# Randomized Clinical Trial of Dialectical Behavior Therapy for Preadolescent Children With Disruptive Mood Dysregulation Disorder: Feasibility and Outcomes

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**Objective:** Persistent irritability and behavior outbursts in disruptive mood dysregulation disorder (DMDD) are associated with severe impairment in childhood and with negative adolescent and adult outcomes. There are no empirically established treatments for DMDD. This study examined the feasibility and preliminary efficacy of dialectical behavior therapy adapted for preadolescent children (DBT-C) with DMDD.

**Method:** Children 7 to 12 years old with DMDD (N = 43) were randomly assigned 1:1 to DBT-C or treatment as usual (TAU). The 6 domains of feasibility included recruitment, randomization, retention, attendance, participants' satisfaction, and therapist adherence. Blinded raters assessed participants at baseline, after 8, 16, 24, and 32 weeks, and at 3-month follow-up. The primary efficacy outcome was the positive response rate on the Clinical Global Impression–Improvement scale. Improvements in behavior outbursts and angry/irritable mood were assessed by the Clinical Global Impression–Severity scale.

**Results:** Mean number of participants randomized per month was 2.53 ± 2.72. Participants in DBT-C (n = 21) attended 89% of sessions compared with 48.6% in TAU (n = 22). Eight TAU participants (36.4%) dropped out compared with none in DBT-C. Parents and children in DBT-C expressed significantly higher treatment satisfaction than those in TAU. The rate of positive response was 90.4% in DBT-C compared with 45.5% in TAU, despite 3 times as many participants in TAU receiving psychiatric medications. Remission rates were 52.4% for DBT-C and 27.3% for TAU. Improvements were maintained at 3-month follow-up. Therapists showed adherence to DBT-C.

**Conclusion:** DBT-C demonstrated feasibility in all prespecified domains. Outcomes also indicated preliminary efficacy of DBT-C.

**Clinical trial registration information**—Adapting DBT for Children With DMDD: Pilot RCT; http://clinicaltrials.gov/; NCT01862549.

**Key words:** dialectical behavior therapy, preadolescent children, disruptive mood dysregulation disorder, emotion dysregulation, randomized clinical trial

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Disruptive mood dysregulation disorder (DMDD) is characterized by severe and recurrent verbal and/or behavioral outbursts that are grossly out of proportion to the situation, inconsistent with developmental level, and occur at least 3 times per week for at least 1 year.[1] Between outbursts, children display a persistently irritable or angry mood. Prevalence rates of DMDD are estimated to be 1%, with up to 26% in clinical samples.[2] Impulsivity and chronic irritability are associated with severe impairment in childhood, adolescence, and adulthood, including personality disorders, substance abuse, mood disorders, and suicidality.[3-5] Children with DMDD also have increased rates of service use in school, mental health systems, child welfare, and juvenile justice.[1]

Emotion regulation, defined as intrinsic capabilities individuals use to modulate the experience and expression of emotions based on internal or external demands,[6] appears to be a core deficit in DMDD.[1] Children with symptoms consistent with DMDD demonstrate dysfunction in neural regions implicated in emotion salience, attention, and reward processing.[7,8] Currently, there are no empirically established treatments for DMDD,[9] with current research indicating mixed results on interventions for children with severe mood dysregulation, a construct that has symptoms consistent with DMDD.[10] Because emotion dysregulation is associated with DMDD, interventions such as dialectical behavior therapy (DBT) that target these deficits[11] could be relevant to this disorder, especially with an addition of a parent training component that has been shown to decrease disruptive behaviors.[12,13]

CG Clinical guidance is available at the end of this article.

DBT is an empirically validated therapy designed to treat emotion dysregulation, suicidal thoughts and behaviors, and nonsuicidal self-injury (NSSI) associated with borderline personality disorder. DBT teaches coping skills and problem solving within a validating environment and has been successfully adapted to treat adults with depression, anxiety, substance abuse, posttraumatic stress disorder, and eating disorders[14-17] and adolescents with suicidality and NSSI.[18] Imaging studies of adults with borderline personality disorder suggest that DBT is associated with adaptive changes in the emotion processing brain circuit.[19,20] An open pilot trial of DBT adapted for preadolescent children (DBT-C) skills training indicated its acceptability by children and parents, a significant increase in adaptive coping skills, and a significant decrease in depressive symptoms, suicidal ideation, and problematic behaviors after treatment.[21]

The aims of this report are to present feasibility and preliminary efficacy results of a randomized clinical trial of DBT-C for DMDD. The 6 domains of feasibility included recruitment, randomization, retention, attendance, participants' satisfaction, and therapist adherence.[22] The following benchmarks were set for DBT-C feasibility: at least 2 participants per month for recruitment; dropout rate lower than 30% for retention (defined as dropped out before week 26); attendance rate of at least 70%; participants' treatment satisfaction and compliance being significantly higher than treatment as usual (TAU); and therapists' adherence score of at least 4.0. The following benchmarks were set for DBT-C preliminary efficacy: at least 20% higher response rate than for TAU; at least 50% remission rate; and significantly greater improvement in functioning than in TAU.

