JAMA Psychiatry | Original Investigation

Efficacy of Dialectical Behavior Therapy for Adolescents at High Risk for Suicide A Randomized Clinical Trial

Elizabeth McCauley, PhD; Michele S. Berk, PhD; Joan R. Asarnow, PhD; Molly Adrian, PhD; Judith Cohen, MD; Kathyrn Korslund, PhD; Claudia Avina, PhD; Jennifer Hughes, PhD; Melanie Harned, PhD; Robert Gallop, PhD; Marsha M. Linehan, PhD

IMPORTANCE Suicide is a leading cause of death among 10- to 24-year-old individuals in the United States; evidence on effective treatment for adolescents who engage in suicidal and self-harm behaviors is limited.

OBJECTIVE To evaluate the efficacy of dialectical behavior therapy (DBT) compared with individual and group supportive therapy (IGST) for reducing suicide attempts, nonsuicidal self-injury, and overall self-harm among high-risk youths.

DESIGN, SETTING, AND PARTICIPANTS This randomized clinical trial was conducted from January 1, 2012, through August 31, 2014, at 4 academic medical centers. A total of 173 participants (pool of 195; 22 withdrew or were excluded) 12 to 18 years of age with a prior lifetime suicide attempt (≥3 prior self-harm episodes, suicidal ideation, or emotional dysregulation) were studied. Adaptive randomization balanced participants across conditions within sites based on age, number of prior suicide attempts, and psychotropic medication use. Participants were followed up for 1 year.

INTERVENTIONS Study participants were randomly assigned to DBT or IGST. Treatment duration was 6 months. Both groups had weekly individual and group psychotherapy, therapist consultation meetings, and parent contact as needed.

MAIN OUTCOMES AND MEASURES A priori planned outcomes were suicide attempts, nonsuicidal self-injury, and total self-harm assessed using the Suicide Attempt Self-Injury Interview

RESULTS A total of 173 adolescents (163 [94.8%] female and 97 [56.4%] white; mean [SD] age, 14.89 [1.47] years) were studied. Significant advantages were found for DBT on all primary outcomes after treatment: suicide attempts (65 [90.3%] of 72 receiving DBT vs 51 [78.9%] of 65 receiving IGST with no suicide attempts; odds ratio [OR], 0.30; 95% CI, 0.10-0.91), nonsuicidal self-injury (41 [56.9%] of 72 receiving DBT vs 26 [40.0%] of 65 receiving IGST with no self-injury; OR, 0.32; 95% CI, 0.13-0.70), and self-harm (39 [54.2%] of 72 receiving DBT vs 24 [36.9%] of 65 receiving IGST with no self-harm; OR, 0.33; 95% CI, 0.14-0.78). Rates of self-harm decreased through 1-year follow-up. The advantage of DBT decreased, with no statistically significant between-group differences from 6 to 12 months (OR, 0.65; 95% CI, 0.12-3.36; P = .61). Treatment completion rates were higher for DBT (75.6%) than for IGST (55.2%), but pattern-mixture models indicated that this difference did not informatively affect outcomes.

CONCLUSIONS AND RELEVANCE The results of this trial support the efficacy of DBT for reducing self-harm and suicide attempts in highly suicidal self-harming adolescents. On the basis of the criteria of 2 independent trials supporting efficacy, results support DBT as the first well-established, empirically supported treatment for decreasing repeated suicide attempts and self-harm in youths.

TRIAL REGISTRATION Clinical Trials.gov Identifier: NCTO1528020.

JAMA Psychiatry. doi:10.1001/jamapsychiatry.2018.1109 Published online June 20, 2018. Invited Commentary

+ Supplemental content

Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Molly Adrian, PhD, Seattle Children's Hospital, University of Washington, 4800 Sand Point Way NE, Seattle, WA 98105 (adriam@uw.edu). uicide is a leading cause of death among adolescents in the United States. Rates of adolescent suicide deaths have increased markedly in the United States between 2007 and 2015. For every death by suicide, there are an estimated 8 to 25 suicide attempts, and more youths engage in nonsuicidal self-injury (NSSI). Frior suicide attempts are indicators of suicide death, and prior suicide attempts and NSSI are indicators of future suicide attempts.

There are no well-established, empirically supported treatments for decreasing suicide attempts or NSSIs in adolescents with elevated suicide risk.5,8-10 Efforts to identify effective interventions must overcome the challenge of engaging suicidal youths in treatment because 60% to 77% of these adolescents demonstrate nonadherence with recommended care.11 A meta-analysis9 of 17 randomized clinical trials (RCTs) comparing defined therapeutic interventions with treatment as usual for youth with histories of self-harm (suicide attempts and NSSI combined) found a significant advantage of therapeutic interventions for reducing selfharm compared with treatment as usual. Dialectical behavioral therapy (DBT), cognitive-behavioral therapy, and mentalization-based therapy were associated with the largest effect sizes; effects were strongest for reduction in overall self-harm, whereas effects for suicide attempts were not statistically significant. Randomized clinical trials demonstrating significant effects on suicide attempts among selfharming youths are limited. 12,13

Dialectical behavioral therapy is a multicomponent cognitive-behavioral treatment that targets treatment engagement and the reduction of self-harm and suicide attempts and focuses on teaching skills for enhancing emotion regulation, distress tolerance, and building a life worth living. ¹⁴ Research on DBT with adults has demonstrated low dropout and efficacy in reducing suicide attempts and NSSI. ¹⁵ Given its effectiveness with adults, DBT has been used for the treatment of suicidal youths with promising results. ¹⁶⁻¹⁸

A recent RCT with self-harming adolescents found large effect sizes for DBT in reducing self-harm and suicidal ideation relative to treatment as usual; effects were maintained at 1-year follow-up. Suicide attempts were, however, not examined as a separate outcome. In the present study, we focused on suicide attempts separately from overall self-harm because of the need to identify treatments that are effective for youths at the highest risk.

We report primary results from a large, multisite RCT with adolescents at high risk for suicide, comparing DBT with individual and group supportive therapy (IGST) designed to match DBT for nonspecific treatment factors. This trial was powered to examine suicide attempt, NSSI, and self-harm outcomes. To strengthen power for detecting effects on suicide attempts, we selected youths at high risk for suicide attempts based on prior suicide attempts, repetitive NSSI, clinically significant suicidal ideation, and emotional dysregulation. This is the first multisite RCT, to our knowledge, that was powered to compare DBT with another manualized treatment with adolescents selected for high suicide risk and to focus on suicide attempts as the primary outcome. A priori hypotheses were that DBT would be associated with fewer suicide at-

Key Points

Question Is dialectical behavior therapy more effective than individual and group supportive therapy in reducing suicide attempts and nonsuicidal self-injury in suicidal adolescents?

