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# A randomized clinical trial comparing family-focused treatment and individual supportive therapy for depression in childhood and early adolescence

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## Accepted Manuscript

A Randomized Clinical Trial Comparing Family-Focused Treatment and Individual Supportive Therapy for Depression in Childhood and Early Adolescence

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## **A Randomized Clinical Trial Comparing Family-Focused Treatment and Individual Supportive Therapy for Depression in Childhood and Early Adolescence**

Running Head: RCT Childhood Depressive Disorders

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This article is discussed in an editorial by Dr. Laura J. Dietz on p. xx.

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## **ABSTRACT**

**Objective.** Despite the morbidity and negative outcomes associated with early-onset depression, few studies have examined the efficacy of psychosocial treatment for depressive disorders during childhood. Integrating family in treatment may have particularly salutary effects during this developmental period. This trial compared immediate posttreatment impacts of family-focused treatment for childhood depression (FFT-CD) and individual supportive psychotherapy (IP) for children aged 7-14 years with depressive disorders.

**Method.** Children were randomized to 15 sessions of FFT-CD ( $n = 67$ ) or IP ( $n = 67$ ) over 4 months. The primary treatment outcome was adequate clinical depression response, defined as a  $\geq 50\%$  reduction on the Children's Depression Rating Scale-Revised (CDRS-R). Additional outcomes included patient-centered outcomes (parent- and child-reported treatment satisfaction), remission (defined as  $CDRS-R \leq 28$ ), change on continuous CDRS-R score, and change on child and parent reports of depressive and non-depressive symptoms and social adjustment.

**Results.** Significant improvement was evident across groups on depressive and non-depressive symptoms, global response, and functioning/social adjustment. Compared to children randomized to IP, children randomized to FFT-CD showed higher rates of adequate clinical depression response (77.7% vs. 59.9%, number needed to treat = 5.72,  $OR = 2.29$ , 95%  $CI [1.001, 5.247]$ ,  $t = 1.97$ ,  $p = .0498$ ). Across treatments families reported high satisfaction; relative to IP families, FFT-CD families reported greater knowledge and skills for managing depression. There were no significant differences between treatment arms on secondary outcomes.

**Conclusion.** Results support the value of psychosocial intervention, underscore the important role families play, and highlight the potential for FFT-CD for supporting recovery among children suffering from depression.

**Clinical trial registration information—**Systems of Support Study for Childhood Depression;

<http://clinicaltrials.gov/>; NCT01159041

**Key words.** Childhood depression treatment; family-focused therapy; intervention; psychoeducation

## **INTRODUCTION**

Approximately 3-4% of preadolescent youths suffer from depressive disorders, and rates increase markedly from childhood through adolescence.<sup>1</sup> Although less prevalent than in adolescence, depression in children is often chronic and severe,<sup>2,3</sup> with significant relapse risk and poor overall functioning,<sup>2,4</sup> bipolar outcome,<sup>4</sup> and residual social impairments.<sup>5</sup> This high morbidity, relapse, and dysfunction may powerfully impede the negotiation of crucial developmental tasks.

Despite significant advances in the treatment of depression in adolescence, few approaches, either psychosocial<sup>6</sup> or pharmacological,<sup>7</sup> have significant empirical support for treating children. Results of a recent meta-analysis raised questions regarding the efficacy of antidepressant medications over placebo for youths in general,<sup>8</sup> and some data suggest potentially less efficacy for children compared to adolescents.<sup>7</sup> Given the general preference for non-medication treatments for children and adolescents with depression and internalizing problems,<sup>9,10</sup> there is a strong need for effective psychosocial interventions. The few randomized clinical trials (RCTs) of psychosocial treatments mostly focus on youths with high depressive symptoms.<sup>11</sup> One small RCT demonstrated significantly reduced depressive symptoms and higher remission rates among youths receiving family-based interpersonal psychotherapy for depressive disorders, compared to child-centered supportive therapy,<sup>12</sup> supporting the promise of a family-based approach.

Family-based interventions may be particularly beneficial during middle to late childhood given developmental considerations, including greater dependence on parents and rapidly changing cognitive capacity. Younger children are strongly embedded in their family context and dependent on parents to provide support and feedback; parents tend to play an active role

interfacing with the community to facilitate development (e.g. enrolling youths in activities/programs) and modeling/teaching coping and key life skills. These facts underscore the need for developmentally-informed treatment during this phase.

