communicating with gesture and symbols, tolerating change and thinking logically.

This broad agenda has led to a broad range of approaches to early, comprehensive and intensive intervention, with concomitant controversial claims for their efficacy. Among the intensive therapeutic approaches, two broad types of intervention, behavioral and social-pragmatic, are typical (Prizant, and Wetherby, 1998).

On one end of the continuum is ABA, a behavioral approach based primarily on teaching practices derived from tenets of learning theory and operant conditioning (Lovaas, 1987). This approach shapes the child with autism's behavior through an operant learning paradigm using discrete behavioral trials to increase language and socialization and decrease repetitive behaviors. ABA usually consists of up to 40 hours per week of one-on-one intervention, involving repetitive practice of tasks where an adult determines the focus and goals of the intervention. Lovaas published results of a study evaluating the efficacy of this intervention in 1987, which had a tremendous impact. It was the first study to present empirically validated gains in children with autism. ABA became one of the dominant ways to work with children with ASD for many years.

In the intervening years, a number of critiques have focused on problems both with the internal and external validity of the Lovaas (1987) study (see for example, Gresham and MacMillan, 1997; Conner, 1998; Magiati and Howlin, 2001; Matson, 2007). The study has been criticized for the use of different IQ tests before and following treatment, and for its reliance on IQ as the sole psychometric measure of functioning.

Recent years have brought additional questions about the efficacy of the ABA model. In particular problems have been reported with a child's ability to generalize, dependency on cues, lack of spontaneity and self-initiated behavior, rote responding, and failure to generalize behavioral gains across settings and responses (Matson et al., 1996; Schreibman, 1997). In addition, more recent studies, which partially replicated the UCLA/Lovaas Model, showed that IQ gains were substantially smaller than in Lovaas' original study (Weiss, 1999; Harris and Handleman, 2000; Smith et al., 2000; Cohen et al., 2006). Some studies indicated little or no adaptive behavioral gains (Salt et al., 2002; Cohen et al., 2006; Reed et al., 2007), and no emotional differences when compared to a control group (Smith et al., 2000).

On the other end of the autism intervention continuum are social-pragmatic approaches that are based on typical child development (see for example, Rogers and Lewis, 1989; Greenspan and Wieder, 1997; Gutstein and Sheely, 2002; Mahoney and Perales, 2003). The prototypical social-pragmatic approach is represented by the Developmental, Individual-Difference, Relationship-Based (DIR)/Floortime™ model of Greenspan and Wieder (Greenspan and Wieder, 1997).

DIR focuses on relationships, social skills, meaningful, spontaneous use of language and communication, and integrated understanding of human development. The integrated model of human development includes interaction with caregivers and the environment, biological, motor and sensory differences, and the child's functional emotional developmental capacities. In addition to the study of 200 children with ASD (Greenspan and Wieder, 1997), there have been more recent studies which have used a relationship-based approach incorporating the fundamentals of the DIR/Floortime model. These studies demonstrate positive results for children with ASD (Mahoney and Perales, 2003; Solomon et al., 2007). However, the biggest challenge with the studies based on the DIR/Floortime model is the absence of a control group.

In Thailand, all of the hospital and special education nurseries use ABA as their main systematic treatment. Ranging from 20–40 hours per week of intensive intervention, it represents the gold standard of treatment. However, this approach is not feasible for almost all of the families in Thailand as there is a national shortage of personnel trained in these approaches. Some institutes provide additional training for parental intervention in specific skills with a range of intervention approaches involving parents in behavior management and promotion of communication skills which are non-intensive, utilizing teaching in everyday situations.

We focus this pilot study on testing whether adding the new DIR/Floortime treatment would confer additional benefits over routine clinical care available to both groups in terms of climbing 'the developmental ladder' and reducing autistic symptoms.

Method

Ethics approval

The study was approved by the Institutional Ethical Committee of Mahidol University. Written informed consent was obtained from the children's parents before enrollment in the study.

Participants

Subject recruitment was conducted by paper, advertising the DIR/Floortime model shown at the National Institute for Child and Family Development, Mahidol University, Thailand. The parents who were interested in this new treatment method could call in for registration or more information. All of the registrations were arranged in sequence and the families were serially called in to the office for screening and to confirm the diagnosis. The children whose diagnoses were confirmed by a developmental pediatrician and met clinical criteria for autistic disorders according to the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV; American Psychiatric Association, 1994) were invited to participate in the study, if they were 2–6 years of age. The children were excluded if a) they had any additional medical diagnosis (e.g. genetic syndromes, diagnosed hearing impairment, diagnosed visual impairment or seizures); b) they were geographically inaccessible for follow-up visits; or c) their parents were not literate or had known chronic psychiatric or physical illness.

