



# School-Based Treatment for Anxiety Research Study (STARS): a Randomized Controlled Effectiveness Trial

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Published online: 20 November 2019

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## Abstract

The current study compared the effectiveness of a school-clinician administered cognitive behavioral treatment (CBT) to treatment as usual (TAU) at post-treatment (i.e., after 12 weeks) and at a 1 year follow-up. Sixty-two school-based clinicians (37 in CBT; 25 in TAU) and 216 students (148 students in CBT; 68 in TAU) participated. Students were ages 6–18 (mean age 10.87; 64% Caucasian & 29% African American; 48.6% female) and all met DSM-IV diagnostic criteria for a primary anxiety disorder. Independent evaluators (IEs) assessed clinical improvement, global functioning, and loss of anxiety diagnoses; children and parents completed measures of anxiety symptoms. At post-treatment, no significant treatment main effects emerged on the primary outcome; 42% and 37% of youth were classified as treatment responders in CBT and TAU respectively. However, parent-report of child anxiety showed greater improvements in CBT relative to TAU ( $d = .29$ ). Moderation analyses at post-treatment indicated that older youth, those with social phobia and more severe anxiety at baseline were more likely to be treatment responders in CBT compared to TAU. At the 1 year follow-up, treatment gains were maintained but no treatment group differences or moderators emerged. CBT and TAU for pediatric anxiety disorders, when delivered by school clinicians were generally similar in effectiveness for lowering anxiety and improving functioning at both post-treatment (on all but the parent measure and for specific subgroups) and 1 year follow-up. Implications for disseminating CBT in the school setting are discussed.

**Keywords** Child anxiety · Treatment · School-based · Treatment as usual · Cognitive behavioral therapy

Pediatric anxiety disorders are common and severely impair children's academic, social, and behavioral

functioning (Swan & Kendall, 2016). Despite the efficacy of CBT for anxiety, dissemination of CBT into community settings has been slow (McHugh & Barlow, 2012). Moreover, less than half of anxious youth receive treatment (Chavira, Stein, Bailey, & Stein, 2004). Significant income and race-based disparities in access and utilization rates also indicate that some treatments are only reaching select populations (Ryan, Jorm, Toumbourou, & Lubman, 2015). The expansion of school-based treatments holds the promise of increasing access to quality evidenced-based care for all (Weist et al., 2017).

CBT delivered in schools for youth with anxiety can be effective (see Sanchez et al., 2018 for review). Several small ( $N < 50$ ) RCTs have compared school-based CBT for anxious youth to a wait-list. In these studies, CBT was superior to the control condition (i.e., no treatment; Bernstein, Layne, Egan, & Tennison, 2005; Chiu et al., 2013; Masia-Warner et al., 2005). However, few studies have compared CBT with an active treatment comparison and results often fail to show treatment group differences (James, James, Cowdrey, Soler, & Choke, 2013). Findings from the most recent Cochrane meta-analysis of CBT for pediatric anxiety disorders (41

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studies;  $N=1806$  youth) concluded there was “limited and inconclusive” data showing CBT to be superior to non-CBT active treatments (James et al., 2013).

Only two studies have compared CBT to an active control condition in schools using non-CBT clinicians (Ginsburg, Becker, Drazdowski, & Tein, 2012; Masia-Warner, Fisher, Shrout, Rathor, & Klein, 2007). Masia-Warner et al. (2016) evaluated a 12-week group-based intervention (i.e., *Skills for Academic and Social Success*; SASS) for adolescents with social anxiety disorder (SOP;  $N=138$  grades 9–11). Youth were randomized to: (a) SASS delivered by school counselors (C-SASS), (b) SASS delivered by doctoral level psychologists (P-SASS), or (c) a control condition, *Skills for Life* (SFL), a nonspecific counseling program. At post-treatment and follow-up between 21–39% of youth in C/P SASS no longer met criteria for SOP, compared to 7–11% in the control condition. There were no differences between SASS delivered by school counselors and psychologists suggesting that with extensive training and supervision, school counselors can deliver CBT with equal success as CBT specialists. However, resources in most public schools are limited; whether similar outcomes can be achieved with less training and supervision is unknown.