To address the needs of children struggling with depression, we developed a family-focused treatment rooted in family and cognitive-behavioral treatment models. As described elsewhere,<sup>13</sup> our Family-Focused Treatment for Child Depression (FFT-CD) focuses on the developmental needs in two major ways. First, throughout FFT-CD, numerous strategies are used to enhance family relationships and foster positive, supportive parent–child interactions. For example, each session includes regular use of tokens or “family thanks notes” for providing positive feedback between members; positive communication skills are directly taught and practiced; and children and parents plan and implement enjoyable family activities. Second, sessions focus on boosting skills for coping with stress and strengthening emotion regulation using techniques such as communication enhancement, problem-solving training, and behavioral activation. Throughout treatment, therapists emphasize the developmentally appropriate provision of parent support to facilitate enhanced emotion regulation. Although FFT-CD utilizes many CBT skills-based components, it differs in its strong emphasis on interpersonal interactions and relationship enhancement.

In our Phase 1 trial, children receiving FFT-CD demonstrated significant improvements in depressive symptom severity and rates of recovery, with 77% of participants no longer meeting criteria for depressive disorder (major depressive disorder [MDD] or dysthymic disorder [DD]) by 3 months posttreatment.<sup>14</sup> Given evidence of safety, feasibility, and benefits, the current two-site RCT was developed to rigorously evaluate FFT-CD compared to individual supportive psychotherapy (IP). Specific aims were to evaluate: 1) the efficacy of FFT-CD, compared to IP, on adequate clinical depression response (primary outcome) at a posttreatment assessment; and 2) the impact of FFT-CD, compared to IP, on patient-centered outcomes (parent- and child-reported satisfaction with and perceived helpfulness of treatment), remission, interviewer-rated

depressive symptoms and global functioning, child and parent report of child depressive symptoms, child-reported social functioning and anxiety symptoms, and parent-reported externalizing and internalizing problems.

## **METHOD**

This protocol was registered with [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01159041) (NCT01159041). Procedures were approved by institutional review boards at both sites and monitored by a National Institute of Mental Health-designated data safety and monitoring board. Parents gave written informed consent, and children gave assent.

### **Participant Selection, Recruitment, and Enrollment**

Participants were recruited by advertisement through local parent magazines, radio, print and internet; coordination with mental health and pediatric facilities; and outreach to schools and parent-teacher associations. Following brief telephone screening, participants were evaluated for eligibility and baseline clinical status. Eligibility criteria for youths included: (a) diagnosis of current MDD, DD, or depressive disorder-not otherwise specified (DD-NOS); (b) age between 7-14; (c) parent/caregiver willing to participate; and (d) willingness to provide informed consent (assent). Exclusion criteria were thought or other disturbances that would interfere with participation in treatment or assessments (e.g., psychotic disorder, pervasive developmental disorder, severe obsessive-compulsive disorder [OCD], active substance abuse/dependence, mental retardation), a conduct disorder that threatened the stability of the home environment (e.g., recent arrests, juvenile justice, and/or children's protective service involvement), or lacked English fluency.

### **Randomization and Blinding**

Eligible participants were randomly assigned in a 1:1 ratio to FFT-CD or IP using a computerized algorithm, with assessment staff masked to treatment allocation. A block randomization strategy was employed, stratified by site, gender, baseline depression diagnosis (syndromal [MDD or DD] vs. subsyndromal [DD-NOS]) and presence vs. absence of

antidepressant medication treatment at baseline, with a random mix of blocks of length 2 and 4.

**Treatment Arms.** The interventions were to have comparable treatment exposure, with both including fifteen 50-60 minute sessions. Because families could not always attend weekly, we allowed up to 22 weeks for completion. To minimize the effects of clinician characteristics and ensure equivalent levels of therapeutic skill across treatment arms, the same therapists administered both interventions. Intensive training, supervision, and monitoring were conducted to prevent contamination across treatment arms.

### **FFT-CD**

FFT-CD is rooted in cognitive-behavioral and family treatments and designed to assist families in developing skills to combat depression and create ways of interacting that protect the child from some of the negative sequelae of stress.<sup>13</sup> Within a broader psychoeducational framework, interpersonal factors impacting the maintenance and treatment of youth depression are emphasized, using models demonstrating the interplay of mood and interpersonal interactions. Families identify specific “downward and upward spirals” affecting their interactions, and learn skills to enhance family functioning and reduce stress, including communication enhancement, behavioral activation, and family problem-solving. Handouts describe skills to be learned, and role-playing, behavioral rehearsal, and homework assignments are used to shape behaviors.

