

A Randomized Controlled Trial of Parent-Child Psychotherapy Targeting Emotion Development for Early Childhood Depression

Joan L. Luby, M.D., Deanna M. Barch, Ph.D., Diana Whalen, Ph.D., Rebecca Tillman, M.S., Kenneth E. Freedland, Ph.D.

Objective: Clinical depression in children as young as age 3 has been validated, and prevalence rates are similar to the school-age disorder. Homotypic continuity between early and later childhood depression has been observed, with alterations in brain function and structure similar to those reported in depressed adults. These findings highlight the importance of identifying and treating depression as early as developmentally possible, given the relative treatment resistance and small effect sizes for treatments later in life. The authors conducted a randomized controlled trial of a dyadic parent-child psychotherapy for early childhood depression that focuses on enhancing the child's emotional competence and emotion regulation.

Method: A modified version of the empirically tested parent-child interaction therapy with a novel "emotion development" module (PCIT-ED) was compared with a waiting list condition in a randomized controlled trial in 229 parent-child dyads with children 3–6.11 years of age. Both study arms lasted 18 weeks.

Results: Children in the PCIT-ED group had lower rates of depression (primary outcome), lower depression severity, and lower impairment compared with those in the waiting list condition (Cohen's *d* values, >1.0). Measures of child emotional functioning and parenting stress and depression were significantly improved in the PCIT-ED group.

Conclusions: The findings from this randomized controlled trial of a parent-child psychotherapy for early childhood depression suggest that earlier identification and intervention in this chronic and relapsing disorder represents a key new pathway for more effective treatment. Manualized PCIT-ED, administered by master's-level clinicians, is feasible for delivery in community health settings.

Am J Psychiatry 2018; 175:1102–1110; doi: 10.1176/appi.ajp.2018.18030321

Over the past two decades, empirical studies have validated clinical depressive disorders in children as young as age 3 (1–5). Early childhood depression has been detected in epidemiological samples in the United States and elsewhere at prevalence rates of 1%–2%, comparable to school-age depression (5–8). Homotypic continuity between early and later childhood depression has been observed in longitudinal studies, establishing developmental continuity of the disorder (9, 10). Alterations in brain function and structure, with patterns similar to those observed in adolescent and adult depression, have been found in school-age children with a history of early childhood depression followed longitudinally, even when depression had remitted (11–13). Additionally, alterations in functional brain activity and connectivity similar to those found in depressed adults have been reported in acutely depressed preschoolers (14–17). These behavioral and brain findings show that clinical depression can arise in early childhood and has phenotypic and biological characteristics similar to those of the adult form. Such findings underscore the importance of

identifying and treating this disorder at these early developmental stages. However, to date there are no empirically tested treatments for early childhood depression.

The need for the development and testing of early interventions for depression is further emphasized by findings that the school-age form of the disorder has proven to be difficult to treat effectively with available interventions. A meta-analysis of cognitive-behavioral therapy in depressed school-age children, a treatment with known efficacy in depressed adolescents, demonstrated only small to moderate effect sizes (0.35 overall) (18). This has led to a call for new models for investigating depressive (and other) disorders using a neurodevelopmental approach (19, 20). In this context, the relatively large effect sizes reported in several early childhood interventions for other forms of psychopathology and developmental disability are of interest (21–23). A number of factors, including the powerful influence of the parent-child relationship, as well as greater neuroplasticity in early childhood (24), may serve as unique contributors to the

See related features: **Editorial** by Dr. Silverman and Dr. Pettit (p. 1051), **CME course** (p. 1151), **AJP Audio** (online), and **Video** by Dr. Pine (online)

robust treatment effects evident in earlier interventions. Similar to the well-established greater efficacy of early interventions to remediate developmental disorders, these promising findings in other childhood psychiatric disorders raise the possibility that earlier interventions in depressive disorders may provide a window of opportunity for more effective treatment.

The urgent need for studies of early psychotherapeutic interventions for depression is further underscored by sharp increases in the use of psychotropic medications for young children (25–27). Zito et al. (28) reported that 20% of all psychotropic prescriptions for preschoolers were antidepressants and that the use of antidepressants increased significantly with increasing age during the preschool period (ages 3–6). Olfson et al. (29) reported striking increases in the prescription of antipsychotics to preschoolers with depression diagnoses after the U.S. Food and Drug Administration issued a black box warning on antidepressants, as well as declining rates of psychotherapy use in preschoolers. Given the unknown efficacy and questions about the long-term safety of these agents in young children, these trends strongly point to the need for a safe and effective psychotherapeutic treatment for preschoolers with depressive disorders.

Given these issues, we sought to develop and test a novel psychotherapy for early childhood depression. To do this, we adapted and tested the widely used and proven effective early intervention for disruptive disorders, parent-child interaction therapy (PCIT), which has been shown to have large and sustained effects (30, 31). Utilizing the basic techniques of PCIT, we added a novel “emotion development” module to address depressive symptoms, dubbed PCIT-ED. Building on promising findings from a pilot study (32), a large-scale randomized controlled trial was launched at the Washington University School of Medicine Early Emotional Development Program.