# METHOD

## Trial Design and Randomization Procedures

The study was a 2-arm trial with children assigned to DBT-C or TAU in a 1:1 ratio using an urn randomized procedure[23] that was managed by an independent statistician. Randomization was stratified by age (cutoff $\geq$ 10 years 0 months) and the presence of suicidal ideations or behaviors or NSSI. All diagnostic assessments were done by the lead authors (F.P. and D.N.) and diagnoses were derived by consensus. Independent evaluators blinded to treatment assignment monitored treatment outcomes. When un-blinding of evaluators occurred, cases were reassigned to another blinded evaluator and narratives were re-rated. Intraclass correlation was computed between the original and re-rated datasets to aid interpretation of the results. An additional clinic intake was required for the TAU group according to setting policies (e.g., psychiatric assessment and insurance verification). Participants in the 2 groups were informed of their treatment group assignment only after all the study and clinic intake procedures were completed. An additional intake for the TAU group entailed up to 2 weeks of delay in the start of treatment, whereas there was no delay required for participants in the DBT-C group. Further, participants in TAU were charged for treatment (through insurance), whereas DBT-C was provided free of charge. The study was approved by the institutional review board of the Weill Cornell Medical College (WCMC; White Plains, NY).

## Setting, Procedure, and Participants

The study was conducted at the WCMC Department of Psychiatry and NewYork-Presbyterian Hospital, Westchester Division. Recruitment sources included referrals to the site clinic; paid advertisements in newspapers, magazines, radio, buses, and internet; referrals from pediatricians and mental health providers; and informational brochures mailed to schools and places of worship. Caregivers provided written informed consent for study participation, and children provided assent. Children were included in the study if they were 7 years 0 months to 12 years 11 months old; met criteria for DMDD; were stabilized on psychiatric medication for at least 6 weeks; and could be treated on an outpatient basis. Children were excluded if they had a documented cognitive disability (IQ $\leq$ 70); had a current psychotic disorder; had a pervasive developmental disorder; could not speak English; or were in state custody.

## Interventions

*DBT Adapted for Preadolescent Children.* DBT-C incorporates all 4 modes of standard outpatient DBT for adults (individual therapy, skills training, phone coaching calls, and therapist team consultation), with the addition of a parent training component.[21,24,25] DBT-C consisted of 32 weekly 90-minute sessions, conducted individually with each family, and divided into child counseling, parent training, and skills training with parents and children. At follow-up (weeks 33–44), up to 2 booster sessions per month were provided. Therapy was provided by PhD- and LCSW-level clinicians who were trained to adherence in DBT-C, including the lead author.

*Treatment as Usual.* Children in TAU received up to 32 weeks of individual therapy. Session duration, frequency, and treatment approach were determined by each clinician. TAU therapists were proscribed from using DBT-informed interventions, which was monitored by weekly session summary reports. TAU therapists were PhD-, MD-, and LCSW-level clinicians, including postdoctoral trainees and child psychiatry residents. Therapists were supervised weekly by senior staff.

## DBT-C Treatment Integrity

DBT-C therapists received a total of 68 hours of training.[26,27] Therapists were trained by the lead author who received DBT intensive training and had been approved as a DBT adherence rater by Dr. Linehan's research group. All DBT-C sessions were videotaped, and 10% were rated for treatment integrity by 1 of 3 independent raters who demonstrated treatment adherence to DBT-C and were approved as adherence raters by the lead author. The selection of sessions for review was random and stratified by therapists, participants, and treatment phases. Of the rated recordings, 20% were coded for interrater reliability. Therapists also completed self-report adherence assessments at the end of each session and participated in weekly consultation meetings.

DBT-C therapists' treatment adherence was rated using the 66-item DBT Adherence Rating Scale, reflecting 12 major DBT strategy domains.[28] Scores range from 0 to 5 per item and represent average strategy ratings across an entire session. A mean score of 4.0 (corresponds to 80% adherence rate) indicates adherent delivery. Interrater agreement is presumed if the difference between mean scores is no higher than 0.3.

## Assessments

Assessments were conducted at baseline, at weeks 8, 16, 24, and 32 (after treatment), and at 3-month follow-up. All assessment staff were trained and supervised by the study coordinator. Assessment duration was on average 4 hours for parents and 2 hours for children for an initial evaluation, 1.5 hours for parents and 30 minutes for children for the subsequent evaluations, and 10 minutes for weekly safety monitoring.

### Sample Characteristics

*Schedule for Affective Disorders and Schizophrenia for School Aged Children: Present and Lifetime Version.* The Schedule for Affective Disorders and Schizophrenia for School Aged Children: Present and Lifetime Version[29] is a semistructured psychiatric diagnostic interview revised for *DSM-5* that is widely used in federally funded studies. The DMDD module was used to determine DMDD diagnosis.