### **IP**

IP used Client Centered Therapy, an adaptation of a manualized approach for children exposed to trauma,<sup>15</sup> that controlled for nonspecific factors, specifically therapist characteristics, time, and treatment exposure. IP emphasized individual sessions, with an initial parent session and brief, supportive parent meetings every 3-4 weeks. The IP goal was to help children gain greater understanding of their emotions through empathic listening; techniques included reflecting and clarifying emotions, nondirective problem-solving, positive feedback, and exploring and labeling children’s emotional/behavioral reactions. Family sessions and cognitive-

behavioral techniques (e.g., active modeling, problem-solving training, cognitive restructuring) were prohibited.

### **Therapist Training and Quality Assurance**

Therapists had at least a master's degree in psychology or social work and attended or observed a two-day workshop for each intervention modality, were certified in each treatment model based on tape review of their first two cases, and were supervised weekly (M.C.T. for FFT-CD; D.A.L. for IP). Booster trainings occurred at study midpoint.

Following certification, therapist adherence and competence were evaluated on three randomly selected sessions for each case. Adherence refers to the degree to which therapists implemented the intervention components specified in the treatment manual; competence refers to the skill with which the therapist integrated family concerns during implementation. Given the same therapists administered both treatments, it was essential to ensure there was no contamination between study arms. Using FFT-CD and IP evaluation measures, we found high therapist adherence to and competence in the assigned treatment in both study arms and strong differentiation between treatments, suggesting that there were minimal cross-over effects (Table 1). On 7-point scales, IP participants received low adherence and competence ratings for FFT-CD and high ratings for IP. Conversely, FFT-CD participants received high ratings for FFT-CD adherence and competence and low ratings for IP adherence ratings. FFT-CD participants received high ratings for IP competence, reflecting similar levels of therapist warmth and genuineness across treatments.

### **Assessments**

Parents and children completed baseline and posttreatment assessments. Raters had at least a master's degree in psychology or social work and were blind to intervention assignment. *DSM-IV-TR*<sup>16</sup> diagnoses were based on information from the Schedule for Affective Disorders and Schizophrenia for School-Aged Children<sup>17</sup> administered to both parents and children. Inter-rater agreement was excellent for depression diagnoses (MDD,  $\kappa = 0.95$ ; any depression

diagnosis,  $\kappa = 0.91$ ) and major classes of comorbid disorders ( $\kappa = 0.76 - 1.00$ ). Depression severity over the past two weeks was measured using the interviewer-rated Child Depression Rating Scale-Revised (CDRS-R;  $ICC = 0.94$ ).<sup>18</sup> Interviewer-rated overall functioning was assessed on the Children's Global Assessment Scale (CGAS;  $ICC = .77$ ).<sup>19</sup> Patient-centered outcomes were assessed on parent- and child-rated 5-point scales of overall satisfaction, degree of symptoms improvement, family problem improvement, parents feeling capable of helping their child, and children feeling capable in solving their problems. Depressive symptoms were assessed using the child- and parent-report Child Depression Inventory (CDI).<sup>20</sup> Social functioning over the past two weeks was indicated on the Social Adjustment Scale for Children - Self-Report (SAS-SR)<sup>21</sup> and anxiety with the Multidimensional Anxiety Scale for Children.<sup>22</sup> Parent-reported internalizing and externalizing problems were assessed with the Child Behavior Checklist.<sup>23</sup>

**Statistical Analyses.** The primary outcome was adequate clinical depression response, defined as a 50% reduction in CDRS-R from baseline to posttreatment, consistent with adolescent depression treatment trials.<sup>6</sup> CDRS-R scores were rescaled to range from 0-90 so as not to create an artificial floor for possible percentage reduction. Given that a score of 28 or less on the CDRS-R is often used as an indicator of remission in medication trials, we included this indicator as a secondary outcome.<sup>7</sup> Further, given the lack of treatment trials for youth 12 years old and younger and the study's initially proposed sample of 7–12-year-olds (which was expanded to aid recruitment), as well as the developmental focus of this treatment on pre-adolescent youth with depression, we have provided sensitivity analyses focused only on the 7–12-year-old participants. Additional secondary outcomes included patient-centered outcomes (parent and child satisfaction with treatment), total depressive symptoms (continuous CDRS-R), child- and parent-reported depressive symptoms, overall and social functioning, anxiety symptoms, and parent-reported internalizing and externalizing problems.