In our pilot work, a modular CBT (M-CBT) was compared to treatment as usual (TAU) delivered by school-based clinicians in a racially diverse sample of youth ages 7 to 17 ( $N=32$ ; 87% African American) who met criteria for a range of anxiety disorders (Ginsburg et al., 2012). Clinicians received 1 day of training and supervision was offered but not mandatory to be consistent with typical school practices. Based on intent-to-treat analyses, youth in both groups showed significant improvement, however, no between group differences were found on any of the clinical outcomes measured at post-treatment or a 3-months follow-up.

The current study extended this line of research by conducting a 2 (intervention conditions)  $\times$  3 (pre-treatment, post-treatment, 1 year follow-up) RCT with 216 youth with anxiety disorders anxious and 62 school-based clinicians and examined whether M-CBT was superior to TAU in: 1) clinical improvement (primary outcome) and global functioning, and 2) reductions in anxiety severity, loss of primary disorder, and loss of all study inclusion anxiety disorders. IEs conducted outcome assessments and parents and children completed questionnaires. Treatment adherence was assessed via audiotaped therapy sessions. Select baseline moderators (e.g., anxiety severity, age, gender, race/ethnicity, specific anxiety disorder) of treatment outcome were examined for the primary outcome. Based on the literature showing mixed findings when CBT was compared to an active comparison, no directional hypotheses were made.

## Methods

### Participants

**Clinicians** Sixty-two volunteer school-based clinicians (across 59 elementary, middle, and high schools in Maryland and Connecticut) who enrolled at least one student served as participants. Clinicians were predominately female (87%) and Caucasian (71%) and were social workers (37%), counselors (5%), school psychologists (48%), and others (10%). Table 1 presents additional clinician characteristics.

**Youth** Eligible students were ages 6–18 and met DSM-IV criteria for a primary anxiety disorder (described below). Youth were excluded if they had a medical or psychiatric condition contraindicating study treatment (e.g., suicidality) and needed immediate or alternative treatment, were receiving psychosocial treatment for anxiety, and/or were in the custody of state social services. Youth on stable doses of medication for a psychiatric disorder were included if they met inclusion criteria. Characteristics of youth at baseline are presented in Table 2.

### Measures

**Clinician Characteristics Form** Clinicians provided demographics and professional experience.

**Child Demographic Questionnaire** Primary caregivers reported demographics for their family (e.g., age, gender, race/ethnicity, parental education).

**Mental Health Service Utilization Form** At post and follow-up assessments, IEs asked parents whether their child utilized any mental health services since the last evaluation. An overall “yes/no” score was used as a control variable.

### Anxiety and Related Outcomes

**Anxiety Disorders Interview Schedule for DSM-IV (ADIS; Silverman & Albano, 1996)** The ADIS is considered the gold standard interview for pediatric anxiety disorders. Diagnoses and Clinician Severity Ratings (CSR, reflecting severity and impairment; range = 0–8; 4 required for diagnosis) were derived from separate child and parent interviews. Trained IEs used their clinical judgment in consultation with an IE supervisor to generate diagnoses and CSR ratings. The “primary” diagnosis was the disorder with the highest CSR. Based on 60 co-rated video-taped evaluations across all timepoints, inter-rater agreement was 85% for the primary diagnosis ( $Kappa = .82$ ). For primary diagnosis of social anxiety disorder specifically, inter-rater agreement was 95% and kappa was .84 ( $n = 60$  co-rated evaluations across all timepoints). For loss of all study entry anxiety disorders (calculated based on