Findings This multisite randomized clinical trial of 173 adolescents indicated a significant advantage for dialectical behavior therapy compared with individual and group supportive therapy for reducing repeat suicide attempts, nonsuicidal self-injury, and total self-harm after treatment. Although the dialectical behavior therapy advantage weakened over time, secondary analyses indicated that youths receiving dialectical behavior therapy were more likely to respond to treatment, indexed by the absence of any self-harm, after treatment and at 12-month follow-up.

Meaning Dialectical behavior therapy is effective for reducing repeat suicide attempts among highly suicidal adolescents, underscoring the value of dialectical behavior therapy in suicide prevention initiatives.

tempts, NSSI episodes, overall self-harm, and lower treatment dropout than IGST.

Methods

Study sites included the Behavior Research and Therapy Clinic, University of Washington, Seattle; Department of Psychiatry, Seattle Children's Hospital, Seattle, Washington; Los Angeles Biomedical Research Institute at Harbor-University of California Los Angeles Medical Center, Los Angeles; and Ronald Reagan UCLA Medical Center, Los Angeles, California. Youths gave written informed assent (or consent if ≥18 years of age), and parents gave written informed consent. The trial protocol can be found in the Supplement. All procedures were approved by each site's institutional review board (University of Washington Institutional Review Board and Los Angeles Biomedical Research Institute at Harbor-University of California Los Angeles Medical Center) and monitored by a data and safety monitoring board.

Participant Selection, Recruitment, and Enrollment

A total of 173 participants were recruited from January 1, 2012, through August 31, 2014, through hospital emergency departments, inpatient and outpatient services, and community programs. Inclusion criteria were as follows: at least 1 lifetime suicide attempt, elevated past-month suicidal ideation (≥24 on the Suicidal Ideation Questionnaire Junior [SIQ-JR]²¹), selfinjury repetition (≥3 lifetime self-harm episodes, including 1 in the 12 weeks before screening), 3 or more borderline personality disorder criteria, ²² and age of 12 to 18 years. Exclusion criteria were as follows: IQ less than 70 on the Kauffman Brief Intelligence Test²³; primary problem of psychosis, mania, anorexia, or life-threatening condition; youth without English fluency; and parent without English or Spanish fluency.

Randomization

Participants were randomized to treatment condition groups using a computerized adaptive minimization randomization

procedure²⁴ that matched participants across conditions within sites on age, number of suicide attempts, number of previous self-injuries, and psychotropic medication use. Recruitment and assessment staff were naive to randomization status and sequence. Participants learned their treatment assignment at the first therapy session.

Treatment Conditions

The interventions were designed to offer comparable treatment exposure. Both treatments used theoretically driven treatment manuals, 6 months of weekly individual and group therapy, parent participation, and the DBT 4-miss rule, ¹⁴ which indicates that adolescents missing 4 consecutive treatment sessions were considered to have dropped out of treatment but remained in the intention-to-treat sample and completed follow-up evaluations.

Dialectical Behavior Therapy

Dialectical behavior therapy for adolescents included 4 components: weekly individual psychotherapy, multifamily group skills training, youth and parent telephone coaching, and weekly therapist team consultation. ^{14,16} Parents were seen individually in session 1 and offered 7 or more family sessions. Because adolescent DBT focuses on increasing validation in parent-teen interactions, parent participation in treatment was in family sessions. Suicide risk was monitored regularly; increased risk triggered use of the Linehan Suicide-Risk Assessment and Management Protocol. ²⁵

Individual and Group Supportive Therapy

Individual and group supportive therapy was a manualized client-centered treatment similar to comparator conditions used in prior RCTs. 26,27 Consistent with the theory of Joiner et al 28 that emphasized "thwarted belongingness" as a suicide risk factor, IGST emphasized acceptance, validation, and feelings of connectedness and belonging. Individual and group supportive therapy included individual sessions, adolescent supportive group therapy, as-needed parent sessions (\leq 7 sessions), and weekly therapist team consultation. Assessment and management of suicidal behavior followed the American Academy of Child and Adolescent Psychiatry practice parameters. 29 Parent participation was in collateral sessions. Therapists were available by telephone during office hours; crisis numbers were provided for 24-hour daily coverage.

Therapist Training and Quality Assurance

Therapists provided treatment in only 1 study arm and attended a multiday training led by the treatment developer (M.M.L. for DBT and J.C. for IGST). Within each treatment group, therapists participated in weekly cross-site training and meetings and weekly site team consultation meetings (DBT) or group supervision (IGST). Treatment adherence was evaluated on randomly selected individual and group sessions once per month for therapists' first study case and once per 8 sessions for subsequent cases. Adherence ratings included detailed feedback and were reviewed weekly with remediation as needed.

Adherence to DBT monitoring used the DBT Adherence Scale (computed 5-point global scale)³⁰ rated by the instru-

ment's codeveloper and calibrated and reliable coders. The treatment developer (J.C.) and reliable coders rated IGST adherence using the IGST/Client Centered Therapy adherence scale. Adherence was strong in both conditions (DBT: 384 sessions [289 individual sessions and 95 group sessions; mean [SD] adherence, 4.1 [0.15] [>4.0 considered to be adherent]; IGST: 386 sessions [315 individual sessions and 71 group sessions; mean [SD] adherence, 99.32% [3.64] [≥90% considered to be adherent]).

Assessments

Assessments occurred at baseline (before treatment), 3 months (middle of treatment), 6 months (end of treatment), 9 months, and 12 months. Assessors naive to treatment group were trained for administration and scoring of each measure. For interview measures (Suicide Attempt Self-Injury Interview [SASII], Schedule for Affective Disorders and Schizophrenia for School-Aged Children [KSADS], and Structured Clinical Interview for the *DSM-IV*, Axis II [SCID-II]) after initial training, assessors were observed, and interviews were corated by a designated criterion standard interviewer until they demonstrated 0.80 interrated reliability; thereafter, 1 in every 15 interviews was randomly selected and corated. For the KSADS and SCID-II, the measure of reliability was diagnostic agreement; for SASII, reliability was measured by item-level agreement.