We compared FFT-CD and IP groups on demographic and clinical characteristics to assess

balance across experimental arms at baseline using t-tests for continuous variables and chi-square for categorical variables. Logistic regression was used to identify factors related to treatment dropout and assessment non-response (i.e., lack of posttreatment assessment). Treatment effects were evaluated using intent-to-treat (ITT) analyses. We fit a logistic regression model for adequate clinical depression response, a dichotomous outcome, with treatment arm as the independent variable. Continuous outcomes were assessed using linear mixed effects models with treatment group (FFT-CD, IP) as the between-subjects factor, time (baseline, posttreatment) as the within-subjects factor, and group-by-time interaction. Site and site-by-treatment interactions were included in initial models but were removed from the final presented models given their non-significance. To illustrate the magnitude of effects, we present proportions, odds ratios (ORs), and number needed to treat (NNT) for binary variables; and group means, adjusted average treatment effects, and Cohen's  $f^2$  for continuous variables. Results without imputation for missing data were similar to the reported ITT analyses, but effects were stronger with the treatment effects for remission significant in completer analyses.

Multiple imputation by chained equations<sup>24</sup> was used to address missing responder and remission status for the 13.4% of participants who did not complete the posttreatment assessment and missing covariates. Imputations were produced separately by treatment arm to avoid biasing treatment-effect estimates. The primary outcome models were run on 5 imputed data sets and estimates combined such that standard errors reflect the variability introduced by the imputation process.<sup>25-27</sup> Variables associated with dropout were included in the imputation model and thus not adjusted for in the final analyses. For continuous outcomes, mixed effects models automatically handle missing data through likelihood estimation, producing unbiased estimates as long as observations are missing at random. Factors associated with non-response to assessment were thus included as covariates in these models.

## **RESULTS**

### **Participant Disposition and Flow Through the Study**

As illustrated in the Consolidated Standards of Reporting Clinical Trials diagram (CONSORT; Figure 1), of 134 children randomized ( $n=67$  FFT-CD,  $n=67$  IP), 116 (86.6%) completed posttreatment assessment, including some treatment dropouts. Across treatment arms the number of treatment sessions attended (FFT-CD  $M = 11.25$ ,  $SD = 4.97$ ; IP  $Mean = 11.78$ ,  $SD = 4.64$ ;  $t(132) = -0.59$ ,  $p = .55$ ) and rates of treatment dropout were comparable ( $OR = 1.26$ ,  $p = .56$ ) with 14.2% of participants classified as early treatment dropouts (0-4 sessions: FFT-CD  $n = 10$ , 14.9%; IP  $n = 9$ , 13.4%), 11.9% as mid-treatment dropouts (5-9 sessions: FFT-CD  $n = 9$ , 13.4%; IP  $n = 7$ , 10.5%) and 73.9% as treatment completers (10-15: FFT-CD  $n = 48$ , 71.7%; IP  $n = 51$ , 76.1%). Assessment non-response was more common among FFT-CD versus IP youths ( $OR = 2.99$ ,  $p = .05$ ). Treatment dropout and assessment non-response at posttreatment were associated with non-white race ( $OR = 3.71$ ,  $p = .002$ ;  $OR = 3.14$ ,  $p = .03$ , respectively), one-parent family composition ( $OR = 3.00$ ,  $p = .007$ ;  $OR = 3.52$ ,  $p = .02$  respectively), lower income ( $OR = 0.62$ ,  $p = .002$ ;  $OR = 0.68$ ,  $p = .04$  respectively), and overall lower depression severity on the pretreatment CDRS-R ( $OR = 0.96$ ,  $p = .04$ ;  $OR = 0.95$ ,  $p = .06$  respectively).

### **Demographic and Clinical Characteristics Across Treatment Groups**

Referrals included 47 (35%) from clinical settings, 59 (44%) from advertising, 14 (10.5%) from schools, and 14 (10.5%) from other sources. Treatment groups did not differ on baseline clinical and demographic variables. Table 2 shows the baseline demographic and clinical characteristics; Table 3 displays the means and standard deviations for the continuous outcomes at baseline and follow-up. The sample was 56% female, had a mean age of almost 11 years, included diverse racial/ethnic groups, and had median income in the \$50,000 - \$74,999 range (approximately 36% of families reported an income below \$50,000, and 45% reported an income above \$75,000). Approximately 60% of youths were living with two parents. Major depressive disorder was the predominant diagnosis (71%), and comorbidity was common. Antidepressant medication usage was uncommon (10%), but prior outpatient and

school-based treatment was common.