Thirty-two participants were enrolled in the study. Children were assigned to either the typical treatment or DIR/Floortime-supplemented treatment groups using stratified random assignment based on age and symptom severity. Four strata were thus generated within both treatments to guarantee baseline similarity: mild autism and age 24–47 months, mild autism and age 48–72 months, severe autism and age 24–47 months, severe autism and age 48–72 months. The Childhood Autism Rating Scale (Schopler et al., 1986) was used to rate the degree of severity. Children with scores from 30 to 40 points on the CARS scale were placed in the mild autism category, and children with scores between 41 and 60 were placed in the severe autism category. There were 8 children in each stratum.

Intervention

The target treatment was based on the DIR/Floortime™ intervention developed by Greenspan and Wieder (Greenspan and Wieder, 1997). The first author, who has degrees in rehabilitation medicine, had been trained in the DIR/Floortime model from books (Greenspan and Wieder, 1998; ICDL, 2000), manuals (Greenspan and Lewis, 2005), the Floortime DVD training series (ICDL, 2005a, 2005b, 2005c), and practiced this technique as a home consultant for two years before the study started.

The study treatment involved intervention entirely with parents of children with ASD, rather than directly with the children themselves. Before the first session, all parents in the intervention group attended a one-day training workshop with the first author, to learn about the DIR/Floortime™ model. In addition, all parents received a 3-hour DVD lecture, recorded from the workshop presented by the first author. The lecture

consisted of the basic concept of DIR technique and the biological challenges of the children with ASD in terms of sensory reactivity, processing of the sensory data and planning motor responses. This lecture also included the details of Greenspan's Six Functional Developmental Levels (FDL) (Greenspan and Wieder, 1997): 1) self regulation and interest in the world; 2) engagement and relating; 3) purposeful emotional interaction; 4) social problem solving; 5) creating ideas and 6) thinking logically.

At the first one-on-one visit, the parents were trained for 1.5 hours. They were trained to observe their child's cues, follow the child's lead, and implement the Floortime™ techniques that were appropriate for their child's current level of functional development to achieve the identified goals.

If the child could not calm down or could not be warm and loving their parents were encouraged to do Floortime level 1: joining their child in an activity that gave them pleasure and maintaining mutual attention and engagement. Floortime level 1 contributed to milestone 1 and 2.

If the child could not engage in two-way gestural communication, did not express a lot of subtle emotions, or could not open and close many gestural communications in a row, their parents were encouraged to do Floortime level 2: using simple communication through animated face to face interaction with increasing back and forth communication. This achievement correlated with milestones 3 and 4.

If the child could not engage in pretend play and/or use words to convey intentions or wishes, the parents were encouraged to do Floortime level 3: helping their child to express needs, wishes and feelings through pretend play and using their ideas in daily conversation. This achievement correlated with milestone 5.

If the child could not connect thoughts logically and hold a conversation for a period of time, the parents were encouraged to do Floortime level 4: helping their child become a logical and critical thinker. This achievement correlated with milestone 6.

All of the parents were advised to help their children exhibit these aforementioned skills through a full range of emotions.

Because children with ASD do not naturally master the milestones in complete sequential order, some parents had to learn more than one technique to promote their child's development.

Modeling involved the investigator showing parents how to use Floortime™ with their child. After parents observed the investigator modeling the skills, they were asked to independently demonstrate the same skills. Modeling skills first and then asking parents to play after having observed the investigator was more accepted by Thai families than asking them to play without previous modeling from the investigator. Coaching involved

the investigator observing the parents playing with their child and giving them feedback about their performance.

In addition, each family had a manual or 'pocket book' that helped them identify activities for semi-structured problem-solving daily exercises. These activities were designed to enhance affect-based communication skills of the children and to improve basic neurological problems. The manual was based on the affect-based language curriculum (ABLC) (Greenspan and Lewis, 2005). The goals and home program were set for each family and they were asked to carry out their Floortime™ and semi-structured problem-solving activities for a minimum of 20 hours per week.

The intervention group was followed up with at the end of the first month. The observer provided feedback to the parents about how they related to their children. Controlling and intrusive responses were replaced with responses aimed at facilitating two-way emotional signaling and communication between parents and their children. Modeling and coaching were used to improve their performance. The goals, methods and techniques of the home program were refined to synchronize with the child's progress.

Families in the intervention group used the study intervention in addition to ongoing routine care of one-on-one treatment intervention based on behavioral or discrete trial principles throughout the study period.