**Table 1** Baseline clinician descriptive and group comparison data

Variable	Total ( <i>N</i> = 62)	M-CBT ( <i>n</i> = 37)	TAU ( <i>n</i> = 25)	<i>p</i> value
Clinician's Age ( <i>M, SD</i> )	42.9 (11.53)	42.78 (11.48)	43.08 (11.84)	.92
Gender (% Female)	87.1%	81.1%	96%	.13
Race/Ethnicity (% Caucasian)	71%	72.2%	75%	1.00
Years Experience ( <i>M, SD</i> )	14.32 (9.95)	14.56 (11.42)	13.96 (7.45)	.82
Degree Type (% doctorate)	13.3%	11.1%	16.7%	.70
Clinician Theoretical Orientation				
Psychodynamic	6.7%	5.6%	8.3%	.673
Behavioral	20%	13.9%	29.2%	.147
Cognitive or CBT	38.3%	44.4%	29.2%	.233
Client-Centered/Humanistic	11.7%	13.9%	8.3%	.511
Interpersonal	1.7%	0%	4.2%	.217
Family Systems	5%	2.8%	8.3%	.333
Other	16.7%	19.4%	12.5%	.480

\*Note: One clinician in the CBT condition and one clinician in the TAU condition did not indicate their theoretical orientation. Clinician report of theoretical orientation varies from independent review of session content (Ginsburg, Muggeo, Caron, Souer, & Pikulski, 2019)

39 co-rated post and follow up evaluations only) inter-rater agreement was 82% and kappa was .74. In order to facilitate comparisons with published research (e.g., Ginsburg et al., 2011) we used the ADIS to derive the following outcomes: 1) remission, defined as loss of all study entry anxiety diagnoses and 2) loss of primary disorder.

**Clinical Global Impression – Severity (CGI-S) and Improvement (CGI-I) Scales (Guy, 1976)** These widely used IE-rating scales provide a global rating of anxiety severity (CGI-S) ranging from 1 (*not at all ill*) to 7 (*extremely ill*) and anxiety improvement (CGI-I; relative to baseline) ranging from 1 (*very much improved*) to 7 (*very much worse*). The primary outcome in this study was “treatment responder” status defined as receiving a CGI-I score of 1 or 2 which was similarly selected to facilitate comparisons with published landmark anxiety treatment trials (e.g., Walkup et al., 2008). Inter-rater agreement, defined as scoring within 1 point, was 98% (kappa .56 based on 55 co-rated taped evaluations across all timepoints) for the CGI-S. Inter-rater agreement for the CGI-I (responder vs non-responder) was 92% (Kappa .83) based on 36 co-rated evaluations from post and follow up evaluations only.

**Children's Global Assessment Scale (CGAS; Shaffer et al., 1983)** The widely used CGAS, completed by IEs, assesses global functioning from 1 (lowest) to 100 (highest). Inter-rater agreement, defined as scoring within the same decile, was 93% and kappa was .66 based on 55 co-rated evaluations across all timepoints.

**Screen for Anxiety-Related Emotional Disorders Parent and Child Versions (SCARED-P/C; Birmaher et al., 1997).** The

SCARED is a widely used 41-item questionnaire, completed by parents and children, which assesses a broad range of child anxiety symptoms. Items are rated using a 3-point Likert scale describing how true the statements are and are summed to create a total score. The scale ranges from 0 (not true/hardly ever true) to 2 (very true/often true). Higher scores reflect higher levels of anxiety. In the current study internal consistency for the child version was .93 and internal consistency for the parent version was .91. The psychometric properties of this measure are favorable (Birmaher et al., 1999).

### Treatment-Related Measures

**Session Summary Forms (SSFs)** After each session, clinicians recorded pertinent treatment data (e.g., strategy, session duration).