Primary Outcomes

Suicide attempts, NSSI, and self-harm were measured using the SASII, which measured the frequency, intent, and medical severity of suicide attempts and NSSI episodes. ²⁵ The SIQ-JR was used to assess suicidal ideation. ²¹

Psychiatric Disorders and Substance Use

The *DSM-IV-TR* diagnoses were made using the mood, anxiety, psychosis, and eating disorder modules from the KSADS. ³¹ Borderline personality traits were assessed using the SCID-II borderline personality disorder module. ²² The Drug Use Screening Inventory (DUSI) ³² was used to assess substance abuse. Externalizing symptoms were assessed using parent report on the Child Behavior Checklist. ³³ Demographic information was assessed through parent report (youth age, sex, race/ethnicity, family income, and number of adults and children in the household).

Statistical Analysis

Treatment groups were compared on baseline demographic and clinical characteristics using χ^2 for binary and categorical variables and 2-tailed t tests for continuous variables. Logistic regression was used to identify factors related to treatment dropout and assessment nonresponse. Treatment effects were evaluated using intention-to-treat analyses. To accommodate continuous and noncontinuous outcome measures (binary, count, and ordinal), analyses were implemented using 2 mixed-effects repeated-measures techniques: mixed-model analysis of variance when change over time was nonlinear and hierarchical linear models when change followed a mathematical profile over time, such as linear, log-linear, piecewise linear, or polynomial. These analyses in-

Table 1. Pretreatment Demographic, Self-injury, and Diagnostic Data by Conditiona

Variable	DBT Group (n = 86)	IGST Group (n = 87)	Total (N = 173)	Statistic	P Value
Female	82 (95.30)	81 (94.19)	163 (94.8)	$\chi^2 = 0.13$.72
Age, mean (SD), y	14.77 (1.50)	15.041.43)	14.89 (1.47)	t ₁₆₉ = 1.24	.22
Race/ethnicity					
White	50 (58.14)	47 (55.29)	97 (56.39)		.72
Native American	1 (1.16)	0 (0)	1 (.58)		
African American	7 (8.14)	5 (5.88)	12 (7.02)	2 2.04	
Asian American	4 (4.65)	6 (7.06)	10 (5.85)	$-\chi_5^2 = 2.84$	
Other	1 (1.16)	3 (3.53)	4 (2.34)		
Hispanic	23 (26.70)	24 (28.24)	48 (27.49)		
Parental marital status					
Married	44 (57.14)	38 (52.05)	82 (54.67)		
Single, divorced, or separated	31 (40.26)	3243.84	6342.00	$\chi_3^2 = 0.68$.88
Widowed	1 (1.30)	2 (2.74)	3 (2.00)	//3	
Other	1 (1.30)	1 (1.37)	1 (1.33)		
Parental educational level					
Less than high school	7 (8.86)	5 (6.76)	12 (7.84)		.91
High school graduate or GED	10 (12.66)	9 (12.16)	19 (12.42)	2 0.54	
Some college or technical school	12 (16.46)	15 (20.274)	28 (18.30)	$\chi_3^2 = 0.54$	
College graduate	49 (62.03)	45 (60.81)	94 (61.44)		
Income, \$					
<15 000	8 (11.94)	7 (10.14)	15 (11.03)		
15 000-29 999	4 (5.97)	5 (7.25)	9 (6.62)	2 6 05	.43
30 000-49 999	8 (11.00)	17 (23.90)	25 (17.40)	$-\chi_3^2 = 6.95$	
≥50 000	52 (71.20)	42 (59.20)	95 (65.3)		
SIQ-JR score, mean (SD)	57.88 (17.01)	56.23 (15.37)	57.06 (16.18)	$t_{171} = 0.67$.51
SASII score (lifetime)					
1	34 (39.5) ^b	37 (42.5)	71 (41.0)	2	.69
>1	52 (60.5)	50 (57.5)	102 (59.0)	$-\chi_1^2 = 0.16$	
NSSI (lifetime), mean (SD)	26.29 (43.06)	29.14 (52.63)	26.32 (47.19)	$t_{171} = 0.34$.73
Disorders					
Depressive ^c	68 (79.10)	77 (88.50)	145 (83.81)	$\chi_1^2 = 2.84$.10
Anxiety ^c	42 (48.80)	51 (59.30)	93 (54.10)	$\chi_1^2 = 2.11$.17
Eating ^{c,d}	1 (1.16)	0	1 (0.68)	$\chi_1^2 = 1.00$.32
Borderline personality disorder ^c	43 (50.00)	49 (56.30)	92 (53.20)	$\chi_1^2 = 0.69$.45
CBCL Externalizing T score, mean (SD)	64.68 (11.27)	62.01 (16.11)	66.05 (8.45)	t ₁₆₆ = 1.25	.21
DUSI average problem density score, mean (SD) ^e	22.73 (24.77)	21.51 (26.43)	22.12 (25.55)	t ₁₆₅ = .31	.76

Abbreviations: CBCL, Child Behavior Checklist; DBT, dialectical behavior therapy; DUSI, Drug Use Screening Inventory; IGST, individual and group supportive therapy; SASII, Suicide Attempt Self-Injury Interview; SIQ-JR, Suicidal Ideation Questionnaire Junior.

- ^a Data are presented as number (percentage) of participants unless otherwise indicated.
- b One participant was accepted into the study who had a bottle of pills, was interrupted before ingesting the medication, and was hospitalized. Because the medication was never ingested, this was not categorized as interrupted. She was deemed to be appropriate for the study based on this event combined with high SIQ-JR score, Difficulties in Emotion Regulation Scale score, and 101 NSSI episodes and was categorized as having 1 lifetime suicide attempt.
- ^c Psychiatric diagnosis was established for the past year and current status; current status is reported in Table 1.
- ^d A total of 143 of 173 participants completed the eating disorders module of the Schedule for Affective Disorders and Schizophrenia for School-Aged Children because of a protocol change.
- ^e The DUSI scores reflect an overall past month problem density score, ranging from 0% to 100%.

cluded treatment group (DBT, IGST) as the between-subjects factor, time (baseline and 3, 6, 9, and 12 months) as the within-subjects factor, and group × time interactions. Pairwise contrasts from the mixed-effects models were used to evaluate between-group differences. Outcomes analyses adjusted for site and assessed for differential treatment effects across site by including a site × treatment interaction. Site × treatment interactions were nonsignificant. Pattern-mixture models assessed whether estimates in the mixed-effects models were informatively dependent on missing data patterns; analyses were not sensitive to missing data patterns. Because higher levels of treatment were predicted in DBT vs IGST, we used pat-

tern-mixture models to evaluate evidence of an informative attrition mechanism defined in this case as differential treatment rates leading to differences in outcomes. ^{36,37}