METHOD

Overview

This single-blind randomized controlled trial compared PCIT-ED to a waiting list control condition. A waiting list control comparison condition was justified on the basis of two factors. First, there is no other empirically tested or widely used treatment for early childhood depression, so use of an active control was not possible. Treatment as usual in most communities is watchful waiting (33). Second, in order to maintain study subjects in a non-treatment arm, a waiting list condition that offered the active treatment after the waiting period has proven to be the most feasible approach, as opposed to watchful waiting or treatment as usual. Participants on the waiting list were therefore offered PCIT-ED on completion of the waiting period if the child remained symptomatic (see Figure S1 in the online supplement). For the primary analyses, participants who were randomly assigned to treatment were compared with those assigned to the waiting list condition.

Recruitment

All study materials and procedures were approved in advance by the Washington University School of Medicine

institutional review board. Written informed consent was obtained from all caregivers and verbal assent from children. The trial was registered with ClinicalTrials.gov. Young children (ages 3.0–6.11) from the St. Louis metropolitan area were screened and recruited from preschools, day care centers, primary care practices, and mental health facilities. We obtained 1,378 completed Preschool Feelings Checklist questionnaires, a validated brief screening measure with good sensitivity and specificity for early childhood depression (34). For children whose scores were ≥ 3 ($N=811$), a more comprehensive telephone screening was conducted in which the depression module of the Preschool Age Psychiatric Assessment (PAPA) was administered to caregivers to further assess children for study inclusion and exclusion criteria. All children who met symptom criteria for early-onset depression on the PAPA (the validated syndrome that requires four instead of five symptoms of depression) and who did not have an autism spectrum disorder, a serious neurological or chronic medical disorder, or a significant developmental delay were invited for an in-person assessment ($N=369$) (see Figure S2 in the online supplement for a CONSORT diagram).

Children on antidepressant medications or in ongoing psychotherapy were excluded because such treatments may be efficacious in ameliorating depression and we sought to test the efficacy of PCIT-ED without augmentation from other treatments. However, children who were on stable dosages of other psychotropic medications without antidepressant properties, such as guanfacine and stimulants, were not excluded. Children on unstable medication dosing (e.g., undergoing active medication titration) and those with unstable caregiving (no long-term stable caregiver) were excluded. Preschoolers who were too severely depressed to wait 18 weeks for treatment (e.g., child or family in acute or serious distress) were excluded and referred for immediate treatment.

All dyads who passed these stages participated in a comprehensive baseline mental health and emotional development assessment (detailed below) at the Washington University School of Medicine Early Emotional Development Program. Children who met criteria for early childhood major depression were randomly assigned to either PCIT-ED or the waiting list condition, with randomization stratified by gender and comorbid externalizing disorders.

Baseline and End-of-Trial Assessment Methods

Children and caregivers were scheduled for a 5-hour baseline assessment. Caregivers were interviewed using the Schedule for Affective Disorders and Schizophrenia–Early Childhood (K-SADS-EC) (35) to assess the child’s psychiatric symptoms and assign DSM-5 diagnoses. Caregivers also completed a battery of psychosocial questionnaires that assessed the child’s emotion regulation and guilt processing, parental psychopathology, parenting practices, and stress. Income-to-needs ratio was computed as the total family income at baseline divided by the federal poverty level, based on family size at baseline.

Measures of depression and comorbid psychopathology or impairment. The K-SADS-EC is a semistructured clinical interview for DSM-5 disorders adapted for use in children ages 3.0–6.11. This measure has test-retest reliability and construct validity, and it generates both categorical and dimensional measures of major DSM-5 disorders (16, 35). The presence and severity of major depression and comorbid disorders were assessed at baseline and at trial completion. All K-SADS-EC interviews were conducted by master's-level clinicians and were videotaped, reviewed for reliability, and calibrated for accuracy. Satisfactory interrater reliability was established before the study started, and kappa values during the study were computed on a monthly basis; the overall kappa value during the study period was 0.74 for major depression and 0.88 for all diagnoses. The depression core score was the number of core depressive symptoms endorsed on the K-SADS-EC.

The Preschool Feelings Checklist, a validated screening checklist with favorable sensitivity, was used to capture high risk for major depression in young children (34). The Preschool Feelings Checklist–Scale Version, a 23-item Likert scale adapted from the original instrument, was administered at the baseline and end-of-trial assessments to measure depression severity via caregiver report (32).

The Children's Global Assessment Scale (CGAS) is a standardized instrument that measures children's global level of impairment; it was completed by the clinician-rater.

The Clinical Global Impressions improvement scale (CGI-I) is a 7-point Likert scale widely used in treatment research that measures the blind clinician-rater's impression of improvement.

The Preschool and Early Childhood Functional Assessment Scale/Child and Adolescent Functional Assessment Scale (PECFAS/CAFAS) is a semistructured measure of functioning rated by the clinician (who achieves reliability prior to administration). It assesses the child's psychosocial functioning and impairment based on parent report of the child's functioning in specific domains and information gleaned from the K-SADS-EC.

Measures of the child's emotion regulation and guilt processing. The Emotion Regulation Checklist, a caregiver-report measure of children's self-regulation, targets affective lability, intensity, valence, and flexibility and includes both positively and negatively weighted items on a Likert scale.

The My Child questionnaire is a widely used caregiver-report measure with established validity and reliability that assesses the child's tendency to experience guilt and how the child addresses these feelings.