**M-CBT Differentiation and Adherence** M-CBT differentiation was assessed on a random sample of 25% of available audiotaped M-CBT (*n* = 281) and TAU (*n* = 114) sessions coded by postdoctoral fellows or psychologists with experience in CBT but unaware of treatment condition. Eleven items corresponding to CBT session structure elements (e.g., agenda-setting, homework; skill rehearsal), were scored as present or absent in both groups. A higher percentage of CBT structure elements (not treatment ingredients such as exposure or cognitive skills training) in M-CBT compared with TAU would indicate successful treatment differentiation. To assess inter-rater reliability, 15% of sessions were double-rated; ICC for the 11-item treatment differentiation variable was .76 (.67 for TAU only group). To assess adherence to M-CBT (i.e., fidelity of CBT skills and only assessed in the M-CBT condition), raters indicated whether the M-CBT session covered

**Table 2** Baseline treatment group comparisons on child demographic and clinical characteristics

Variable	Total ( <i>N</i> = 216)	M-CBT ( <i>n</i> = 148)	TAU ( <i>n</i> = 68)	<i>p</i> value
Age ( <i>M, SD</i> )	10.87 (3.27)	10.61 (3.12)	11.44 (3.53)	.10
Gender (% Female)	48.6%	48.6%	48.5%	.98
Race/Ethnicity (%)				.18
Non-Hispanic White	63.9%	56.8%	47.1%	
Others	28.7%	43.2%	52.9%	
Parent Edu. (% College or higher)	65.7%	71.3%	53.8%	.02
Primary Diagnosis (%)				.20
SAD	13.4%	14.9%	10.3%	
SOP	21.8%	17.6%	30.9%	
GAD	61.6%	64.9%	54.4%	
SP	1.4%	1.4%	1.5%	
NOS	1.9%	1.4%	2.9%	
Total # of Diagnoses ( <i>M, SD</i> )	2.13 (1.02)	2.12 (0.99)	2.13 (1.08)	
% with Comorbid Diagnosis	69.9%	73.0%	63.2%	
SAD	9.7%	11.5%	5.9%	
SOP	23.1%	25.0%	19.1%	
GAD	17.1%	16.9%	17.6%	
CGI-S ( <i>M, SD</i> )	5.19 (0.77)	5.17 (0.73)	5.25 (0.85)	.47
CGAS ( <i>M, SD</i> )	48.31 (5.78)	48.64 (5.39)	47.59 (6.55)	.25
SCARED-P ( <i>M, SD</i> )	27.22 (13.17)	27.30 (13.33)	27.05 (12.95)	.90
SCARED-C ( <i>M, SD</i> )	32.47 (15.50)	32.31 (15.67)	32.81 (15.24)	.84

*M-CBT* Modular Cognitive Behavioral Therapy, *TAU* Treatment as Usual, *SAD* separation anxiety disorder, *SOP* social phobia, *GAD* generalized anxiety disorder, *SP* specific phobia, *NOS* not otherwise specified, *CGI-S* Clinical Global Impression Severity Scale, *CGAS* Children's Global Assessment Scale

specific module objectives (present/absent) and are reported as a percentage.

### Description of Treatment Conditions

Treatments were administered individually over 12 sessions. Each session was expected to be 30–40 min to fit into a typical class/lunch period.

**Modular Cognitive Behavioral Therapy (M-CBT)** M-CBT was adapted from empirically supported CBT manuals (Ginsburg et al., 2012; Chorpita, Taylor, Francis, Moffitt, & Austin, 2004; Kendall & Hedtke, 2006; Silverman et al., 1999) and consisted of seven core modules: psychoeducation, exposure, rewards, cognitive restructuring, problem-solving, somatic/relaxation skills, and relapse prevention; an optional parental psychoeducation module was available. The sequence of administering the modules was flexible; with the exception that psychoeducation and exposure respectively occurred first and second and that each subsequent session was expected to include an exposure component.

**Treatment as Usual (TAU)** TAU reflected the therapeutic strategies that clinicians would typically provide to students with anxiety (e.g., supportive therapy).