We conducted secondary analyses to assess the clinical significance of between-group differences on outcomes at the post-treatment and final follow-up points, using the method of Jacobson and Truax³⁸ for evaluating clinical significance. Clinically significant change was defined as no self-harm during the interval. All dropouts and missing data were replaced using multiple imputation based on averaging 10 iterative Markov-Chain Monte Carlo imputations to complete the missing data, providing a full intention-to-treat analysis. To further test results,

sensitivity analyses were conducted with all dropouts and missing data replaced by the previous available assessment. Proportions, odds ratios (ORs), number needed to treat, adjusted mean treatment effects, and the Cohen d for continuous variables are presented for magnitude of effects. Degrees of freedom for all mixed-effects models were estimated with the approximation of Kenward and Roger. 35 Confidence intervals were model-based derived as a function of the estimate, standard error, and respective distribution of the test statistic (ie, Wald χ^2 for ordinal mixed effects model and t distribution for the linear mixed effects model). For the SIQ-JR, we conducted a piecewise model examining change from baseline to after intervention and after intervention through follow-up.

The study was designed to have a sample of 170, which is powered accounting for 20% attrition to detect a 20% difference in binary outcomes and a Cohen d = 0.35 for continuous outcomes with 86.2% power for binary outcomes and 84.1% power for continuous outcomes. 39,40 Power calculations and all analyses were all based on 2-tailed t tests. P<.05 was considered to be statistically significant.

Results

Participant Flow and Characteristics

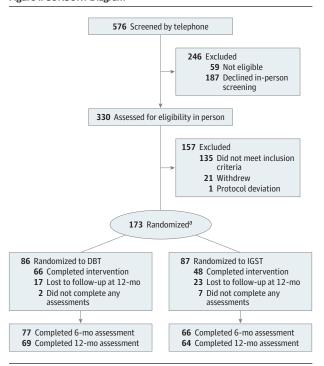
Table 2. Treatment Participation

A total of 173 adolescents (163 [94.8%] female and 97 [56.4%] white; mean [SD] age, 14.89 [1.47] years) were studied (Table 1). Eighty-four youths (97.7%) randomized to the DBT group and 80 (91.9%) to the IGST group completed 1 or more postbaseline assessment (Figure 1). The number of participants missing all follow-up evaluations was not significantly different between groups (DBT: 2 [2.3%] of 86; IGST: 7 [8.0%] of 87; Fisher exact test P = .17).

Compared with youths in the IGST group, youths in the DBT group participated in more individual and group treatment sessions and remained in treatment for more weeks (Table 2). Higher treatment completion (defined as ≥24 individual sessions) rates were observed for DBT than for IGST participants (39 [45.4%] of 86 vs 14 [16.1%] of 87; $\chi_1^2 = 17.42$; P < .001). Patterns of completion were defined as follows:

fewer than 16 individual sessions indicated a low completion rate; 16 to 23 individual sessions, moderate completion rate; and 24 or more, high completion rate. Rates per arm across the 3 patterns (low, moderate, and high) were 24.4%, 30.2%, and 45.4%, respectively, for DBT and 44.8%, 39.1%, and 16.1%, respectively, for IGST ($\chi^2 = 18.21, P < .001$). Analyses of patternmixture models (suicide attempt: $F_{2.171}$ = 1.45, P = .24; NSSI: $F_{2,171} = 0.81$, P = .44; self-harm: $F_{2,171} = 0.70$, P = .50; SIQ-JR: $F_{2,171}$ = 1.65, P = .19) revealed no evidence of an informative attrition mechanism on the analyses described below, indicat-

Figure 1. CONSORT Diagram



DBT indicates dialectical behavior therapy; IGST, individual and group supportive therapy.

Group Differences

Variable	DBT Group	IGST Group	Statistic	P Value
Individual treatment sessions	19.97 (7.71) [2-31]	15.29 (8.39) [1-31]	t ₁₇₁ = 3.82	<.001
Participating in sessions, %				
0-15	24.40	44.80		
16-23	30.20	39.10	NA	NA
≥24	45.40	16.10		
Group treatment sessions	16.86 (6.60) [0-24]	13.13 (7.27) [0-24]	$t_{171} = 3.54$	<.001
Participating in sessions, %				

No. of Participants, Mean (SD) [Range]

0-15 14.00 24.10 7.00 16-23 19.50 NA NA 79.00 24 56.30 Weeks in treatment 23.40 (8.33) 18.70 (9.81) .008 $t_{171} = 2.67$

Abbreviations: DBT, dialectical behavior therapy; IGST, individual and group supportive therapy; NA, not applicable.

a Included in intent-to-treat analysis.

Table 3. Outcome Measures

Outcome	No./Total No. (%) of Participants			Odds Ratio (95% CI) or Estimated (SE)	
	6 mo: Baseline	6-mo: Baseline to After Treatment	12 mo: After Treatment to End of Follow-up ^a	Difference at End of Active Treatment	Difference at Final Follow-up
No. of suicide attempts ^b					
IGST					
0	16/87 (18.4)	51/65 (78.5)	52/58 (89.7)		0.65 (0.12.2.26)
1	41/87 (47.1)	9/65 (13.9)	6/58 (10.3)		
≥2	30/87 (34.5)	5/65 (7.7)	0/58 (0)	0.30 (0.10.0.01)(
DBT				0.30 (0.10-0.91) ^c	0.65 (0.12-3.36)
0	15/86 (17.4)	65/72 (90.3)	66/71 (93.0)		
1	42/86 (48.8)	6/72 (8.3)	3/71 (4.2)		
≥2	29/86 (33.7)	1/72 (1.4)	2/71 (2.8)		
No. of NSSI episodes ^b					
IGST					2.52.624.452
0	4/87 (4.6)	26/65 (40.0)	30/58 (51.7)		
1-3	20/87 (23.0)	20/65 (30.8)	22 (37.9)		
4-6	12/87 (13.8)	8/65 (12.3)	1/58 (1.7)		
≥7	51/87 (58.6)	11/65 (16.9)	5/58 (8.6)		
DBT				0.32 (0.13-0.77) ^c	0.60 (0.24-1.52)
0	6/86 (7.0)	41/72 (56.9)	44/71 (62.0)		
1-3	20/86 (23.3)	21/72 (29.2)	19/71 (26.8)		
4-6	9/86 (10.5)	3/72 (4.2)	4/71 (5.6)		
≥7	51/86 (59.3)	7/72 (9.7)	4/71 (5.6)		
No. of self-harm episodes ^b					
IGST					
0	0/87 (0)	24/65 (36.9)	28/58 (48.3)		
1-3	19/87 (21.8)	22/65 (33.9)	24/58 (41.4)		
4-9	19/87 (21.8)	11/65 (16.9)	2/58 (3.5)		
≥10	49/87 (53.5)	8/65 (12.3)	4/58 (6.9)		
DBT				0.33 (0.14-0.78) ^c	0.58 (0.23-1.46)
0	0/86 (0)	39/72 (54.2)	44 (62.0)		
1-3	18/86 (20.9)	23/72 (31.9)	18/71 (25.4)		
4-9	22/86 (25.6)	3/72 (4.2)	7/71 (9.9)		
≥10	46/86 (53.5)	7/72 (9.7)	2/71 (2.8)		