Measures of parenting style, stress, and depression severity. The Parenting Stress Index is a reliable and valid caregiver-report measure designed to measure the magnitude of stress within the parent-child dyad via caregiver report.

The Coping With Children's Negative Emotions scale is a valid and reliable caregiver-report measure of parental

coping styles and strategies in response to children's expression of negative emotions.

The Beck Depression Inventory–II (BDI-II), a reliable and valid self-report measure, was used to assess severity of depression in caregivers.

Randomization Procedures

The SAS procedure PLAN was used to generate a randomization table for each combination of the two stratifying variables. A permuted block design was utilized so that group assignment would be relatively balanced among each of the four stratification groups (male and female, with and without externalizing comorbidity). The randomization assignments were created before the study began and were saved in a password-protected Excel file that only the data manager had access to. Prior to randomization, the assignments were concealed from all study personnel other than the data manager.

Blinding of End-of-Trial Assessment

Upon treatment or waiting list completion, an assessment was conducted in which the above-listed measures were repeated. All clinician-administered ratings were completed by independent raters (master's-level clinicians) who were blind to treatment group and otherwise uninvolved in the study (see the online supplement for more details about maintaining the blind). Families were instructed not to reveal their group assignment to the rater and to avoid use of treatment language or terminology. Events where the blind was broken were tracked.

Treatment

Parent Child Interaction Therapy–Emotion Development (PCIT-ED) is a dyadic parent-child psychotherapy expanded and adapted from the well-validated and widely used PCIT (30). A novel emotion development module was added and follows completion of standard PCIT modules, which were limited to 12 sessions. The eight-session emotion development module builds on empirical findings in emotional development utilizing the basic techniques of PCIT (teaching of parent followed by coaching the parent in interactions with the child in vivo, using a bug-in-the-ear device) to focus on enhancing the child's emotional competence (36) and emotion regulation (37). This approach addresses early childhood depression as a disorder of emotional development characterized by impairments in the ability to recognize, understand, and regulate emotions in self and others, as well as targeting increased reactivity to negative stimuli and decreased reactivity to positive stimuli. Enhancement of these skills is achieved by training the parent to serve as a more effective external emotion regulator and emotion coach for the child. Therefore, the emotion development module directly targets the parent's skill as an emotion teacher and facilitator for the child. To achieve this, discussion of challenging emotional situations and real-life events as well as emotionally evocative events in vivo are used, during which therapists

TABLE 1. Baseline Demographic and Diagnostic Characteristics of Participants in a Randomized Controlled Trial of Parent-Child Interaction Therapy–Emotion Development (PCIT-ED)^a

Measure	Waiting List Group (N=115)		PCIT-ED Group (N=114)		Comparison	
	Mean	SD	Mean	SD	t	p
Demographic characteristics						
Age (years)	5.28	1.13	5.14	0.97	1.00	0.319
Income-to-needs ratio	2.85	1.35	3.13	1.31	−1.55	0.123
	N	%	N	%	χ^2	p
Female	42	36.5	38	33.3	0.26	0.613
Hispanic	10	8.7	15	13.2	1.17	0.279
Race						
Caucasian	82	71.3	94	82.5	Fisher's exact test	0.103
African American	17	14.8	9	7.9		
Asian	0	0.0	1	0.9		
More than one race	16	13.9	10	8.8		
	Mean	SD	Mean	SD	t	p
Symptom severity						
Depression core score ^b	5.71	1.51	5.49	1.47	1.13	0.261
Preschool Feelings Checklist–Scale Version score	41.58	11.22	38.75	9.58	2.05	0.041
Children's Global Assessment Scale score	42.67	6.60	44.00	6.54	−1.52	0.130
Preschool and Early Childhood Functional Assessment Scale/Child and Adolescent Functional Assessment Scale	11.88	3.53	11.91	4.04	−0.05	0.959
Maternal depression						
Beck Depression Inventory–II score	12.10	9.76	10.62	8.53	1.22	0.225
	N	%	N	%	χ^2	p
Baseline consensus diagnoses						
Major depressive disorder	115	100.0	114	100.0	—	—
Mania or hypomania	2	1.7	2	1.8	Fisher's exact test	1.000
Anxiety disorder	49	42.6	45	39.5		
ADHD	38	33.0	30	46.3	1.24	0.265
Oppositional defiant disorder	56	48.7	58	50.9	0.11	0.741
Conduct disorder	3	2.6	3	2.6	Fisher's exact test	1.000

^a ADHD=attention deficit hyperactivity disorder.^b Depression core score is the number of core depressive symptoms endorsed on the Schedule for Affective Disorders and Schizophrenia–Early Childhood.

coach the parent to use a skill set that validates and tolerates the child's emotions and assists the child in regulating intense emotions. The length of the manualized treatment is 20 sessions conducted over 18 weeks. Therapist training and intervention fidelity monitoring procedures as well as number of sessions completed are described in detail in the online supplement.