*Sensory Processing Measure: Home Form.* The Sensory Processing Measure: Home Form[30] is a 75-item parent report that assesses functioning across 5 sensory systems on a 4-point scale. Internal consistencies range from 0.77 to 0.95 across subscales, and test-retest reliability ranges from 0.94 to 0.98.

*Services Assessment Form.* The Services Assessment Form, adapted from the Services Assessment for Children and Adolescents,[31] evaluates the frequency of emergency room visits, inpatient admissions, day treatment, emergency mobile psychiatric services, residential placements, and psychopharmacologic management.

*The Columbia Suicide and Self-Injury Severity Rating Scale.* The Columbia Suicide and Self-Injury Severity Rating Scale extended the Columbia Suicide Severity Rating Scale[32] to include items on NSSI. This instrument has strong convergent validity, sensitivity to change, predictive and incremental validity, and good internal consistency (intensity subscale $\alpha = 0.73$–$0.94$)[33] and has been widely used in pediatric clinical trials.

*The Hollingshead Four-Factor Index.* The Hollingshead Four-Factor Index classifies a person's socioeconomic status on a scale from 1 to 5, with higher scores indicating a higher socioeconomic status (Hollingshead AB: Four-factor index of social status. Unpublished manuscript. New Haven, CT: Yale University; 1975).

### Feasibility and Acceptability Measures

*Child and Parent Self-Reports.* The Therapy Satisfaction Questionnaire–Parent and Child Versions (TSQ)[21] are 7-item measures rated on a 4-point scale, with a higher score indicating higher level of satisfaction. The TSQ assesses the degree to which the program was helpful, child-friendly, and comprehensible.

### Therapist Ratings

The Therapist Satisfaction Scale (TSS) is a 15-item measure, developed for this study, rated on a 4-point scale, with a higher score indicating a higher level of therapists' satisfaction with their treatment model.

The Psychosocial Treatment Compliance Scale (PTCS) is a 17-item measure of patients' therapy participation and attendance on a 5-point scale, from "never" to "always," with higher item scores representing better compliance.[34] The measure has excellent test-retest reliability (0.90 for participation; 0.86 for attendance) and internal consistency (0.96 for participation; 0.87 for attendance). For this study, total compliance scores were calculated by averaging items, excluding items 5, 9, and 10, because they were not representative of processes in either treatment condition.

The Session Summary Sheet was rated by therapists at the end of each session to assess the treatment modality used (up to 9 modalities could be selected) and the duration of in-session and out-of-session contact.

The Treatment Adherence Checklist, based on the DBT Adherence Rating Scale,[28] is a DBT-C therapist's self-report of completion of session tasks and adherence to strategies.

### Preliminary Efficacy Measures (Rated by Independent Blinded Clinical Psychologists)

The Clinical Global Impression Scales (CGI)[35] are widely used measures in pediatric clinical trials.[35] CGI-Severity (CGI-S) is a 7-item scale ranging from a score of 1 (not ill) to 4 (meets diagnostic threshold) to 7 (requires residential/inpatient care). CGI-S for DMDD was derived by rating the severity of mood symptoms and behavioral outbursts. CGI-Improvement (CGI-I) is a 7-item scale that compares the current rating of severity with that at baseline and ranges from a score of 1 (very much improved) to 4 (no change) to 7 (very much worse). By convention, ratings of 1 (very much improved) or 2 (much improved) are used to define positive treatment response. A positive response on the CGI-I was prespecified as the main efficacy outcome, with week 32 as the end point. Remission was defined as a CGI-S score no higher than 3 (mildly ill, no impairment) rated consecutively for weeks 16, 24, and 32.[36] Because CGI-S is a categorical measure, the severity scores were dichotomized into "at diagnostic threshold" (score $\geq 4$) and "below diagnostic threshold" (score $\leq 3$).

The Children's Global Assessment Scale (CGAS)[37] is a measure of global functioning in children. Children are rated on a scale from 1 (extremely impaired) to 100 (superior functioning). The measure has excellent interrater reliability (intraclass coefficient 0.84) and test-retest reliability (intraclass coefficient 0.69–0.95).

### Safety Monitoring

Safety was monitored before each treatment visit using the Checklist of Adverse Incidents. Adverse incidents were reported to the participant's therapist by study personnel before the treatment session. The trial was monitored by the WCMC Data and Safety Monitoring Board.