Abbreviations: DBT, dialectical behavior therapy; IGST, individual and group supportive therapy; NSSI, nonsuicidal self-injury.

ing that results were not accounted for by differential treatment exposure.

Suicide and Self-harm: Primary Outcomes

From baseline to 6 months, 7 of 72 youths (9.7%) in the DBT group vs 14 of 65 youths (21.5%) in the IGST group reported suicide attempts. Corresponding rates reported between the 6-month and 12-month evaluations were 6 of 86 youths (7.0%) receiving DBT and 6 of 58 youths (10.3%) receiving IGST; 1 adolescent in the IGST group died by suicide in the follow-up period. The numbers of suicide attempts, NSSIs, and self-harm episodes were analyzed within a generalized linear mixed-effects model framework for ordinal data. ⁴¹ Using prespecified cut points based on prior trials, ⁴² frequency of suicide at-

tempts was categorized as 0, 1, or 2 or more; NSSIs as 0, 1 through 3, 4 through 6, and 7 or more; and self-harm episodes as 0, 1 through 3, 4 through 9, and 10 or more. All tests were 2-tailed using robust SEs. Significant advantages were found for DBT on all primary outcomes after treatment (**Table 3** and **Figure 2**), as indicated by the observed event rates with ORs below 1 indicating that the odds of being at a higher ordinal level are less for DBT compared with IGST. We examined the sensitivity of our ordinal mixed-effects results based on observed data categories; this analysis yielded approximate balance on the nonzero portion that consisted of any vs none for suicide attempts (OR, 0.27; 95% CI, 0.07-0.99); 0, 1, 2 through 4, 5 through 15, and 16 or more for NSSI acts (OR, 0.34; 95% CI, 0.14-0.81); and 0, 1, 2 and 3, 4 through 12, and 13 or more

^a Outcomes analyzed through a piecewise linear HLM with 2 phases of change: baseline through the end of active treatment (6 months) and end of active treatment through follow-up (12 months). Baseline values are based on the past 6 months.

^b Outcomes analyzed through an ordinal mixed-effects model that controlled for baseline level of severity. Descriptive data for suicide attempts, nonsuicidal self-injury, and self-harm episodes represent observed ordinal categories.

^c P < .05.

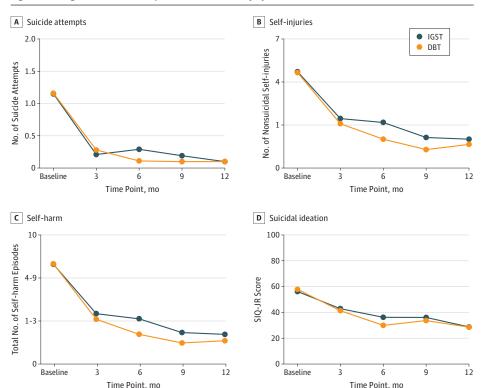


Figure 2. Changes in Suicide Attempts, Nonsuicidal Self-injury, Self-harm, and Suicidal Ideation

Outcomes analyzed through a piecewise hierarchical linear model with 2 phases of change (baseline through the end of active treatment [6 months] and end of active treatment through follow-up [12 months]). Baseline values are based on the past 6 months. DBT indicates dialectical behavior therapy; IGST, individual and group supportive therapy; SIQ-JR, Suicidal Ideation Questionnaire Junior.

for self-harm acts (OR, 0.32; 95% CI, 0.14-0.75). When the ORs in Table 3 were converted to number needed to treat estimates, for the DBT group to have an additional adolescent with no suicide attempted compared with the IGST group, the number needed to treat was 8.46. Similarly, the number needed to treat estimates were 5.92 for NSSI and 5.78 for self-harm, representing a small to medium effect size range. ⁴³

Secondary analyses indicated that DBT was associated with significantly higher rates of clinically significant change, defined as the absence of any self-harm. At 6 months, in the DBT group, 40 of 86 (46.5%) showed no self-harm vs 24 of 87 (27.6%) in the IGST group; at 12 months, 44 of 86 (51.2%) in the DBT group and 28 of 87 (32.2%) in the IGST group were self-harm free. Sensitivity analyses using previous response carried forward yielded similar results.

For the SIQ-JR, the mean profile plot indicated that change during the study did not follow a linear trajectory but instead 2 phases of change. A significant advantage for DBT emerged through the end of active treatment (6 months) (t_{169} = 2.20, Cohen d = 0.34, P = .03) but not from end of treatment through end of follow-up (12 months) (t_{169} = 0.73, Cohen d = 0.11, P = .46). The effect sizes contrast the rate and amount of change during the 2 phases on a standardized scale. After quantifying these effects on the SIQ-JR scale, compared with IGST, DBT had a mean (SE) additional reduction of 7.05 (3.21) points at 6 months, which decreased to 2.38 (3.25) points at 12 months.