Meanwhile, the children in the control groups continued their routine care for three months while they were waiting for the DIR/Floortime™ parent training. The baseline assessment and follow-up time schedule were similar to those of the intervention group.

Measures

Baseline demographic data included the children's profiles and their families' characteristics: marital status, having siblings or not, educational status of the mother, working status of the parents and participation in a special education (or regular) preschool program.

Primary outcome measurement

The Functional Emotional Assessment Scale (FEAS) (child behaviors) (Greenspan et al., 2001) is an observational measure that was used at the beginning of the first session and the end of the study to measure changes in children's functional development. The FEAS is a valid and reliable, age-normed, clinical rating scale that could be applied to videotaped interactions between children and their caregivers. A 15-minute videotaped child-parent interaction was collected for each child. Each parent was asked to play with their child as they normally would at home using a standard

set of toys (including symbolic, tactile and movement play materials). The change of the FEAS child score was used as the primary outcome of the overall progression.

The assessment team consisted of two developmental psychologists who had experience in assessing children with autism and were blinded to the children's group status. Intra-class correlation coefficient was applied to test the agreement between two raters. Data from 20 randomly chosen subjects were analyzed and it was found that the correlation coefficient was 0.96.

At the follow-up period, all of the children were assessed by the same FEAS items as the beginning of the study. The scores from two assessors were averaged. The increment of the averaged follow-up score from the averaged baseline score was used to determine the improvement.

Secondary outcomes measurement

The Childhood Autism Rating Scale (CARS) (Schopler et al., 1986) was used to rate the degree of autistic symptoms on a scale of 15–60. The decrement of the follow-up score from the baseline score was used to determine the improvement.

Developmental rating of the children was estimated by the parent at baseline and the end of the study using the Functional Emotional Developmental Questionnaire (FEDQ) (Greenspan and Greenspan, 2002). The questionnaire was related to Greenspan's Six Functional Development Levels (FDL): 1) shared attention and regulation; 2) engagement and relating; 3) purposeful emotional interaction; 4) social problem solving; 5) creating ideas; and 6) thinking logically. The difference between the increments determined the clinical progression.

The original version of the FEDQ was translated into Thai by the first author and then translated back into English by a fluent English speaker. The Thai version was tested for its face validity by three health care professionals who had worked in the field for more than 3 years and by one parent of a child with ASD. All of them agreed that the FEDQ had face validity as they appeared to measure the fundamental development of the children. They then examined each item of the questionnaire to find the content validity. It was found that the intra-class coefficient of each item varied from 0.75–1. The content validity of the Thai version of the FEDQ was then accepted.

Compliance, contamination and co-intervention

At the first visit, the parents were supplied with a set of weekly logs in order to help them estimate the average number of hours per week that they used the home-based DIR/Floortime™ technique as well as any other methods of interventions for their child.

Because it was nearly impossible to control the co-intervention, the input from other health and education services (e.g. part-time placement in a nursery, kindergarten) were reported.

Results

Baseline characteristics of the children with ASD and their families

Table 1 summarizes the demographic and pre-treatment scores of the intervention and control groups. The gender make-up is an 8:1 male to female ratio. Ten of sixteen children (62.5%) of the control group and 13 of 16 children (81.2%) of the intervention group were diagnosed with autistic disorder. The remaining children were classified with Pervasive Developmental Disorder, Not Otherwise Specified (PDD-NOS). The difference of these ratios was not statistically significant ($p = .430$). There was no statistical difference in the other baseline parameters of either group including average age of the children at entry, level of development and symptom severity.

In the sub-category of the overall status, the proportion of the children who had islands of the capacity to symbolize in the intervention group (10 of 16) seemed to be greater than the proportion in the control group (6 of 16) but the difference was not statistically significant (chi-square test, $p = .16$).

Regarding the families, parents in the intervention group tended to have lower levels of education than the parents in the control group and the ratio of children who had a sibling in the intervention was lower than in the control group. However, these differences were not statistically significant (chi-square test, $p = .10$).

At the beginning of the study, most of the participants in the intervention group ($n = 14$) and the control group ($n = 14$) attended either full-time or part-time special education or a (regular) preschool program for 22.6 (SD = 15.2) and 19.5 (SD = 9.9) hours per week accordingly. They also received a mixture of services including one-on-one speech therapy, occupational therapy or other treatments based on behavioral principles with 3.1 hours per week for the intervention group and an average of 3.3 hours per week for the control group.

During the study period, 11 families in the intervention group used home-based DIR/Floortime™ activities in addition to their routine programs, 3 families decreased their child's time in a pre-school classroom and 2 families stopped attending the schools in order to increase their Floortime™ at home. During the study, the intervention group performed the DIR/Floortime™ intervention at an average of 15.2 hours per week (SD = 12.4).