### Analytic Plan

Sample characteristics, retention, attendance, response and remission rates per condition, medication use rates, and CGI-S outburst, mood, and global scores were compared using $\chi^2$ and Fisher exact tests. Independent Welch 2-sample $t$ tests were performed for the TSQ, TSS, PTCS, and CGAS. Paired-samples $t$ tests were used to evaluate any improvements from after treatment to follow-up within groups. To assess mediation of number of sessions and average session time on CGI-I at week 32, average causal mediation effects were estimated at post hoc. All $p$ values were 2-sided with statistical significance evaluated at the 0.05 $\alpha$ level. All analyses were performed in R 3.2.1 for Windows (R Foundation, Vienna, Austria). The CGI and CGAS were missing 12.79% of observations, and intent-to-treat analyses with last observation carried forward were used to estimate results.

## RESULTS

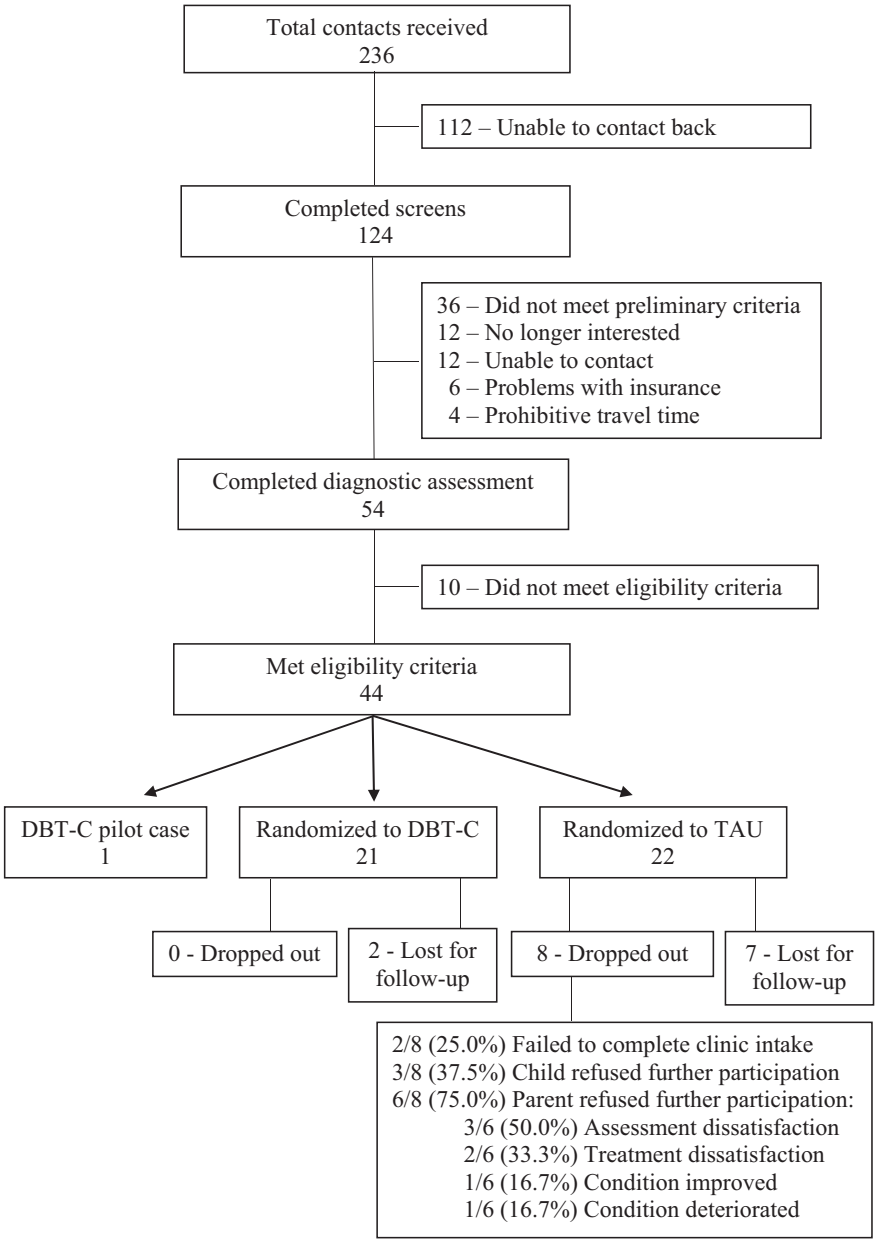
### Study Flow and Sample Characteristics

During the 16-month recruitment period, 124 participants were screened, 44 were deemed eligible, and 43 were randomized to DBT-C (21 participants) and TAU (22 participants; Figure 1). Mean randomization rate was $2.53 \pm 2.72$ per month. Participants' characteristics are presented in Table 1.

### Interventions

DBT-C sessions were 0.5% child only, 2.8% parent only, and 96.8% parent and child, with mean session duration of $86.55 \pm 12.76$ minutes (range 20–120), with breakdown of $17.00 \pm 19.41$ for individual child therapy, $29.44 \pm 17.09$ for parent training, and $40.02 \pm 23.98$ for skills training. Mean number of out-of-session contacts (e.g., skills coaching) per

**FIGURE 1** Sample flow. Note: DBT-C = dialectical behavior therapy for preadolescent children; TAU = treatment as usual.




participant was 8.19 ± 5.40, and mean contact in minutes was 13.58 ± 13.22 (range 1–90).