Discussion

These results demonstrate the efficacy of DBT among adolescents for reducing suicide attempts, NSSI, and self-harm in a sample selected for elevated suicide risk. This is the first adolescent RCT to our knowledge to demonstrate that DBT is effective at decreasing suicide attempts. Use of manualized treatment as a control condition, designed to match DBT for nonspecific treatment components, further supports the value of DBT. Although the hypothesized posttreatment advantage for DBT occurred at 6 months, there were no statistically significant group differences at 12 months on primary outcomes because youths in both groups improved over time, providing some support for the IGST control condition. Secondary analyses of clinically significant change, as indexed by the absence of self-harm, revealed a statistically significant advantage for DBT at 12 months, with half of the youths in the DBT group reporting no self-harm vs one-third of youths in the IGST group. Although promising, these were secondary analyses; additional research should evaluate whether trials with greater statistical power or those including continuation or alternative treatment strategies might yield more sustained treatment benefits. The lack of sustained effects supports consideration of a more long-term treatment approach that views risk as continuing over time and incorporates preventive monitoring and intervention strategies. Future work is needed to address these challenges and provide families with realistic treatment expectations.

Youths in the DBT group attended significantly more treatment sessions than did youths in the IGST group and were significantly more likely to complete treatment. Although results of pattern-mixture models found no evidence of an informative attrition mechanism, 44 we cannot rule out the possibility that differential treatment exposure is a mechanism that leads to the DBT outcomes. Stronger DBT treatment retention is, however, an important finding given prior research that found difficulties with treatment engagement and adherence among suicidal and self-harming youths. 10 Although parents were involved in both treatments, DBT included greater family involvement, in which parents and youths learned coping skills as opposed to IGST's nondirective approach. This difference may have contributed to both greater retention and treatment effects, particularly because stronger family components are associated with treatment benefits for adolescent self-harm.9,12,13

Limitations

Study limitations included the predominantly female sample. Although consistent with the higher rates of suicide attempts in females and female samples in trials recruiting suicide-attempting youths, ^{45,46} males are more likely to die by suicide. Inclusion criteria were chosen to ensure the focus on suicidal and self-harming adolescents; future work is needed to

determine whether alternative inclusion criteria (eg, multiple suicide attempts) may alter outcomes, yield more male participants, and determine whether our findings generalize to males. The 4 study sites were diverse in ethnic and racial composition, but results may not generalize more broadly. This was a highly controlled RCT with rigorous quality control and highly trained therapists; it is important to determine whether similar results emerge when treatment is delivered under more routine practice conditions.

Conclusions

This multisite RCT evaluating DBT compared with another manualized treatment demonstrated advantages of DBT for reducing both suicide attempt and self-harm among youth at high risk for suicide. With the prior DBT^{19,20} RCT, there are now 2 independent RCTs with diverse samples and 250 self-harming youths demonstrating the efficacy of DBT for reducing self-harm in adolescents. These cross-study results support DBT as the first well-established, empirically supported treatment for decreasing self-harm in youths at high suicide risk. Our findings add to data supporting other promising treatment approaches, including cognitive-behavioral therapy, mentalization-based therapy, and family-based treatments. 9,12,13,47-49 Ongoing research is needed to advance the goal of reducing suicide deaths.

ARTICLE INFORMATION

Accepted for Publication: March 27, 2018. Published Online: June 20, 2018. doi:10.1001/jamapsychiatry.2018.1109

Author Affiliations: Seattle Children's Research Institute, Seattle, Washington (McCauley, Adrian): Department of Psychiatry, University of Washington, Seattle (McCauley, Adrian): Los Angeles Biomedical Research Institute at Harbor-University of California Los Angeles Medical Center, Los Angeles (Berk, Avina); Department of Psychiatry and Biobehaviorial Sciences, David Geffen School of Medicine at UCLA (University of California, Los Angeles), Los Angeles (Berk, Asarnow, Avina, Hughes); Allegheny Health Network, Drexel University College of Medicine, Philadelphia, Pennsylvania (Cohen); Department of Psychology, University of Washington, Seattle (Korslund, Harned, Linehan); Department of Psychiatry, University of Texas Southwestern, Dallas (Hughes); Department of Mathematics, West Chester University of Pennsylvania, West Chester (Gallop).

Author Contributions: Drs Linehan and Gallop had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: McCauley, Gallop,

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: McCauley, Berk, Asarnow, Adrian, Avina, Gallop. Critical revision of the manuscript for important intellectual content: McCauley, Berk, Asarnow, Adrian, Cohen, Korslund, Hughes, Harned, Linehan. Statistical analysis: Adrian, Harned, Gallop. Obtained funding: McCauley, Berk, Asarnow, Linehan.

Administrative, technical, or material support: McCauley, Berk, Asarnow, Adrian, Cohen, Korslund, Avina, Hughes, Harned.

Study supervision: McCauley, Berk, Asarnow, Adrian, Cohen, Korslund, Linehan.

Conflict of Interest Disclosures: Drs McCauley Berk, Adrian, Cohen, Korslund, Hughes, and Avina reported receiving grant support from the National Institute of Mental Health (NIMH), National Institutes of Health. Dr Asarnow reported receiving grant support and support from the American Psychological Association and the Society of Clinical Child and Adolescent Psychology and serving as a consultant on quality improvement interventions for depression and suicidal/self-harm behavior. Dr Harned reported receiving grant support and personal fees from the Behavioral Tech LLC outside the work represented in this article. Dr Linehan reported receiving royalties from Guilford Press for books that she has written on dialectical behavior therapy, royalties for training materials from Behavioral Tech LLC, and compensation for dialectical behavior therapy workshops, online programs, and books. No other disclosures were

Funding/Support: The study was funded by grants 5R01MH090159 (Drs Linehan and McCauley, principal investigators at University of Washington, Seattle Children's Hospital) and R01MH93898 (Drs Berk and Asarnow, principal investigators at Los Angeles sites) from the NIMH.

Role of the Funder/Sponsor: The NIMH project officer provided oversight of the study, monitored

study recruitment milestones, and worked with the principal investigators to amend the recruitment timeline as needed to meet the goals of the project. The decision to publish the data and its interpretation was made by Drs Linehan, McCauley, Berk, and Asarnow and supported by all the coauthors.

Meeting Presentations: Preliminary findings from this study were presented the Association for Behavioral and Cognitive Therapies Annual Meeting; October 28, 2016; New York, New York; and the International Academy of Suicide Research/ American Foundation for Suicide Prevention Annual Summit on Suicide Research; November 6, 2017; Henderson, Nevada.