Table 1 Demographic and pre-treatment scores of the intervention and control groups

	Control group n = 16	Intervention group n = 16	Statistics
<i>The children</i>			
Mean age in months (SD)	51.5 (13.9)	56.6 (10.1)	$p = .24^*$
Gender (male/female)	13/3	15/1	$p = .60^*$
Diagnosis (autism/PDD-NOS)	10/6	13/3	$p = .43^*$
Mean CARS (SD)	39.7 (6.6)	37.2 (6.2)	$p = .28^*$
Mean FEAS (SD)	23.5 (12.6)	24.4 (12.7)	$p = .86^*$
Mean FEDQ (SD)	40.7 (15.3)	44.0 (12.9)	$p = .51^*$
<i>Overall status</i>			
No affective engagement	0	0	$p = .26^{**}$
Only intermittent engagement, no reciprocal communication	4	3	
Intermittent reciprocal communication, no symbolization	6	3	
Islands of symbolization	6	10	
Associated with moderate-to-severe motor planning problem	5	6	$p = .71^{***}$
On medication	5	5	$p = .50^{***}$
Participation in special education (or regular) preschool program	11	11	$p = .50^{***}$
Average hour per week (SD) of paramedical services (e.g. speech therapy, occupational therapy)	3.3 (1.4)	3.1 (1.8)	$p = .62^*$
<i>Their families</i>			
Mother has bachelor degree or higher	14	10	$p = .22^{***}$
Mother in full- or part-time employment	4	6	$p = .70^{***}$
Two-parent household	14	15	$p = .54^{***}$
Sibling in family (yes/no)	8/8	3/13	$p = .06^{***}$

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* from Student-t test; ** from chi-square for trend test; *** from chi-square test.

Note. SD = standard deviation; PDD-NOS = pervasive developmental disorder – not otherwise specified; CARS = Childhood Autism Rating Scale (Schopler et al., 1986); FEAS = Functional Emotional Assessment Scale (Greenspan et al., 2000); FEDQ = Functional Emotional Developmental Questionnaire (Greenspan and Greenspan, 2002).

Fourteen families in the control group continued their routine care whereas two families in the control group acquired Floortime™ techniques from their friends who were already trained and they used this technique in addition to their routine care with their children during the control period. In order to protect the RCT design, an 'intention to treat' analysis approach was undertaken.

Thirty-one subjects completed the study. One parent from the intervention group refused to use Floortime™ technique and decided to drop from the study after the first visit because they did not appreciate the goal set for their child of increasing engagement before trying to make the child 'talk'.

Table 2 shows the mean (SD) changes of the three outcomes for the control and intervention groups. The change of the FEAS score for the control group reflects the overall developmental progression of only 1.9 (SD = 6.1), compared to the increment of 7.0 (SD = 6.3) for the intervention group. The Student *t* test shows that the difference is statistically significant ($p = .031$). If the primary outcome of the child who dropped out of the study was estimated as a worst-case scenario (zero gain in FEAS) the difference is still statistically significant ($F = 4.6, p = .045$).

The CARS score change reflecting the overall autistic severity improvement of both groups shows a significantly greater decrease for the intervention group as compared to the control group.

Developmental rating of the children was estimated by the parent using the Thai version of the Functional Emotional Questionnaires at baseline and follow-up. The change in data for the intervention group shows that there was a more statistically significant gain in it than in the data of the control group.

If the secondary outcomes of the child who dropped out of the study were estimated as worst-case scenarios (zero change in CARS score and FEDQ) the differences are still statistically significant ($F = 1.9, p = .004$ for CARS and $F = 6.4, p = .007$ for FEDQ).

Table 2 Mean (SD) changes in standard scores

	<i>Control</i> (<i>n</i> = 16)	<i>Intervention</i> (<i>n</i> = 15)	<i>Statistics</i>
FEAS	1.9 (6.1)	7.0 (6.3)	$p = .031$
CARS	0.8 (1.2)	2.9 (2.0)	$p = .002$
FEDQ	0.8 (1.4)	7.7 (8.1)	$p = .006$

Note. FEAS = Functional Emotional Assessment Scale (Greenspan et al., 2000); CARS = Childhood Autism Rating Scale (Schopler et al., 1986); FEDQ = Functional Emotional Developmental Questionnaires (Greenspan and Greenspan, 2002).