### **Primary Clinical Outcome**

As illustrated in Table 4, ITT analyses indicated a statistically significant group effect for adequate clinical depression response based on a CDRS-R reduction of  $\geq 50\%$ , with those randomized to FFT-CD more likely to show this response than those randomized to IP (77.7% vs. 59.9%,  $NNT = 5.72$ ,  $OR = 2.291$ , 95%  $CI [1.001, 5.247]$ ,  $t = 1.97$ ,  $p = .0498$ ). The ITT model with imputation was consistent with the complete data model (79.6% FFT vs. 59.7% IP,  $NNT = 5.0$ ,  $OR = 2.64$ , 95%  $CI [1.15, 6.08]$ ,  $\chi^2 = 5.37$ ,  $df = 1$ ,  $p = .0205$ ). As noted in Table 4, the group difference in remission did not rise to the level of statistical significance ( $p = .1043$ ) in ITT analyses. However, in the model using complete data, FFT-CD children had significantly higher rates of remission compared to IP children (53.7% FFT vs. 35.5% IP,  $NNT = 5.5$ ,  $OR = 2.11$ , 95%  $CI [1.001, 4.448]$ ,  $\chi^2 = 3.89$ ,  $df = 1$ ,  $p = .0486$ ). There were no statistically significant differences between the two intervention conditions within the 7–12-year-old subsample in ITT analyses. However, as with the full sample, the results were strongest for adequate clinical depression response, which showed a trend-level treatment effect in the ITT analyses ( $p = .0895$ ) and a significant effect favoring FFT-CD in the completer analyses (84.6% FFT vs. 64.4% IP,  $NNT = 4.96$ ,  $OR = 3.03$ , 95%  $CI [1.049, 8.782]$ ,  $\chi^2 = 4.40$ ,  $df = 1$ ,  $p = .0360$ ).

Patient-centered outcomes included overall treatment satisfaction and satisfaction on specific domains targeted in FFT-CD (e.g., parental understanding of how to help their child, child belief that treatment helped them get along better with their family). Similar overall satisfaction was reported across conditions (Table 5), with most parents and children “strongly agreeing” that they were satisfied with treatment. Compared with IP parents, FFT-CD parents agreed more with statements that treatment helped them understand a) how to manage their child’s depression and b) what to do/not do to help their child. FFT-CD children agreed more with the statement that attending sessions helped them get along better with their family,

relative to IP children.

### **Secondary Continuous Outcomes**

Raw data on continuous outcomes, pre- and posttreatment, are included in Table 3. As illustrated in Table 6, after adjusting for race, income, and family composition, there was a significant time effect on all measures, with children showing improvement from baseline to posttreatment on depression severity (CDRS-R, CDI), functioning (CGAS, SAS-SR), and comorbid symptoms (MASC, CBCL Internalizing and Externalizing); however, there were no treatment group nor treatment group-by-time interaction effects.

### **Predictors and Moderators of Treatment Outcome**

We examined demographic (age group, gender, race, family composition, family income) and clinical variables (syndromal versus subsyndromal depression, baseline CDRS score, comorbid anxiety disorder, comorbid disruptive behavior disorder, chronicity, current antidepressant medication) as potential predictors and moderators of treatment response but found no significant effects.

## **DISCUSSION**

This study reports immediate posttreatment data from an RCT comparing FFT-CD to IP for the treatment of depressive disorders in 7–14-year-olds – the largest study to date to evaluate a psychosocial treatment specifically designed for children with primary depressive disorders. Major findings were: 1) FFT-CD was associated with increased likelihood of an adequate depression clinical response (reduction in CDRS-R score  $\geq$  50%), compared to IP, with the NNT estimate suggesting that treating roughly 5.72 children with FFT-CD would lead to one additional positive treatment response as compared to IP; 2) both FFT-CD and IP led to improvements, with 77.7% responding to FFT-CD and 59.9% to IP; 3) parent and child satisfaction was high for both treatments, but FFT-CD recipients reported being better able to manage depression and associated problems; and 4) across treatments, improvements over time were observed across measures of depression, functioning/social adjustment, and non-

depressive symptoms.

The finding that children improved over time is consistent with the literature indicating that depressive disorders in children tend to resolve with time and diverse treatment approaches yield benefits – the so-called dodo bird verdict (“all have won and all shall have prizes”).<sup>28</sup> Consistent with study hypotheses, FFT-CD was associated with greater depression clinical response than individual supportive therapy and greater remission rates in completer analyses. These results are consistent with Dietz et al.<sup>12</sup> showing the superiority of family-based interpersonal therapy compared to individual client-centered therapy, and other studies supporting benefits of family treatments for childhood mood disorders<sup>29</sup> and other child<sup>30,31</sup> as well as adolescent disorders.<sup>32,33</sup> This advantage for FFT-CD is noteworthy given that IP was an active treatment condition and that child and parent satisfaction was high and similar across conditions.