Additional Contributions: Gretchen Gudmundsen, PhD, Seattle Children's Hospital, Seattle, Washington, and Deborah Tate, LCSW, Harbor-University of California Los Angeles Medical Center, Los Angeles, served as IGST therapy supervisors, and Susan Bland, MSW, University of Washington, Seattle, and Nicole Starace, PhD, Harbor-University of California Los Angeles Medical Center, Los Angeles, provided oversight of the assessment component of the project. Yevgeny Botanov, PhD, and Jennifer Shaver, PhD, University of Washington, Seattle, prepared the data sets for analyses. Heather Cook, Med, provided editorial and formatting support. They were all compensated for their work. We thank the adolescents and their parents or guardians for participating in this clinical trial; the therapists who served as treatment practitioners for this project; the supporting staff and volunteers who helped with administration of the study, data collection. data entry, and data management; and the

members of the Data and Safety Management Board (Donald Guthrie, PhD; David Brent, MD; Cheryl King, PhD; and Richard Reis, MD).

REFERENCES

- 1. Curtin SC, Warner M, Hedegaard H. Increase in suicide in the United States, 1999-2014. *NCHS Data Brief*. 2016;(241):1-8.
- 2. Mościcki EK. Epidemiology of completed and attempted suicide: toward a framework for prevention. *Clin Neurosci Res.* 2001;1(5):310-323. doi:10.1016/S1566-2772(01)00032-9
- **3**. Asarnow JR, Porta G, Spirito A, et al. Suicide attempts and nonsuicidal self-injury in the treatment of resistant depression in adolescents: findings from the TORDIA study. *J Am Acad Child Adolesc Psychiatry*. 2011;50(8):772-781. doi:10.1016/j.jaac.2011.04.003
- 4. Cox LJ, Stanley BH, Melhem NM, et al. A longitudinal study of nonsuicidal self-injury in offspring at high risk for mood disorder. *J Clin Psychiatry*. 2012;73(6):821-828. doi:10.4088/JCP.11m07250
- 5. Berk MS, Hughes J. Cognitive behavioral approaches for treating suicidal behavior in adolescents. *Curr Psychiatry Rev.* 2016;12(1):4-13.
- **6.** Wilkinson P, Kelvin R, Roberts C, Dubicka B, Goodyer I. Clinical and psychosocial predictors of suicide attempts and nonsuicidal self-injury in the Adolescent Depression Antidepressants and Psychotherapy Trial (ADAPT). *Am J Psychiatry*. 2011;168(5):495-501. doi:10.1176/appi.ajp.2010 10050718
- 7. Franklin JC, Ribeiro JD, Fox KR, et al. Risk factors for suicidal thoughts and behaviors: a meta-analysis of 50 years of research. *Psychol Bull*. 2017;143(2): 187-232. doi:10.1037/bul0000084
- **8**. Glenn CR, Franklin JC, Nock MK. Evidence-based psychosocial treatments for self-injurious thoughts and behaviors in youth. *J Clin Child Adolesc Psychol*. 2015;44(1):1-29. doi:10.1080/15374416.2014.945211
- 9. Ougrin D, Tranah T, Stahl D, Moran P, Asarnow JR. Therapeutic interventions for suicide attempts and self-harm in adolescents: systematic review and meta-analysis. *J Am Acad Child Adolesc Psychiatry*. 2015;54(2):97-107.e2. doi:10.1016/j.jaac .2014.10.009
- **10**. Brent DA, McMakin DL, Kennard BD, Goldstein TR, Mayes TL, Douaihy AB. Protecting adolescents from self-harm: a critical review of intervention studies. *J Am Acad Child Adolesc Psychiatry*. 2013;52(12):1260-1271. doi:10.1016/j.jaac.2013.09.009
- 11. Burns BJ, Costello EJ, Angold A, et al. Children's mental health service use across service sectors. Health Aff (Millwood). 1995;14(3):147-159. doi:10 .1377/hlthaff.14.3.147
- 12. Asarnow JR, Hughes JL, Babeva KN, Sugar CA. Cognitive-behavioral family treatment for suicide attempt prevention: a randomized controlled trial. *J Am Acad Child Adolesc Psychiatry*. 2017;56(6): 506-514. doi:10.1016/j.jaac.2017.03.015
- **13.** Esposito-Smythers C, Spirito A, Kahler CW, Hunt J, Monti P. Treatment of co-occurring substance abuse and suicidality among adolescents: a randomized trial. *J Consult Clin Psychol.* 2011;79(6):728-739.

- **14.** Linehan M. Cognitive-Behavioral Treatment of Borderline Personality Disorder. New York, NY: Guilford Press: 1993.
- **15.** Linehan MM, Korslund KE, Harned MS, et al. Dialectical behavior therapy for high suicide risk in individuals with borderline personality disorder: a randomized clinical trial and component analysis. *JAMA Psychiatry*. 2015;72(5):475-482. doi:10.1001/jamapsychiatry.2014.3039
- **16.** Miller AL, Rathus JH, Linehan MM. *Dialectical Behavior Therapy with Suicidal Adolescents*. New York, NY: Guilford Press; 2006.
- 17. Sunseri PA. Preliminary outcomes on the use of dialectical behavior therapy to reduce hospitalization among adolescents in residential care. *Residential Treat Child Youth*. 2004;21(4): 59-76. doi:10.1300/J007v21n04
- **18.** Shelton D, Kesten K, Zhang W, Trestman R. Impact of a dialectic behavior therapy-corrections modified (DBT-CM) upon behaviorally challenged incarcerated male adolescents. *J Child Adolesc Psychiatr Nurs*. 2011;24(2):105-113. doi:10.1111/j..1744-6171.2011.00275.x
- 19. Mehlum L, Tørmoen AJ, Ramberg M, et al. Dialectical behavior therapy for adolescents with repeated suicidal and self-harming behavior: a randomized trial. *J Am Acad Child Adolesc Psychiatry*. 2014;53(10):1082-1091. doi:10.1016/j.jaac.2014.07.003
- **20**. Mehlum L, Ramberg M, Tørmoen AJ, et al. Dialectical behavior therapy compared with enhanced usual care for adolescents with repeated suicidal and self-harming behavior: Outcomes over a one-year follow-up. *J Am Acad Child Adolesc Psychiatry*. 2016;55(4):295-300. doi:10.1016/j.jaac.2016.01.005
- 21. Reynolds WM. Suicidal Ideation Questionnaire. Lutz, FL: Psychological Assessment Resources; 1987.
- **22.** First MB, Gibbon M, Spitzer RL, Benjamin LS. *User's Guide for the Structured Clinical Interview for DSM-IV Axis II Personality Disorders: SCID-II.* Washington, DC: American Psychiatric Association Publishing: 1997.
- 23. Kaufman AS, Kaufman NL. *Kaufman Brief Intelligence Test—Second Edition (KBIT-2)*. Circle Pines,
 MN: American Guidance Service; 2009.
- **24.** Scott NW, McPherson GC, Ramsay CR, Campbell MK. The method of minimization for allocation to clinical trials: a review. *Control Clin Trials*. 2002;23(6):662-674. doi:10.1016/S0197-2456(02) 00242-8
- **25.** Linehan MM, Comtois KA, Brown MZ, Heard HL, Wagner A. Suicide Attempt Self-Injury Interview (SASII): development, reliability, and validity of a scale to assess suicide attempts and intentional self-injury. *Psychol Assess*. 2006;18(3): 303-312. doi:10.1037/1040-3590.18.3.303
- **26**. Brent DA, Holder D, Kolko D, et al. A clinical psychotherapy trial for adolescent depression comparing cognitive, family, and supportive therapy. *Arch Gen Psychiatry*. 1997;54(9):877-885. doi:10.1001/archpsyc.1997.01830210125017
- **27**. Cohen JA, Mannarino AP, Knudsen K. Treating sexually abused children: 1 year follow-up of a randomized controlled trial. *Child Abuse Negl*. 2005;29(2):135-145. doi:10.1016/j.chiabu.2004.12 .005