TAU sessions were 10.7% child only, 11.0% parent only, and 78.2% parent and child, with mean session duration of 47.36 ± 7.56 minutes (range 25–95), with a breakdown of 21.99 ± 17.45 for individual child therapy, 8.18 ± 15.50 for parent(s) meetings, and 17.01 ± 17.32 for joint sessions. Therapists' self-reported treatment approaches were 52.1% supportive, 46.3% cognitive-behavioral therapy, 42.9% parent training, 30.4% family therapy, 21.4% psychodynamic, 20.2% interpersonal, and 13.1% motivational enhancement. Mean number of out-of-session contacts per participant was 3.60 ± 4.14, and mean contact time was 9.74 ± 8.34 minutes (range 1–45). TAU therapists' self-reports indicated that DBT skills were taught in only 1.2% of sessions.

## Treatment Participation and Satisfaction

The average number of sessions per participant in DBT-C and TAU was 28.48 ± 3.19 and 15.55 ± 8.34, respectively. Overall attendance in DBT-C was 89.0% compared with 48.6% for TAU (Table 2). In DBT-C, 100% of participants completed the intervention compared with 63.6% in TAU ($p < .004$), because 8 participants dropped out. On average, participants who started treatment dropped out after session

**TABLE 1** Sample Characteristics at Baseline

| Characteristic | DBT-C (n = 21) | TAU (n = 22) | $t(df)/\chi^2$ | *p* |
|---|---|---|---|---|
| Age (range 7–12 y), mean ± SD | 9.19 ± 1.86 | 9.27 ± 1.64 | 0.15 (39.79) | .88 |
| Boys, n (%) | 12 (57.1) | 12 (54.5) | 0.30 | .86 |
| Hispanic, n (%) | 0 | 5 (22.7) | 5.40 | .02 |
| Caucasian, n (%) | 17 (81.0) | 16 (72.7) | 0.41 | .52 |
| African American, n (%) | 1 (4.7) | 4 (18.2) | 1.89 | .17 |
| Other, n (%) | 2 (9.5) | 1 (4.5) | 0.41 | .52 |
| Asian, n (%) | 0 | 1 (4.5) | 0.98 | .32 |
| SES (range 3–5), mean ± SD | 4.43 ± 0.60 | 4.43 ± 0.68 | 0.00 (39.41) | 1.00 |
| Psychiatric diagnoses, n (%) | | | | |
| ADHD | 7 (33.3) | 10 (45.5) | 0.66 | .42 |
| Anxiety disorders | 8 (38.1) | 4 (18.2) | 2.11 | .15 |
| Enuresis or encopresis | 2 (9.5) | 3 (13.6) | 0.18 | .67 |
| PTSD | 0 | 1 (4.5) | 0.98 | .32 |
| Tics | 1 (4.7) | 0 | 1.07 | .30 |
| 1 diagnosis | 7 (33.3) | 6 (27.3) | 0.19 | .67 |
| 2 diagnoses | 10 (47.6) | 14 (63.6) | 1.12 | .29 |
| 3 diagnoses | 4 (19.0) | 2 (9.1) | 0.89 | .35 |
| CGI Global Severity score 4, n (%) | 4 (19.0) | 5 (22.7) | 0.09 | .77 |
| CGI Global Severity score 5, n (%) | 8 (38.1) | 11 (50.0) | 0.62 | .43 |
| CGI Global Severity score 6, n (%) | 9 (42.9) | 4 (18.2) | 3.10 | .08 |
| Sensory processing problems, n (%) | | | | |
| Some problems in ≥1 area (60T–69T) | 15 (71.4) | 17 (77.3) | 0.53 | .47 |
| Dysfunction in ≥1 area (70T–80T) | 5 (23.8) | 5 (22.7) | 0.00 | 1.00 |
| Suicidal ideations, n (%) | 12 (57.1) | 12 (54.5) | 0.03 | .86 |
| Suicidal behaviors, n (%) | 1 (4.8) | 1 (4.5) | 0.00 | .97 |
| NSSI urges, n (%) | 10 (47.6) | 8 (36.4) | 0.56 | .46 |
| NSSI behaviors, n (%) | 9 (42.9) | 7 (31.8) | 0.56 | .45 |
| Previous outpatient therapy, n (%) | 16 (76.2) | 20 (90.1) | 1.71 | .19 |
| Special services at school, n (%) | 11 (52.4) | 9 (40.1) | 0.57 | .45 |
| Psychiatric medications, n (%) | | | | |
| Stimulants | 3 (14.3) | 2 (9.1) | 0.28 | .60 |
| Antipsychotics | 2 (9.5) | 3 (13.6) | 0.17 | .67 |
| Antidepressants | 1 (4.8) | 3 (13.6) | 1.10 | .32 |
| Mood stabilizer | 0 | 1 (4.5) | 0.98 | .32 |
| Anxiolytic | 0 | 1 (4.5) | 0.98 | .32 |
| Other | 1 (4.8) | 1 (4.5) | 0.00 | .97 |
| No medications | 17 (81.0) | 14 (63.6) | 1.60 | .21 |
| 1 medication | 1 (4.8) | 5 (22.7) | 2.89 | .09 |
| ≥2 medications | 3 (14.3) | 3 (13.6) | 0.00 | .95 |