Analysis

Baseline demographic, diagnostic, and severity characteristics were compared in the PCIT-ED and waiting list groups using t tests for continuous variables and chi-square tests for dichotomous variables. The primary outcome measure of major depression diagnosis and the secondary outcome measures of major depression severity and scores on the Preschool Feelings Checklist–Scale Version, CGAS,

PECFAS/CAFAS, and BDI-II were analyzed in all study subjects who underwent randomized assignment, using multiple imputation to ensure that there were no missing values at the end-of-trial assessment (38). Major depression diagnosis was analyzed using logistic regression, and the continuous measures were analyzed using general linear models. All models covaried for the baseline characteristic corresponding to the dependent variable and the stratification variables gender and baseline externalizing disorder. Details of the imputation methods are provided in the online supplement. Secondary analyses compared PCIT-ED and waiting list participants who completed the end-of-trial assessment, regardless of whether they had completed all study assessments or therapy sessions. As in the primary analyses, continuous measures were analyzed with general linear models and dichotomous measures with logistic regression.

TABLE 2. Assessment of Outcome Measures at Trial Completion in a Randomized Controlled Trial of Parent-Child Interaction Therapy–Emotion Development (PCIT-ED)^a

Measure	Waiting List Compared With PCIT-ED					
	Estimate	SE	t	p	Odds ratio	95% CI
Primary outcome measure						
Major depressive disorder diagnosis	1.20	0.18	6.60	<0.001	9.52	8.44, 10.74
Secondary outcome measures						
Depression core score ^b	2.34	0.26	9.11	<0.001	1.01	
Preschool Feelings Checklist–Scale Version score	11.91	1.29	9.26	<0.001	1.04	
Children’s Global Assessment Scale score	–20.49	2.31	–8.87	<0.001	1.16	
Preschool and Early Childhood Functional Assessment Scale/Child and Adolescent Functional Assessment Scale score	3.19	0.46	6.91	<0.001	0.78	
Beck Depression Inventory–II score	2.04	0.76	2.68	0.007	0.24	

^a False discovery rate–corrected p values did not differ from standard p values. Missing end-of-trial data were imputed using multiple imputation. Cohen’s d is for the change from baseline to end-of-trial assessment averaged across 25 imputed data sets. Odds ratio are computed from combined data from 25 imputed data sets. Analyses covary for baseline characteristics, gender, and baseline externalizing disorder.

^b Depression core score is the number of core depressive symptoms endorsed on the Schedule for Affective Disorders and Schizophrenia–Early Childhood.

These models also covaried for baseline characteristics, gender, and baseline externalizing disorder.

Effect sizes for analyses of multiply imputed data were calculated using the imputed data sets. For continuous variables, means and standard deviations for the difference between baseline and end-of-trial scores were obtained and averaged across the 25 data sets. These statistics were then used to compute Cohen’s d. An odds ratio and 95% confidence interval for major depression diagnosis at trial completion (the primary outcome) were computed using data from all 25 imputed data sets. For the analysis of participants who completed the trial, effect size was calculated as follows: For continuous variables, the partial eta-squared was obtained from the general linear model that took covariates into account. In addition, Cohen’s d was calculated by comparing the change in scores from baseline to trial completion in each group. For dichotomous variables, effect size was the odds ratio, which was reported with its 95% confidence interval.

With 91 participants in the waiting list group 100 in the PCIT-ED group completing the study, a difference in rates of end-of-trial major depression diagnosis of 19.5% could be detected with 90% power. To account for multiple comparisons, false discovery rate p values were computed for each set of analyses.

RESULTS

The end-of-trial assessment occurred a mean of 169.1 days (SD=24.9) after baseline in the PCIT-ED group and 139.2 days (SD=11.0) after baseline in waiting list group ($t=10.92$, $p<0.001$).

A total of 229 parent-child dyads were included in the study. Table 1 details baseline demographic, maternal depression, diagnostic, and depression severity characteristics in the two

groups. Children in the waiting list group were significantly more impaired on the Preschool Feelings Checklist–Scale Version.

As seen in Table 2, results of analyses conducted on multiply imputed end-of-trial data including all children who underwent randomized assignment showed significant differences between the PCIT-ED and waiting list groups on major depression diagnosis and secondary outcomes, with PCIT-ED subjects showing decreased major depression severity. Table 3 presents comparisons of major depression diagnosis, remission rates (defined by not meeting diagnostic criteria for

major depression and a reduction $\geq 50\%$ in depression core score from baseline to trial completion), and depression severity, as well as comorbid diagnostic characteristics among participants who completed the end-of-trial assessment. Children in the PCIT-ED group were significantly less likely than those in the waiting list group to meet criteria for major depression in the past month, more likely to have achieved remission, and more likely to score lower on major depression severity based on the K-SADS-EC sum scores (Cohen’s $d=1.02$) and Preschool Feelings Checklist–Scale Version (Cohen’s $d=1.11$). They were also less impaired than those in the waiting list group, as indicated by the CGAS (Cohen’s $d=1.16$) and the PECFAS/CAFAS (Cohen’s $d=0.91$). Global improvement, measured with the CGI-I, indicated significant improvement from baseline to trial completion in the PCIT-ED group compared with the waiting list group (Cohen’s $d=1.25$). In addition, rates of comorbid disorders at trial completion, including anxiety disorders and oppositional defiant disorder, were significantly lower in the PCIT-ED group.