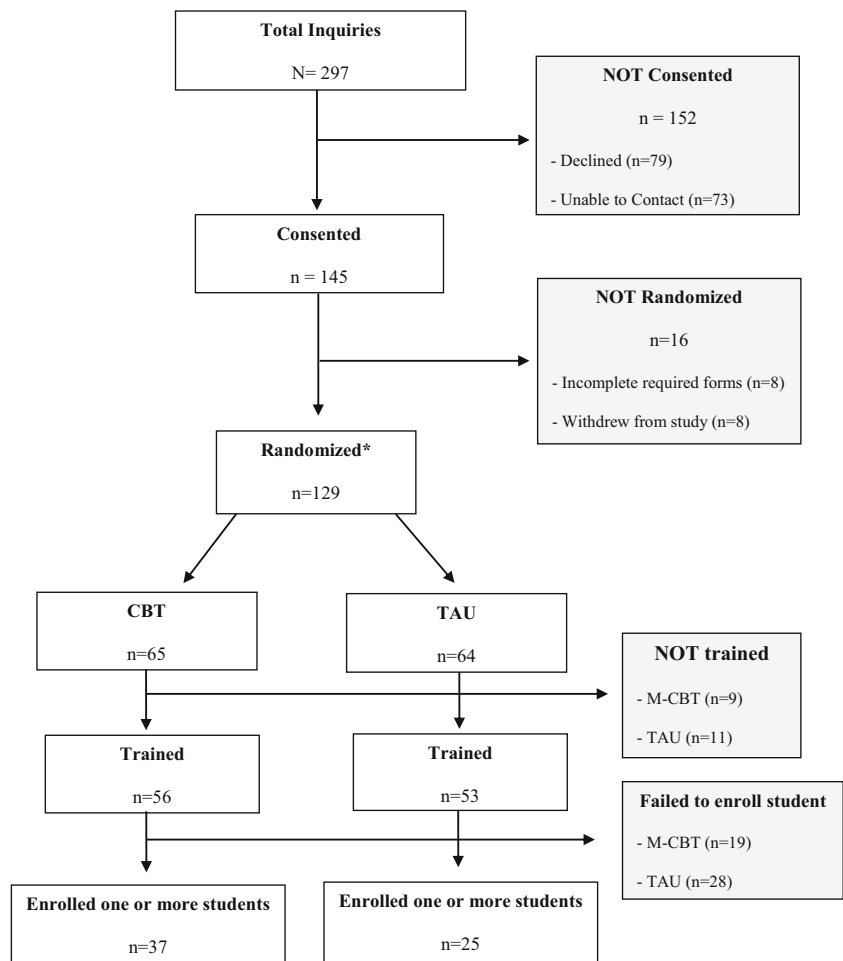
### Procedures

Study procedures were approved by the University's Institutional Review Board, school districts and principals<sup>1</sup>. Participants signed informed consent/assent prior to completing study tasks.

Clinicians and students were recruited between 2012 and 2017. Clinicians were recruited via district supervisors, professional development seminars, and word-of-mouth. Because there was generally one clinician per school and to reduce risk of cross treatment contamination, randomization was at the school level (i.e., youth were not randomized within clinician). In cases where a school had more than one interested clinician, clinicians in that school were assigned to the school's randomized condition. In study years 1–4, schools and their clinicians were matched on school type (high, middle, elementary) and years of experience and randomly assigned (1:1) to M-CBT or TAU using a web-based randomization plan generator. See CONSORT Fig. 1. Clinicians

<sup>1</sup> The original study protocol published on ClinicalTrials.gov varies from the current manuscript in that some secondary outcome measures will appear in a separate manuscript and several new outcome measures (e.g., remission variable) were added to facilitate comparisons to published RCTs. The current study also under-recruited.