*Note: ADHD = attention-deficit/hyperactivity disorder; CGI = Clinical Global Impression Scale; DBT-C = dialectical behavior therapy for preadolescent children; NSSI = nonsuicidal self-injury; PTSD = posttraumatic stress disorder; SES = socioeconomic status; TAU = treatment as usual.*

12 (range 6–19), with the following breakdown per month: 2 participants during month 3, 1 participant during month 4, 2 participants during month 6, and 1 participant during month 7. The most frequent reason for dropping out (87.5%) was child and/or parent refusal to participate further (Figure 1). No participants expressed dissatisfaction with randomization as the reason for dropping out. Parent treatment compliance on the PTCS and child and parent acceptability and satisfaction on the TSQ were significantly higher in DBT-C compared with TAU; however, there were no significant differences for child treatment compliance on the PTCS and therapist treatment satisfaction on the TSS (Table 2).

## DBT-C Treatment Integrity

For therapist self-reports on adherence, 3.5% of forms were missing. Therapists' self-reports of the implementation of prescribed procedures indicated 95.9% adherence to DBT-C strategies, 96.9% adherence to delivery of tasks, and completion of session topics at 93.7% for individual therapy, 95.5% for parent training, and 95.7% for skills training. Independent rating of session video recordings indicated therapists' mean overall adherence score of 4.20 ± 0.15, with 4.23 ± 0.17 for individual sessions, 4.17 ± 0.14 for parent training, and 4.17 ± 0.12 for skills training. Interrater reliability for the total adherence level was 0.85. Mean interrater reliability for the 12 strategy domains was 0.71.

**TABLE 2** Feasibility and Acceptability Outcomes

| | DBT-C | | | TAU | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Outcome | n | Mean | SD | n | Mean | SD | *t* | *df* | *p* | Cohen *d* | 95% CI |
| Sessions attended, n | 21 | 28.48 | 3.19 | 22 | 15.55 | 8.34 | 6.77 | 27.25 | .000 | 2.03 | 1.25 to 2.81 |
| TSQ-Child | 21 | 22.90 | 5.64 | 18 | 18.39 | 6.26 | 2.35 | 34.63 | .03 | .76 | 0.07 to 1.45 |
| TSQ-Parent | 21 | 26.29 | 2.17 | 20 | 20.50 | 6.72 | 3.68 | 22.76 | .001 | 5.44 | 4.49 to 6.42 |
| PTCS-Parent | 22 | 4.33 | .61 | 19 | 3.90 | .61 | 2.23 | 38.10 | .03 | .70 | 0.03 to 1.37 |
| PTCS-Child | 22 | 3.71 | .71 | 19 | 3.30 | .72 | 1.82 | 37.96 | .08 | .57 | −0.09 to 1.23 |
| TSS | 25 | 45.00 | 10.62 | 21 | 43.71 | 8.83 | .45 | 43.99 | .66 | .13 | −0.48 to 0.74 |

*Note: DBT-C = dialectical behavior therapy for preadolescent children; PTCS = Psychosocial Treatment Compliance Scale; TAU = treatment as usual; TSQ = Treatment Satisfaction Questionnaire; TSS = Therapist Satisfaction Scale.*

## Treatment Response

Independent blinded assessors rated CGI-S and CGI-I. Agreement between independent raters was defined as the same score given between raters on temper outbursts, mood severity, and improvement. Interrater reliability was 0.82. Un-blinding of raters occurred for 20.0% of ratings. Comparison between original and re-rated observations indicated a mean intraclass correlation of 0.98 (range 0.91–1.00).

The rate of positive response on the CGI-I was 90.4% (n = 19 of 21) for DBT-C and 45.5% for TAU (n = 10 of 22; $\chi^2 = 9.92$, $p = .002$). Almost twice as many children in DBT-C (n = 11, 52.4%) as in TAU (n = 6, 27.3%) achieved remission ($\chi^2 = 2.83$, $p = .09$). Participants in DBT-C compared with TAU reached a significantly higher level of functioning on the CGAS (Table 3) and had significantly greater decrease in CGI-S global scores (Table 4). Four participants in TAU started new medications during the trial compared with none in DBT-C. Overall, the number of children whose treatment included psychiatric medication was 3 times higher in TAU (n = 12, 54.4%) than in DBT-C (n = 4, 19.1%; $p = .03$), with 4 participants in TAU starting medications past baseline compared with none in DBT-C. Mediation analyses showed no significant average causal mediation effects on CGI-I at week 32 for average time in session (point estimate 0.02, 95% CI −0.10 to 0.15, $p = .71$) or number of sessions (point estimate −0.09, 95% CI −0.20 to 0.00, $p = .05$).