Although effects were in the expected direction, treatment groups did not differ significantly on the other secondary outcomes. This is likely a function of several factors. First, lack of differences on continuous measures may reflect unexplained variability that was eliminated when dichotomizing the primary outcome. Second, the sample reflected the frequent heterogeneity typical of youth depression, and non-specific effects of IP had potent impact across a range of variables. Third, although the study was powered for medium effect sizes, effects may have been smaller for secondary and exploratory outcomes. Finally, analyses of later outcomes may be important for clarifying the value of FFT-CD relative to other treatments on a range of measures, as other studies of FFT in bipolar illness have found the advantages of FFT to be stronger at later follow-up points.<sup>34,35</sup>

Satisfaction and adherence data reflect strong parent and child alliances and that, across conditions, therapists were able to build rapport and foster therapeutic relationships – important non-specific treatment factors. When asked how much treatment helped them positively interact as a family, FFT-CD parents and children were more likely to endorse greater understanding

and improved behaviors in response to treatment, suggesting perceived changes in the target mechanisms of FFT-CD.

Methodological strengths included full, reliable diagnostic evaluation at all time points with blind assessment by independent evaluators; equivalence of groups across baseline demographic and clinical characteristics; an active comparison condition controlling for non-specific treatment factors (e.g., therapist factors, time, dose); and clear differentiation between treatment arms. The study also has limitations. First, lacking an inactive control group, we cannot determine the degree to which improvement might be attributed to the tendency for depressive disorders to remit over time, although the average length of depressive episodes in children in clinical settings may typically be 7-9 months,<sup>2</sup> suggesting both study treatments may have accelerated recovery. Given the deleterious impact of youth depressive disorders, it was unethical to include an untreated group. Second, although the treatment model was originally designed for children ages 7-12,<sup>14</sup> because of the low rate of depressive disorders in preadolescents and the impact of this age effect on recruitment, we expanded to an upper age limit of 14 years. FFT-CD may be particularly beneficial during childhood but comparable to IP as youths enter adolescence. This study was underpowered to detect treatment group-by-age interactions or other moderation effects. Third, the same therapists provided both FFT-CD and IP. Although this strategy ensured both treatments were delivered with similarly high levels of therapeutic skill and minimized clinician differences across treatments, it introduced the possibility for cross-over effects between conditions and therapist allegiance to one condition. However, fidelity ratings included consideration of therapists' use of treatment-specific interventions (prescribed) as well as non-use of alternative intervention strategies (proscribed); high adherence to both treatments provides strong evidence that there was little contamination across modalities. Additionally, high competence ratings in both arms suggest that, despite any potential therapist allegiances, they delivered both interventions well.

Overall, our findings underscore the value of psychosocial interventions in the treatment

of depressive disorders in childhood. The high rate of response to IP may be a function of nonspecific factors, as well as the passage of time,<sup>28</sup> and is consistent with other studies that employed this client-centered approach.<sup>15</sup> During this period of development, a strategy that formally integrates the family within treatment and provides specific and tailored skills/strategies for managing stress may have some advantage over a less structured, supportive approach. FFT-CD with its strong emphasis on enhancing family strengths and coping may provide an ideal approach during this developmental period.

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Table 1. Treatment Adherence/Competence

Type of Treatment	FFT-CD Mean (SD)	IP Mean (SD)
<b>FFT-CD</b>		
Competence in FFT-CD	6.43 (1.10)	1.75 (1.26)
Adherence to FFT-CD	6.34 (1.44)	1.07 (0.26)
<b>IP</b>		
Competence in IP	6.95 (0.17)	7.00 (0)
Adherence to IP	1.03 (0.25)	6.57 (1.38)

Note: All scales were rated from (1) not at all competent/adherent to (7) extremely competent/adherent. FFT-CD = Family-Focused Treatment for Childhood Depression; IP = Individual Psychotherapy.