The PCIT-ED group also differed significantly from the waiting list group at trial completion on measures of emotional development and regulation. Specifically, at the end-of-trial assessment, children in the PCIT-ED group were rated by their caregivers on the Emotion Regulation Checklist as exhibiting less emotional lability (a mean of 29.2 [SD=6.4] compared with 37.2 [SD=7.6]; $t=-9.83$, $p<0.001$; Cohen’s $d=1.21$) and more emotion regulation (a mean of 26.4 [SD=3.5] compared with 24.1 [SD=3.3]; $t=5.36$, $p<0.001$; Cohen’s $d=0.69$), as well as greater guilt reparation on the My Child questionnaire (a mean of 27.4 [SD=5.3] compared with 24.7 [SD=5.0]; $t=5.13$, $p<0.001$; Cohen’s $d=0.70$). There were significant differences in parental characteristics between the PCIT-ED and waiting list groups at the end-of-trial assessment, with parents who completed PCIT-ED having

TABLE 3. Diagnostic and Severity Characteristics in Participants Who Completed the End-of-Trial Assessment in a Randomized Controlled Trial of Parent-Child Interaction Therapy–Emotion Development (PCIT-ED)^a

Measure	Waiting List Group (N=91)		PCIT-ED Group (N=100)		Waiting List Compared With PCIT-ED			
	%	N	%	N	χ^2	p	Odds ratio	95% CI
Primary outcome measure								
Major depressive disorder diagnosis	74.7	68	22.0	22	46.92	<0.001	12.15	5.95, 24.82
Secondary outcome measures								
Remission								
Remission of major depression ^b	23.1	21	73.0	73	42.86	<0.001	0.10	0.05, 0.20
Preschool Feelings Checklist–Scale Version score reduced $\geq 50\%$, no major depression	5.6	5	43.4	43	26.43	<0.001	0.07	0.03, 0.20
	Mean	SD	Mean	SD	t	p	Partial η^2	Cohen's d
Severity								
Depression core score ^c	4.15	2.04	1.74	1.69	9.11	<0.001	0.31	1.02
Preschool Feelings Checklist–Scale Version score	33.20	11.10	20.10	9.65	9.44	<0.001	0.33	1.11
Impairment								
Children's Global Assessment Scale score	55.75	17.14	76.83	16.61	−8.62	<0.001	0.29	1.16
Preschool and Early Childhood Functional Assessment Scale/Child and Adolescent Functional Assessment Scale score	8.07	4.02	4.83	3.22	7.15	<0.001	0.23	0.91
Clinical Global Impressions improvement score	3.40	1.25	2.07	0.86	8.67	<0.001	0.29	1.25
	%	N	%	N	χ^2	p	Odds ratio	95% CI
Comorbidities								
Mania or hypomania	0.0	0	0.0	0	—	—	—	—
Anxiety disorder	26.4	24	10.1	10	10.37	0.001	4.52	1.80, 11.31
ADHD	22.0	20	13.1	13	1.50	0.221	1.72	0.72, 4.12
Oppositional defiant disorder	38.5	35	14.1	14	16.95	<0.001	5.95	2.55, 13.89
Conduct disorder	1.1	1	1.0	1	—	—	—	—

^a False discovery rate—corrected p values did not differ from standard p values. Cohen's d is for the change from baseline to trial completion. Analyses covary for baseline characteristics, gender, and baseline externalizing disorder. ADHD=attention deficit hyperactivity disorder.

^b Remission was defined as not meeting diagnostic criteria for major depressive disorder and a reduction $\geq 50\%$ in depression core score from baseline to trial completion.

^c Depression core score is the number of core depressive symptoms endorsed on the Schedule for Affective Disorders and Schizophrenia–Early Childhood.

decreased personal symptoms of depression and lower scores on parenting stress in addition to employing more parenting techniques that focused on emotion reflection and processing (Table 4). The correlation between change in maternal BDI-II score and change in child Preschool Feelings Checklist–Scale Version score from baseline to trial completion was 0.387 ($p < 0.001$) in the PCIT-ED group. Baseline comparisons for emotion, cognitive, executive, and parenting characteristics are summarized in Tables S2 and S3 in the online supplement. The treatment was rated by parents as highly acceptable, with an overall mean rating of 67.3 ($SD=6.4$) out of 75 on the Eyberg Therapy Attitude Inventory and 96% of parents rating their impression of the therapy program as “good” or “very good.”

DISCUSSION

This randomized controlled trial compared a parent-child psychotherapy—an adaptation of PCIT with a new module

focused on emotional development (PCIT-ED)—with a waiting list control condition for the treatment of early childhood depression. The findings show that the treatment was effective in producing remission of depression and marked decreases in depression severity compared with the waiting list condition. Children in the PCIT-ED group also showed marked improvements in general functioning and decreases in impairment. To our knowledge, this is the first empirically supported psychotherapeutic intervention specific to early childhood depression. Based on its efficacy and effect sizes, this treatment now represents an important new low-risk, effective option for the treatment of early childhood depression. Other important features of this intervention that make it highly feasible and cost-effective for public health delivery are that it can be delivered by trained master's-level therapists and that it is a relatively brief, 20-session manualized treatment.