During the 3-month follow-up, participants in DBT-C and TAU attended 3.57 ± 3.11 and 4.00 ± 3.14 sessions, respectively. Positive response on the CGI-I at follow-up was 95.2% (n = 20 of 21) for DBT-C compared with 45.5% (n = 10 of 22) for TAU ($\chi^2 = 12.63$, $p = .000$). Participants in DBT-C compared with TAU continued to maintain a significantly greater improvement in CGAS (Table 3). CGAS ratings significantly improved from posttreatment to follow-up for DBT-C ($t_{21} = 2.64$, $p = .02$). For DBT-C, 61.9% (n = 13) of participants maintained the same GCI-S global level from the end of the treatment through follow-up, 28.6% (n = 6) decreased in severity, and 9.5% (n = 2) increased in severity. For TAU, 63.6% (n = 14) participants maintained outcomes, 13.6% (n = 3) decreased in severity, and 22.7% (n = 5) increased in severity.

## Treatment Safety

For DBT-C, no serious adverse events and 132 adverse events were reported. For TAU, there were 2 serious adverse events (non-psychiatric hospitalizations) and 98 adverse events reported. The following adverse events were reported for DBT-C and TAU: deterioration in functioning (e.g., increase in aggression), 81 and 64, respectively; suicidal ideation, 20 and 14; physical illness (e.g., headache) that interfered with functioning (e.g., missed school day, required medical attention), 21 and 13; NSSI, 10 and 2; and reports to child protective services, 0 and 5.

**TABLE 3** Children's Global Assessment Scale (CGAS) Outcomes for All Time Points

| | CGAS | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | DBT-C | | | TAU | | | | | | | |
| Week | n | Mean | SD | n | Mean | SD | *t* | *df* | *p* | Cohen *d* | 95% CI |
| 00 | 21 | 40.67 | 5.37 | 22 | 44.64 | 9.28 | −1.73 | 33.93 | .09 | −0.52 | −1.16 to 0.12 |
| 08 | 21 | 52.52 | 13.52 | 22 | 48.68 | 11.47 | 1.00 | 39.26 | .32 | 0.31 | −0.33 to 0.94 |
| 16 | 21 | 61.00 | 16.12 | 22 | 53.00 | 15.39 | 1.66 | 40.65 | .10 | 0.51 | −0.13 to 1.15 |
| 24 | 21 | 64.62 | 16.63 | 22 | 56.41 | 18.47 | 1.53 | 40.87 | .13 | 0.47 | −0.17 to 1.11 |
| 32 | 21 | 69.43 | 15.36 | 22 | 58.00 | 18.08 | 2.24 | 40.47 | .03 | 0.95 | 0.18 to 1.72 |
| FU | 21 | 75.24 | 14.30 | 22 | 55.77 | 17.94 | 3.94 | 39.76 | .00 | 1.20 | 0.53 to 1.87 |

*Note: DBT-C = dialectical behavior therapy for preadolescent children; FU = 3-month follow-up; TAU = treatment as usual.*

**TABLE 4** Clinical Global Impression Scale–Severity (CGI-S) Outcomes for All Time Points

| | CGI-S Outburst | | | | | CGI-S Mood | | | | | CGI-S Global | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | DBT-C, n (%) | | TAU, n (%) | | | DBT-C, n (%) | | TAU, n (%) | | | DBT-C, n (%) | | TAU, n (%) | | |
| Week | ≥4 | ≤3 | ≥4 | ≤3 | *p* | ≥4 | ≤3 | ≥4 | ≤3 | *p* | ≥4 | ≤3 | ≥4 | ≤3 | *p* |
| 00 | 21 (100) | 0 (0.0) | 21 (95.5) | 1 (4.6) | 1 | 21 (100) | 0 (0.0) | 20 (90.9) | 2 (9.1) | .49 | 21 (100) | 0 (0.0) | 20 (90.9) | 2 (9.1) | .49 |
| 08 | 15 (71.4) | 6 (28.6) | 18 (81.8) | 4 (18.2) | .49 | 12 (57.1) | 9 (42.9) | 15 (68.2) | 7 (31.8) | .54 | 11 (52.4) | 10 (47.6) | 14 (63.6) | 8 (36.4) | .54 |
| 16 | 12 (57.1) | 9 (42.9) | 17 (77.3) | 5 (22.7) | .20 | 6 (28.6) | 15 (71.4) | 15 (68.2) | 7 (31.8) | .02 | 6 (28.6) | 15 (71.4) | 15 (68.2) | 7 (31.8) | .02 |
| 24 | 8 (38.1) | 13 (61.9) | 13 (59.1) | 9 (40.9) | .23 | 6 (28.6) | 15 (71.4) | 14 (63.6) | 8 (36.4) | .03 | 5 (23.8) | 16 (76.2) | 13 (59.1) | 9 (40.9) | .03 |
| 32 | 6 (28.6) | 15 (71.4) | 13 (59.1) | 9 (40.9) | .07 | 2 (9.5) | 19 (90.5) | 11 (50.0) | 11 (50.0) | .01 | 2 (9.5) | 19 (90.5) | 11 (50.0) | 11 (50.0) | .01 |
| FU | 5 (23.8) | 16 (76.2) | 14 (63.6) | 8 (36.4) | .01 | 3 (14.3) | 18 (85.7) | 13 (59.1) | 9 (40.9) | .00 | 2 (9.5) | 19 (90.5) | 11 (50.0) | 11 (50.0) | .01 |