Table 2. Sample Characteristics

	Total (n = 134)	FFT-CD (n = 67)	IP (n = 67)	p-value
<b>Child Age Mean (SD)</b>	10.84 (2.09)	10.73 (2.10)	10.96 (2.09)	.54
<b>Child Age Group, n(%)</b>				.84
Childhood (ages 7-12)	99 (74)	50 (75)	49 (73)	
Early adolescent (13-14)	35 (26)	17 (25)	18 (27)	
<b>Child Gender, n(%)</b>				.86
Female	75 (56)	37 (55)	38 (57)	
Male	59 (44)	30 (45)	29 (43)	
<b>Child Race/Ethnicity, n(%)</b>				.57
Caucasian	68 (51)	37 (55)	31 (46)	
Latino/Hispanic	20 (15)	10 (15)	10 (15)	
African-American	35 (26)	14 (21)	21 (31)	
Other	11 (8)	6 (9)	5 (8)	
<b>Family Composition, n(%)</b>				.31
Two parents	80 (60)	43 (64)	37 (55)	
One parent/guardian	54 (40)	24 (36)	30 (45)	
<b>Family Income Mean (SD)</b>	3.84 (1.31)	3.95 (1.26)	3.72 (1.36)	.31
<b>Child Depression Diagnosis, n(%)</b>				.71
Major depression	89 (66)	43 (64)	46 (69)	
Dysthymic disorder	24 (18)	12 (18)	12 (18)	
Double depression	7 (5)	3 (4)	4 (5)	
Depressive disorder NOS	14 (11)	9 (14)	5 (8)	
<b>Diagnostic Comorbidity, n(%)</b>				
Anxiety disorders	50 (37)	21 (31)	29 (43)	.15
Disruptive behavior disorder	56 (42)	24 (36)	32 (48)	.16
<b>Treatment Utilization</b>				
<b>Medication – Current, n(%)</b>				
Any	32 (24)	14 (21)	17 (26)	.54
Antidepressant	15 (10)	6 (9)	9 (13)	.41
Stimulant	14 (10)	6 (9)	8 (12)	.57
Other	10 (7)	7 (10)	3 (4)	.19
<b>Treatment Service History, n(%)</b>				
Intensive	6 (4)	3 (4)	3 (4)	.95
Outpatient	55 (41)	27 (40)	28 (42)	.74
School-based	71 (53)	33 (49)	38 (57)	.28
Medical	42 (31)	23 (34)	19 (28)	.49
Other	10 (7)	6 (9)	4 (6)	.54

Note: Income ranges from 1 (< \$14,000 annually) to 5 (> \$75,000 annually). “Disruptive behavior disorder” includes attention-deficit/hyperactivity disorder, oppositional defiant disorder, and conduct disorders. Treatment Service History: Individuals may be in multiple categories. “Intensive” describes inpatient, partial hospitalization or day treatment; “outpatient” describes therapy and crisis services; “school-based” describes special class or school, counselor, or psychologist or other mental health service; “medical” describes physician or ER visits; “other” describes religious or holistic practitioners; “medication other” describes guanfacine, divalproex sodium, aripiprazole, clonidine, clonazepam. FFT-CD = family-focused treatment for childhood depression; IP = individual psychotherapy; NOS = not otherwise specified.

Table 3. Pre- and Posttreatment Descriptive Statistics, by Condition

Variable	Pretreatment		Posttreatment	
	FFT-CD	IP	FFT-CD	IP
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
<b>Depressive Symptoms</b>				
CDRS-R	53.07 (10.42)	54.10 (12.31)	30.85 (11.31)	34.42 (12.48)
CDI - CR	15.57 (11.11)	15.11 (10.44)	7.30 (8.99)	9.72 (8.14)
CDI - PR	26.33 (7.54)	26.78 (7.42)	16.22 (7.83)	17.82 (8.68)
<b>Functioning</b>				
CGAS	53.15 (5.89)	53.96 (6.04)	63.70 (9.61)	64.65 (10.74)
SAS-CR	50.09 (15.18)	50.85 (15.05)	42.09 (12.50)	45.68 (12.21)
<b>Comorbid Problems</b>				
MASC-CR	50.75 (20.92)	54.42 (17.87)	47.17 (21.93)	49.70 (19.51)
CBC-IP	69.78 (7.93)	70.35 (9.87)	59.77 (11.98)	61.63 (10.60)
CBC-EP	61.57 (8.45)	60.67 (10.13)	54.77 (10.91)	56.57 (9.45)

Note: CBC-EP = Child Behavior Checklist – Externalizing Problems; CBC-IP = Child Behavior Checklist – Internalizing Problems; CDI = Children’s Depression Inventory; CDRS-R = Children’s Depression Rating Scale - Revised; CGAS = Children’s Global Assessment Scale; CR = child report; FFT-CD = family-focused treatment for childhood depression; IP = individual psychotherapy; MASC-CR = Multidimensional Anxiety Scale for Children – Child Report; PR = parent report; SAS-CR = Social Adjustment Scale – Child Report.