In addition to remediation of depression and marked reductions in impairment, children in the PCIT-ED group

TABLE 4. Measures of Parenting Characteristics in Participants Who Completed the End-of-Trial Assessment in a Randomized Controlled Trial of Parent-Child Interaction Therapy–Emotion Development (PCIT-ED)^a

Measure	Waiting List Group (N=90)		PCIT-ED Group (N=96)		Waiting List Compared With PCIT-ED				
	Mean	SD	Mean	SD	t	p	FDR p	Partial η^2	Cohen's d
Parenting Stress Index ^b									
Distractibility/hyperactivity	27.72	7.54	21.16	6.34	7.04	<0.001	<0.001	0.21	0.79
Adaptability	29.60	6.20	25.29	5.77	6.52	<0.001	<0.001	0.19	0.90
Reinforces parent	11.09	4.27	9.41	3.36	3.46	<0.001	0.001	0.06	0.39
Demandingness	26.79	7.28	21.71	6.77	5.48	<0.001	<0.001	0.14	0.70
Mood	18.51	3.63	14.48	4.03	7.83	<0.001	<0.001	0.25	1.02
Acceptability	13.61	2.47	11.35	2.93	5.01	<0.001	<0.001	0.12	0.53
Child domain	127.33	24.77	103.40	22.66	8.00	<0.001	<0.001	0.26	1.06
Competence	29.07	7.58	26.63	7.19	1.75	0.082	0.113	0.02	0.20
Isolation	14.38	5.19	12.84	4.39	2.52	0.013	0.023	0.03	0.30
Attachment	12.38	4.37	11.33	3.52	1.20	0.233	0.285	0.01	0.08
Health	11.64	3.78	10.77	3.85	0.74	0.462	0.523	0.00	0.00
Role restriction	18.46	6.14	17.96	5.35	0.57	0.568	0.568	0.00	0.08
Depression	20.73	6.67	19.08	5.94	1.75	0.082	0.113	0.02	0.20
Spouse	18.10	7.08	17.83	6.86	-0.68	0.499	0.523	0.00	0.13
Life stress	5.38	6.21	4.77	7.35	0.70	0.482	0.523	0.00	0.09
Parent domain	124.73	31.32	116.45	29.37	1.26	0.208	0.269	0.01	0.14
Total stress	252.07	49.19	219.84	47.23	5.04	<0.001	<0.001	0.12	0.70
Defensive responding	36.83	11.04	34.28	10.09	1.98	0.049	0.077	0.02	0.26
Parental depression									
Beck Depression Inventory–II score ^c	8.87	8.98	6.14	7.17	2.36	0.020	0.033	0.03	0.24
Coping With Children's Negative Emotions scale ^d									
Expressive encouragement	5.22	1.24	6.00	0.88	-6.22	<0.001	<0.001	0.17	0.81
Emotion-focused reactions	5.84	0.83	5.42	1.03	3.94	0.001	<0.001	0.08	0.56
Minimization reactions	2.13	0.78	1.69	0.65	5.58	<0.001	<0.001	0.14	0.70

^a Cohen's d is for the change from baseline to trial completion. Analyses covary for baseline characteristics, gender, and baseline externalizing disorder. FDR=false discovery rate.

^b Lower scores on the Parenting Stress Index represent more adaptive behavior.

^c For the Beck Depression Inventory–II, Ns were 91 for the waiting list group and 100 for the PCIT-ED group.

^d For the Coping With Children's Negative Emotions scale, Ns were 90 for the waiting list group and 99 for the PCIT-ED group.

also showed improvements in emotional functioning in areas directly targeted by the treatment—specifically, emotion regulation and guilt processing. Emotion dysregulation and excessive guilt with low ability for proactive reparation are known features of early childhood depression (39). The findings of this study suggest that these emotion development targets, key to affective disorders and functioning more generally, are modifiable in early childhood. It will be important to determine whether gains in these emotional parameters are sustained over time, as is often seen in other early developmental interventions, including standard PCIT.

This parent-child treatment, which also focused on modifying parenting, had marked positive effects on parenting stress and depression experienced by caregivers. Parents who received the active treatment displayed more emotionally focused parenting techniques and reported marked reductions in stress and a greater sense of positive responsiveness from their child. Also notable was that the treatment resulted in significant reductions in parental depression, even though this was not a direct target of treatment. This is consistent with findings from an earlier pilot study of PCIT-ED (32) and may represent a virtuous cycle whereby child depression remission results in improvements

in parental depression, a new direction of effect, as the reverse direction has been previously documented (40). These findings, taken together, suggest a number of positive benefits for parents from the treatment.

The use of a waiting list control condition was a limitation of the study. While effect sizes were relatively large, a waiting list control condition does not provide an ideal comparison condition. However, in a disorder and age group for which there was no available empirically proven treatment, this was a necessary first step. Further studies will be needed to compare PCIT-ED with other, more active comparison conditions to better estimate clinically meaningful effects that can be compared with treatments in older children (where effect sizes may be based on active comparisons). In addition, a short follow-up period is another limitation. It will be important to test how gains made in treatment endure over time. Such a longitudinal follow-up would provide a test of the additional value of early intervention from a lifespan perspective.