- 28. Joiner TE Jr, Van Orden KA, Witte TK, Rudd MD. *The Interpersonal Theory of Suicide: Guidance for Working with Suicidal Clients*. Washington, DC: American Psychological Association; 2009.
- **29.** Pliszka S; AACAP Work Group on Quality Issues. Practice parameter for the assessment and treatment of children and adolescents with attention-deficit/hyperactivity disorder. *J Am Acad Child Adolesc Psychiatry*. 2007;46(7):894-921.
- **30**. Linehan MM, Korslund KE. *Dialectical Behavior Therapy Adherence Manual*. Seattle: University of Washington, Unpublished Work; 2003.
- **31**. Kaufman J, Birmaher B, Brent D, et al. Schedule for affective disorders and schizophrenia for school-age children-present and lifetime version (K-SADS-PL): initial reliability and validity data. *J Am Acad Child Adolesc Psychiatry*. 1997;36(7):980-988. doi:10.1097/00004583-199707000-00021
- **32**. Tarter RE, Hegedus AM. The drug use screening inventory: its applications in the evaluation and treatment of alcohol and other drug abuse. *Alcohol Res Health*. 1991;15(1):65.
- **33.** Achenbach TM, Rescorla L. *ASEBA School-Age Forms & Profiles.* Burlington, VT: Aseba; 2001. http://aseba.com/ordering/ASEBA%2OReliability%20and%20Validity-School%20Age.pdf. Accessed May 30, 2017.
- **34**. Agresti A. *Categorical Data Analysis*. New York, NY: John Wiley & Sons Inc; 1990.
- **35**. Kenward MG, Roger JH. Small sample inference for fixed effects from restricted maximum likelihood. *Biometrics*. 1997;53(3):983-997. doi:10 .2307/2533558
- **36**. Hedeker D, Gibbons RD. Application of random-effects pattern-mixture models for missing data in longitudinal studies. *Psychol Methods*. 1997; 2(1):64-78. doi:10.1037/1082-989X.2.1.64
- **37**. Hedeker D, Gibbons RD. *Longitudinal Data Analysis*. New York, NY: John Wiley & Sons; 2006.
- **38**. Jacobson NS, Truax P. Clinical significance: a statistical approach to defining meaningful change in psychotherapy research. *J Consult Clin Psychol*. 1991;59(1):12-19.
- **39**. Keller MB, McCullough JP, Klein DN, et al. A comparison of nefazodone, the cognitive behavioral-analysis system of psychotherapy, and their combination for the treatment of chronic depression. *N Engl J Med*. 2000;342(20):1462-1470. doi:10.1056/NEJM200005183422001
- **40**. Ahn C, Overall JE, Tonidandel S. Sample size and power calculations in repeated measurement analysis. *Comput Methods Programs Biomed*. 2001; 64(2):121-124. doi:10.1016/S0169-2607(00)00095-X
- **41**. Hedeker D, Mermelstein RJ. Analysis of longitudinal substance use outcomes using ordinal random-effects regression models. *Addiction*. 2000;95(11s3):381-394. doi:10.1046/j.1360-0443.95.11s3.7.x
- **42.** Linehan MM, McDavid JD, Brown MZ, Sayrs JHR, Gallop RJ. Olanzapine plus dialectical behavior therapy for women with high irritability who meet criteria for borderline personality disorder: a double-blind, placebo-controlled pilot study. *J Clin Psychiatry*. 2008;69(6): 999-1005.

- **43**. Kraemer HC, Kupfer DJ. Size of treatment effects and their importance to clinical research and practice. *Biol Psychiatry*. 2006;59(11):990-996.
- **44**. Rubin DB. Inference and missing data. *Biometrika*. 1976;63(3):581-592. doi:10.1093/biomet/63.3.581
- **45**. Brent DA, Greenhill LL, Compton S, et al. The Treatment of Adolescent Suicide Attempters study (TASA): predictors of suicidal events in an open treatment trial. *J Am Acad Child Adolesc*
- *Psychiatry*. 2009;48(10):987-996. doi:10.1097/CHI .0b013e3181b5dbe4
- **46**. Donaldson D, Spirito A, Esposito-Smythers C. Treatment for adolescents following a suicide attempt: results of a pilot trial. *J Am Acad Child Adolesc Psychiatry*. 2005;44(2):113-120. doi:10.1097/00004583-200502000-00003
- **47**. Pineda J, Dadds MR. Family intervention for adolescents with suicidal behavior: a randomized controlled trial and mediation analysis. *J Am Acad Child Adolesc Psychiatry*. 2013;52(8):851-862.
- **48**. Huey SJ Jr, Henggeler SW, Rowland MD, et al. Multisystemic therapy effects on attempted suicide by youths presenting psychiatric emergencies. *J Am Acad Child Adolesc Psychiatry*. 2004;43(2):183-190.
- **49**. Diamond G, Russon J, Levy S. Attachment-based family therapy: a review of the empirical support. *Fam Process*. 2016;55(3):595-610. doi:10.1111/famp.12241