*Note: DBT-C = dialectical behavior therapy for preadolescent children; FU = 3-month follow-up; TAU = treatment as usual.*

## DISCUSSION

To our knowledge, this is the first published randomized clinical trial of DBT adapted for preadolescent children. This study included an active psychosocial control condition with medication management, rather than a waitlist or an open, uncontrolled design. DBT-C demonstrated feasibility and preliminary efficacy in all prespecified domains. Recruitment success was potentially related to the substantial impairment of children with DMDD and the lack of available treatment resources in the community. A credible control condition also likely improved recruitment and decreased the risk of dropping out related to randomization. Compared with other samples of children with DMDD,[38,39] the present sample had a much higher rate of suicidality and NSSI. We believe this discrepancy might stem from our efforts to recruit treatment-seeking youth with the highest level of symptom severity that can be treated on an outpatient basis.

Retention was high in DBT-C, with dropouts occurring only in TAU. The low dropout and high patient satisfaction rates in DBT-C are notable, specifically given that interventions with high treatment demands, such as in DBT-C, are often associated with a high dropout rate. Assessment burden did not appear to significantly affect retention. Treatment retention in TAU was challenging, although the treatment choices were based on a comprehensive evaluation, tailored to the child's needs, and permitted use of medication. The average time of dropping out from TAU was after session 12, suggesting that dropping out was not related to the randomization dissatisfaction.

Compared with TAU, DBT-C had a significantly larger percentage of children with a positive response. The high positive response rate (90.4%) is not an unusual result for DBT efficacy studies.[40,41] Importantly, in DBT-C, improvements were achieved without the need to start new psychiatric medications; only children who were on psychiatric medications at baseline continued to receive psychopharmacologic management. The parent component of DBT-C (e.g., training parents to validate and to model, elicit, and reinforce skills use) might have contributed to retention, positive outcomes, and no reports to child protective services. The DBT-C model presumes the development of a validating and change-ready environment as the main therapeutic ingredient. Because parent involvement was high in TAU, the differences in the content of training between conditions might have contributed to outcomes.

There are several limitations. First, DBT-C was a manual-based intervention, whereas TAU did not adhere to a specific manual. However, TAU therapists were supervised closely for each treatment plan. Further, therapists' levels of satisfaction with provided treatments were similar between conditions, suggesting that therapists' enthusiasm about the provided interventions might not have contributed to the obtained results. Second, there was a substantial difference between the number of attended sessions and session lengths between conditions. However, these factors did not

appear to affect outcomes. Third, participants in DBT-C received therapy free of charge. In contrast, participants in TAU were charged for treatment (through insurance). This structural difference might have affected the dropout rate in TAU, although participants did not state payment for services as a reason for dropping out. A confirmatory efficacy trial is needed with a more structured TAU, with built-in strategies for retention and without requirement for payment. Further research needs to examine the effects of DBT-C on specific outcomes, including depression and anxiety, and evaluation of mediating factors, including emotion regulation, creation of validating environment, and treatment duration. &

### CG Clinical Guidance

- DBT-C can be used with preadolescent children (7–12 years of age) with severe emotional and behavioral dysregulation, including suicidality and NSSI.
- Children and their parents find DBT-C acceptable, understandable, interesting, child-friendly, and helpful.
- Parental active participation and compliance with treatment could be more important than a child's compliance and engagement for symptom relief.
- The content of parent training can affect outcomes. Teaching parenting techniques alone (e.g., reinforcement, extinction, punishment, shaping) might not be as effective as in combination with training parents on how to validate (which serves as a foundation for change), create a change-ready environment (e.g., model skills use, improve parent–child relationship, daily practice of skills with children), and achieve emotion regulation needed to successfully implement behavior modification techniques (e.g., ability to tolerate escalation during extinction bursts).
- Symptom relief can be achieved without supplemental psychopharmacologic interventions.
- Although DBT-C has high treatment demands, rapid improvement in functioning could help maintain engagement and prevent dropping out.

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