Table 4: Clinical Outcome by Treatment Group With Intent to Treat and Completer Analyses

	Intent-to-Treat				Completer			
	FFT-CD %	IP %	OR	NNT	FFT-CD %	IP %	OR	NNT
<b>Full Sample</b>	<b>n = 67</b>	<b>n = 67</b>			<b>n = 54</b>	<b>n = 62</b>		
Adequate clinical depression response, CDRS-R $\geq$ 50% <sup>a</sup>	77.4%	59.9%	2.29	5.72	79.6%	59.7%	2.64	5.01
Remission, CDRS $\leq$ 28 <sup>b</sup>	52.3%	37.3%	1.84	6.70	53.7%	35.5%	2.11	5.50
<b>7–12-year-old children only</b>	<b>n = 50</b>	<b>n = 49</b>			<b>n = 39</b>	<b>n = 45</b>		
Adequate clinical depression response, CDRS-R $\geq$ 50% <sup>c</sup>	81.9%	64.6%	2.48	5.78	84.6%	64.4%	3.03	4.96
Remission, CDRS $\leq$ 28 <sup>d</sup>	52.7%	41.9%	1.54	9.27	53.9%	40.0%	1.75	7.22

Note: Completer includes those with posttreatment assessment data regardless of treatment participation.

CDRS (-R) = Children’s Depression Rating Scale (-Revised); FFT-CD = family-focused treatment for childhood depression; IP = individual psychotherapy; NNT = number needed to treat; OR = odds ratio.

<sup>a</sup> ITT  $t = 1.97, p = .0498$ ; Completer  $\chi^2 = 5.37, df = 1, p = .0205$

<sup>b</sup> ITT  $t = 1.63, p = .1043$ ; Completer  $\chi^2 = 3.89, df = 1, p = .0486$

<sup>c</sup> ITT  $t = 1.72, p = .0895$ ; Completer  $\chi^2 = 4.40, df = 1, p = .0360$

<sup>d</sup> ITT  $t = 0.99, p = .3200$ ; Completer  $\chi^2 = 1.61, df = 1, p = .2044$

Table 5. Patient-Centered Outcomes

Variable	FFT-CD	IP	t-value	df	p-value	d
	Mean (SD)	Mean (SD)				
<b>Parent Report</b>						
Overall satisfaction	1.62 (0.87)	1.52 (0.91)	-0.560	101.00	.58	-0.11
Attending sessions helped me understand how to manage my child's depression	1.96 (0.95)	2.51 (1.17)	2.63	98.74	.01	0.52
Attending sessions helped me understand how to help my child at home	1.72 (0.88)	2.43 (1.19)	3.48	95.89	<.001	0.68
<b>Child Report</b>						
Overall satisfaction	1.79 (0.94)	1.80 (1.21)	0.04	96.00	.97	0.01
Attending sessions helped me get along better with my family	1.80 (1.03)	2.26 (1.20)	2.12	105.00	.04	0.41
Attending sessions helped me deal with problems	1.74 (0.88)	2.18 (1.38)	1.98	92.63	.05	0.39

Note: Scales were rated from (1) strongly agree to (5) strongly disagree. FFT-CD = family-focused treatment for childhood depression; IP = individual psychotherapy.

Table 6. Change From Baseline to Posttreatment on Secondary Outcomes

	Group		Time		Group x Time		Estimated Tx Effect	
	F	p-value	F	p-value	F	p-value	Beta	f <sup>2</sup>
<b>Depressive Symptoms</b>								
CDRS-R	0.37	.54	397.68	<.0001	2.02	.16	-2.99	.018
CDI-CR	0.00	.97	58.02	<.0001	2.65	.11	-2.82	.025
CDI-PR	0.58	.45	161.79	<.0001	0.21	.65	-0.69	.002
<b>Functioning</b>								
CGAS	1.52	.22	144.30	<.0001	0.11	.74	-0.59	.0001
SAS-SR	0.14	.71	32.08	<.0001	0.90	.34	-2.15	.008
<b>Comorbid Problems</b>								
Multidimensional Anxiety Scale for Children	0.23	.63	5.85	.017	0.32	.58	1.69	.003
CBCL Externalizing Problems	0.08	.78	62.04	<.0001	1.26	.26	-1.62	.013
CBCL Internalizing Problems	0.66	.42	152.30	<.0001	0.67	.41	-1.23	.007

Note: Estimated treatment effects correspond to the group by time interaction coefficient in the mixed models, which gives the difference in change scores for the family-focused treatment for childhood depression (FFT-CD) and individual psychotherapy (IP) groups, adjusted for race, income, and family composition. Cohen's  $f^2$  is the standard effect size for regression models, based on variance explained; values of .02, .15, and .35 are small, medium, and large, respectively. CBCL = Child Behavior Checklist; CDI = Child Depression Inventory; CDRS-R = Child Depression Rating Scale-Revised; CGAS = Children's Global Assessment Scale; CR = child report; PR = parent report; SAS-SR = Social Adjustment Scale-Self Report; Tx = treatment.

Figure 1. Participant flow across the study. Note: FFT = family-focused treatment; IP = individual psychotherapy.