While PCIT itself has been established as a powerfully effective intervention for early childhood disruptive behavior, it has not previously been tested for the treatment of depression. Furthermore, few studies have investigated parent-child psychotherapies for their efficacy for clinical-

Patient Perspective

“Michael,” age 5, was referred to treatment because of his irritable and sad mood and his tendency to blame himself for things and make self-deprecatory statements. Despite his mother’s observation that he was well liked by his peers, he often said, “No one likes me.” In the emotion development sessions of treatment, Michael and his mother reviewed events in preschool when he felt rejected by peers, and the therapist coached the mother to help him read more accurately and reinterpret his peers’ responses. The mother was also coached to help Michael identify and express his feelings more clearly. During an exercise designed to induce guilt, the mother was coached to provide reassurance to Michael, explaining that the transgression was not his fault, and to engage in proactive reparation (such as coming up with a

solution on how to repair the problem) rather than retreating into shame or fearing rejection. Over time, these skills were practiced at home, and Michael’s mother’s reactions to his negative affect changed dramatically. “Instead of telling him not to cry or to not let it bother him, as I had gotten into the habit of doing,” she said, “I learned he needed to understand and explore his negative feelings and that I needed to tolerate them before we could learn together to help him react differently.” Michael learned to identify what made him feel bad about himself and to pick up on the signals from peers that they did want to play with him. By the end of treatment, his self-esteem was improved and he began to enjoy activities and play. He also sought out his mother when he was struggling with negative feelings to help him resolve them.

level diagnoses in early childhood. Another finding, related to this, was that comorbid disorders, including oppositional defiant disorder and anxiety disorders, were also significantly reduced in the PCIT-ED group. The study findings suggest that early intervention for depression may be a window of opportunity to modify emotional functioning, utilizing the powerful influence of the parent-child relationship during this relatively neuroplastic developmental period to remediate depressive symptoms. Given that depression is a chronic and relapsing disorder, these findings on an early, low-cost, low-risk psychotherapeutic intervention suggest that early identification and treatment of depressive disorders should become a public health priority.

AUTHOR AND ARTICLE INFORMATION

From the Department of Psychiatry, the Department of Radiology, and the Department of Psychological and Brain Sciences, Washington University in St. Louis.

Address correspondence to Dr. Luby (lubyj@wustl.edu).

Supported by NIMH grant 5R01MH098454-04.

ClinicalTrials.gov identifier: NCT02076425.

Dr. Luby has received research support from NIMH and royalties from Guilford Press. Dr. Freedland has received research grants from the National Heart, Lung, and Blood Institute and an editorial honorarium from the Society for Health Psychology. The other authors report no financial relationships with commercial interests.

Received March 20, 2018; accepted April 6, 2018; published online June 20, 2018.

REFERENCES

1. Luby JL, Heffelfinger AK, Mrakotsky C, et al: Preschool major depressive disorder: preliminary validation for developmentally modified DSM-IV criteria. *J Am Acad Child Adolesc Psychiatry* 2002; 41:928–937
2. Luby JL, Heffelfinger AK, Mrakotsky C, et al: The clinical picture of depression in preschool children. *J Am Acad Child Adolesc Psychiatry* 2003; 42:340–348
3. Luby JL, Mrakotsky C, Heffelfinger A, et al: Characteristics of depressed preschoolers with and without anhedonia: evidence for a melancholic depressive subtype in young children. *Am J Psychiatry* 2004; 161:1998–2004
4. Luby JL, Belden AC, Pautsch J, et al: The clinical significance of preschool depression: impairment in functioning and clinical markers of the disorder. *J Affect Disord* 2009; 112:111–119
5. Egger HL, Angold A: Common emotional and behavioral disorders in preschool children: presentation, nosology, and epidemiology. *J Child Psychol Psychiatry* 2006; 47:313–337
6. Wichstrøm L, Berg-Nielsen TS, Angold A, et al: Prevalence of psychiatric disorders in preschoolers. *J Child Psychol Psychiatry* 2012; 53:695–705
7. Lavigne JV, Lebaillly SA, Hopkins J, et al: The prevalence of ADHD, ODD, depression, and anxiety in a community sample of 4-year-olds. *J Clin Child Adolesc Psychol* 2009; 38:315–328
8. Gleason MM, Zamfirescu A, Egger HL, et al: Epidemiology of psychiatric disorders in very young children in a Romanian pediatric setting. *Eur Child Adolesc Psychiatry* 2011; 20:527–535
9. Luby JL, Si X, Belden AC, et al: Preschool depression: homotypic continuity and course over 24 months. *Arch Gen Psychiatry* 2009; 66:897–905
10. Bufferd SJ, Dougherty LR, Carlson GA, et al: Psychiatric disorders in preschoolers: continuity from ages 3 to 6. *Am J Psychiatry* 2012; 169:1157–1164
11. Gaffrey MS, Luby JL, Repovš G, et al: Subgenual cingulate connectivity in children with a history of preschool depression. *Neuroreport* 2010; 21:1182–1188
12. Luking KR, Repovš G, Belden AC, et al: Functional connectivity of the amygdala in early-childhood-onset depression. *J Am Acad Child Adolesc Psychiatry* 2011; 50:1027–41.e3, e3
13. Barch DM, Gaffrey MS, Botteron KN, et al: Functional brain activation to emotionally valenced faces in school-aged children with a history of preschool-onset major depression. *Biol Psychiatry* 2012; 72:1035–1042
14. Gaffrey MS, Luby JL, Belden AC, et al: Association between depression severity and amygdala reactivity during sad face viewing in depressed preschoolers: an fMRI study. *J Affect Disord* 2011; 129:364–370
15. Gaffrey MS, Barch DM, Singer J, et al: Disrupted amygdala reactivity in depressed 4- to 6-year-old children. *J Am Acad Child Adolesc Psychiatry* 2013; 52:737–746