Fidelity and outcomes

We compared the results of the intervention group to parents' reports of fidelity in delivering the weekly hours of intervention. It was found that the parents who added home-based DIR/Floortime™ intervention 10 hours per week or more ($n = 9$) made greater gains in FEAS than the parents who added the intervention less than 10 hours per week ($n = 6$), but the difference was not statistically significant ($p = .095$).

Discussion

This pilot study reported an RCT of a DIR/Floortime™ parent training intervention for preschool children with ASD. It employed a low-cost and widely applicable professional-as-consultant, parent-as-therapist model.

Overall the parents in this study were well educated and families were intact. Many families had one parent who was not working outside. Half of the families had only one child. The families in this pilot study were volunteers and thus more likely to get the benefit from a parent training model.

Even though the aim of the study was to test the efficacy of Greenspan's DIR (Developmental, Individual-Difference, Relationship-Bases)/Floortime model (Greenspan and Wieder, 1997) added to the children's routine care, there were some families in the intervention group who decided to partially or totally change their approaches; 5 families decreased or stopped their children's time in a pre-school classroom in order to increase their Floortime™ at home. The reason for their decision was their satisfaction with the results after they started the new intervention.

On the contrary, there were many parents who appreciated the results of their attempt but found it difficult to implement and maintain the recommended activities as much as they wished, often because of demands of other children, work, or their family life. Another difficulty encountered was that parents had to change their practice from giving 'an order' and waiting for 'the right response' to challenging their children to be truly interactive with them.

On the primary outcome measure, the intervention group showed a gain of 7.0 points during the 3-month period, which was a statistically significant difference compared to the gain of 1.9 points in the comparison group. Translated clinically, the newly added intervention could help the autistic child to better engage, relate and communicate with their caregiver than those who received the routine behavioral interventions.

A similar effect was found on the secondary outcome measures. The differences were directly attributed to the home-based training. This data confirms the results of the treatment intervention based on DIR/Floortime theory reported by Solomon and colleagues (2007).

Compared to the results of Solomon's study, in which the FEAS increased from 38.1 to 44.6 within a 1-year period of DIR/Floortime-based intervention, our children in the intervention group showed similar results within a shorter duration. The positive results shown in such a short period could be explained by the fact that at baseline our children had fewer opportunities for interaction and lacked adequate and appropriate treatment. They went to school too early and spent more time in school than those in Solomon's study. Many children in this study participated in special education or regular preschool programs even while they were not yet fully engaged with their parents. In such a situation the teacher or teacher's aides could not conduct one-on-one interaction with each child, and the partially engaged autistic child was therefore being left self-absorbed most of the time.

Another reason for this impressive improvement related to the fact that children in our study had lower baseline scores than those in Solomon's. This prevented the possibility of a ceiling effect, and also allowed DIR/Floortime™ work to address more basic capacities such as regulation and attention.

In addition, it was found that the majority of the parents in the beginning of our study did not know how to play with their children. They spent most of their time controlling and teaching their children. This may be the results of Thai culture and educational background that do not prefer the young to express themselves but rather do only what adults tell them to do. This was different from the parents in Solomon's study. As a result, the parent in our study had a greater chance to improve their abilities after being coached.

In the situation of being determined as under-treated, adding home-based DIR/Floortime™ intervention for an average of 15.2 hours per week for three months could ensure more statistically favorable outcomes.

There were a number of methodological limitations. Since the recruitment process included a flyer advertising this new intervention, the results of the study could have been affected by involving families that were particularly interested in learning this new intervention. There was some contamination, with varying types and amounts of interventions in the control group. Additionally, the treatment group also contained a varying amount of intervention.

Families in the intervention group used DIR/Floortime™ in addition to their children's routine and behavioral treatment, whereas the control group received only their routine behavioral care. It is possible that the results, which demonstrated gains in the intervention group, could be attributed not only to the DIR/Floortime intervention, but simply to more time spent with parents and more time spent in intensive intervention.

The outcome measurement also presented some limitations. Our main measurement was the FEAS, which is DIR theory-specific. Information on other important outcomes was not measured, such as cognitive skills, social functioning and school performance. Additionally, the impact of the competing demands of other children, work, and family life was not measured.

Although it is difficult to verify the accuracy of parent's reports regarding the number of hours spent doing the intervention at home, parents' logs have been systematically used by other studies evaluating parents' delivery of intervention (Solomon et al., 2007; Mahoney and Perales, 2005; Dawson et al., 2010).

In conclusion, this trial confirmed the replicability of the home-based DIR/Floortime™ intervention across sites. A large-scale randomized controlled trial should be carried out to enable investigators to analyze variables, such as subjects' characteristics, that may be associated with favorable or unfavorable responses to interventions. In addition, the outcome measurement should be more comprehensive.

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