**Fig. 1** STARS consort diagram for clinician participants



within the schools randomized to M-CBT attended a 1-day training, were assigned a clinical supervisor, and received treatment materials (e.g., forms, handouts, treatment manual, and a case summary for each child). Clinicians in schools randomized to TAU were offered one half-day training on anxiety symptoms to assist with recruitment, assigned a non-CBT supervisor, and provided with study materials that included an anxiety screener, forms, and a case summary. In study year 5, to address an imbalance between the numbers of students enrolled in M-CBT and TAU (see CONSORT diagram), the randomization ratio was altered to 3:1 (TAU to M-CBT). Clinicians were reimbursed \$62.50 per student and offered \$35.00 per hour to participate in supervision for up to 12 h.

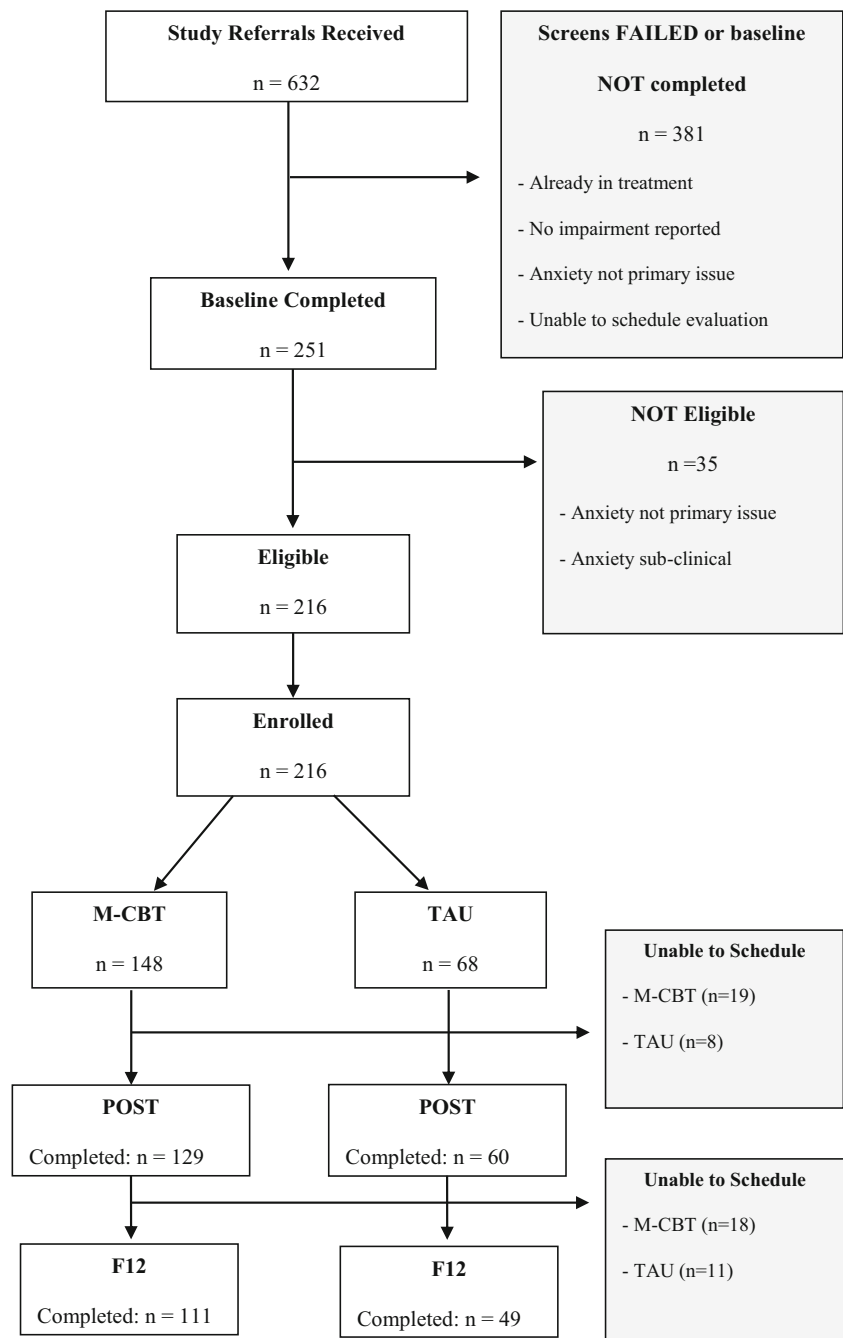
Students were recruited via referrals from clinicians, school personnel, parents, or self-referrals. Families contacted study staff and completed a phone screen to determine whether the child would be appropriate for the study based on key inclusion criteria (e.g., age, anxiety severity). If appropriate, an in-person baseline evaluation was conducted with the student and their primary care giver (84.3% mother; 9.7% father; 6.0% other such as grandparent). and if the student met