16. Gaffrey MS, Barch DM, Bogdan R, et al: Amygdala reward reactivity mediates the association between preschool stress response and depression severity. *Biol Psychiatry* 2018; 83:128–136
17. Belden AC, Irvin K, Hajcak G, et al: Neural correlates of reward processing in depressed and healthy preschool-age children. *J Am Acad Child Adolesc Psychiatry* 2016; 55:1081–1089
18. Weisz JR, McCarty CA, Valeri SM: Effects of psychotherapy for depression in children and adolescents: a meta-analysis. *Psychol Bull* 2006; 132:132–149
19. Hyman SE: Can neuroscience be integrated into the DSM-V? *Nat Rev Neurosci* 2007; 8:725–732
20. Insel T, Cuthbert B, Garvey M, et al: Research Domain Criteria (RDoC): toward a new classification framework for research on mental disorders. *Am J Psychiatry* 2010; 167:748–751
21. Dawson G: Early behavioral intervention, brain plasticity, and the prevention of autism spectrum disorder. *Dev Psychopathol* 2008; 20: 775–803
22. Webster-Stratton C, Hammond M: Treating children with early-onset conduct problems: a comparison of child and parent training interventions. *J Consult Clin Psychol* 1997; 65:93–109
23. Webster-Stratton C, Reid MJ, Hammond M: Treating children with early-onset conduct problems: intervention outcomes for parent, child, and teacher training. *J Clin Child Adolesc Psychol* 2004; 33:105–124
24. Johnson MH: Sensitive periods in functional brain development: problems and prospects. *Dev Psychobiol* 2005; 46:287–292
25. DeBar LL, Lynch F, Powell J, et al: Use of psychotropic agents in preschool children: associated symptoms, diagnoses, and health care services in a health maintenance organization. *Arch Pediatr Adolesc Med* 2003; 157:150–157
26. Rushton JL, Whitmire JT: Pediatric stimulant and selective serotonin reuptake inhibitor prescription trends: 1992 to 1998. *Arch Pediatr Adolesc Med* 2001; 155:560–565
27. Zito JM, Safer DJ, dosReis S, et al: Trends in the prescribing of psychotropic medications to preschoolers. *JAMA* 2000; 283: 1025–1030
28. Zito JM, Safer DJ, DosReis S, et al: Rising prevalence of antidepressants among US youths. *Pediatrics* 2002; 109:721–727
29. Olsson M, Crystal S, Huang C, et al: Trends in antipsychotic drug use by very young, privately insured children. *J Am Acad Child Adolesc Psychiatry* 2010; 49:13–23
30. Eyberg SM, Funderburk BW, Hembree-Kigin TL, et al: Parent-child interaction therapy with behavior problem children: one and two year maintenance of treatment effects in the family. *Child Fam Behav Ther* 2001; 23:1–20
31. Brestan EV, Eyberg SM: Effective psychosocial treatments of conduct-disordered children and adolescents: 29 years, 82 studies, and 5,272 kids. *J Clin Child Psychol* 1998; 27:180–189
32. Luby J, Lenze S, Tillman R: A novel early intervention for preschool depression: findings from a pilot randomized controlled trial. *J Child Psychol Psychiatry* 2012; 53:313–322
33. Freedland KE, Mohr DC, Davidson KW, et al: Usual and unusual care: existing practice control groups in randomized controlled trials of behavioral interventions. *Psychosom Med* 2011; 73:323–335
34. Luby JL, Heffelfinger A, Koenig-McNaught AL, et al: The Preschool Feelings Checklist: a brief and sensitive screening measure for depression in young children. *J Am Acad Child Adolesc Psychiatry* 2004; 43:708–717
35. Gaffrey MS, Luby JL: Kiddie-Schedule for Affective Disorders and Schizophrenia–Early Childhood Version (KSADS-EC), 2012 Working Draft. St Louis, Washington University, 2012
36. Saarni C: The Development of Emotional Competence. New York, Guilford, 1999
37. Lenze SN, Pautsch J, Luby J: Parent-child interaction therapy emotion development: a novel treatment for depression in preschool children. *Depress Anxiety* 2011; 28:153–159
38. Little RJ, D'Agostino R, Cohen ML, et al: The prevention and treatment of missing data in clinical trials. *N Engl J Med* 2012; 367: 1355–1360
39. Luby J, Belden A, Sullivan J, et al: Shame and guilt in preschool depression: evidence for elevations in self-conscious emotions in depression as early as age 3. *J Child Psychol Psychiatry* 2009; 50:1156–1166
40. Weissman MM, Wickramaratne P, Pilowsky DJ, et al: Treatment of maternal depression in a medication clinical trial and its effect on children. *Am J Psychiatry* 2015; 172:450–459