inclusion criteria, they began treatment (M-CBT or TAU). Treatment sessions occurred during the school day and all sessions were to be audiotaped. A post-treatment (12 weeks after treatment initiation) and 1-year follow-up assessment was conducted with the same student and caregiver. IEs instructed families not to reveal information about the treatment they received (e.g., therapist name, number of sessions, content of sessions) to preserve masking. Families were compensated \$40 per assessment Fig. 2.

**Data Analytic Plan**

For preliminary analyses, we conducted univariate and multivariate outlier analyses on the continuous outcome variables to identify influential data points (Kutner, Nachtsheim, Neter, & Li, 2005) using Cook’s *d* as the index. We also compared child attrition rates across conditions using  $\chi^2$  tests and performed 2 by 2 (condition by attrition status) analysis of variance or logistic regression on each baseline measure. We assessed the equivalence of clinicians and youths in M-CBT and TAU on treatment and demographic variables as well as

**Fig. 2** STARS consort diagram for family participants



baseline measures of the outcome variables using  $\chi^2$  tests for categorical variables and *t*-tests for continuous variables.

Analyses of covariance or logistic regression were used to assess the intervention effects on anxiety outcomes, controlling for baseline status on the outcome (if there was no baseline measure, the baseline CGI-S was included), child age, gender, ethnicity (non-Hispanic White vs. others), and study site. We estimated that we had power of .80 to detect mean difference with Cohen's  $d \geq .37$ , and  $OR \geq 2.25$  assuming the base rate of success for the control group is .50, accounting for the design effect [i.e.,  $(1 + (n-1) \cdot ICC)$ ;  $n = \text{cluster size}$ ]. Note

that effect sizes for moderation effects are, in general, small (see McClelland & Judd, 1993) and thus we are powered only to detect medium to large moderation effects. Receiving other mental health services and interval (days) between the assessments were examined as potential co-variables but these did not affect the results. The intent-to-treat approach was applied to evaluate intervention effects. All outcome analyses were performed in Mplus 8 (Muthén & Muthén, 1998–2017) using full information maximum likelihood estimation for handling missing data and making use of all available data for all individuals. Intraclass correlations (ICCs) for clusters of children



within clinicians were not ignorable ( $ICC = .06$  across all assessments, range = 0–.21; average cluster size = 3.5 (TAU = 2.7; CBT = 4.0), range = 1–14 (TAU = 1–9; CBT = 1–14)]. A sandwich estimator was used to adjust standard error estimates for clustering by clinicians (Yuan & Bentler, 2000).

We also investigated whether program effects were moderated by baseline anxiety severity, anxiety disorder (GAD, SOP, SAD), age, gender, and race/ethnicity (non-Hispanic White versus others), one moderator at a time. For significant moderated effects, we probed simple main effects, which were computed at the mean and at one standard deviation above/below the mean of a continuous moderator (to investigate the direction of intervention effects) and at each level of a categorical moderator (Aiken & West, 1991). Cohen's  $d$  or odds ratio (OR) is reported for the significant main and simple main effects (Chen, Cohen, & Chen, 2010; Cohen, 1988).

## Results

### Preliminary Analyses

No influential data points were identified. Youth attrition rate did not significantly differ across conditions at post-treatment,  $\chi^2(1) = 0.13$ ,  $p = .73$  or 1 year follow-up,  $\chi^2(1) = 0.17$ ,  $p = .68$ ; there were no significant differences across the attrition status main effects or condition by attrition status interaction effects on the baseline variables. Rates of missing data were 14% and 27% for IE rated forms at post and follow up respectively; 26% and 43% for child-rated SCARED and 24% and 41% for parent-rated SCARED at post and follow up respectively. As noted, missing data was handled using maximum likelihood estimation.

Tables 1 and 2 display treatment group comparisons at baseline and show that clinician and youth in M-CBT and TAU groups were comparable; however, a higher proportion of parents in the M-CBT compared to TAU had a college or advanced degree. This variable was added as a covariate in all analyses of treatment effects.

Youth in both groups received an average of 9 sessions (9.07 in M-CBT versus 9.56 in TAU;  $p = .41$ ); youth in M-CBT had on average longer sessions (26 versus 20 min;  $p = .001$ ). The treatments were significantly differentiated, with M-CBT, compared to TAU, sessions containing, 77% versus 32% of the 11 CBT structure components respectively ( $p < .001$ ). The most commonly used CBT session structure elements in TAU were conducting a mood/anxiety check-in (78%), teaching or reviewing a skill (66%) and working toward a specific treatment goal (62%); the least used CBT elements were review of assigned homework (14%), review of content from previous session (22%) and modeling a skill (27%). Additional details about the TAU content can be found

in (Ginsburg et al., 2019). The average adherence to M-CBT across the modules was 74%. Adherence by module (only present for M-CBT condition) was: Psychoeducation (76%), Exposure (69%), Changing Thoughts (80%), Relaxation (78%), Problem Solving (73%), Relapse Prevention (66%), and Parent Psychoeducation (100%). Examples of non-CBT elements used by M-CBT clinicians described by IEs qualitatively included play therapy, board games, casual conversation, advice giving, and drawing activities.

Fifty of the 62 (81%) clinicians used the optional supervision offered by the study's clinical supervisor. In the M-CBT condition, 34 (92%) clinicians used supervision and among these the average number of meetings was 11 ( $SD = 8.78$ ). Sixteen (64%) of the TAU clinicians used supervision and the average number of meetings was 11 ( $SD = 13.44$ ). There was no statistically significant treatment difference in the number of supervision meetings ( $t(48) = -.082$ ,  $p = .935$ ).

### Child Outcomes

Table 3 summarizes comparisons of M-CBT and TAU for anxiety and related outcomes at post and 1-year follow-up. None of the group main effects for post- and 1-year follow-ups were statistically significant, with the exception of parent-report SCARED at post-treatment. Students in M-CBT had significantly lower parent-report Total SCARED scores than students in TAU (adjusted  $M_{M-CBT} = 21.65$ ,  $M_{TAU} = 24.45$ ; unstandardized  $B = -2.80$ ,  $SE = 1.43$ ,  $z = -1.96$ ,  $p = .05$ ;  $d = .29$ ).

In terms of moderation effects, significant treatment group  $\times$  age interactions and treatment group  $\times$  baseline anxiety severity interactions were found for responder status ( $B = .32$ ,  $SE = 1.27$ ,  $z = 2.55$ ,  $p = .01$ ;  $B = 1.63$ ,  $SE = .55$ ,  $z = 2.98$ ,  $p = .003$ ; respectively) at post-treatment. No moderation effects were found for 1-year follow-up. The interaction and simple effects analyses indicated that the beneficial effects of M-CBT were strongest for youth who were older and/or had higher baseline CGI-S scores. Analyses of simple main effects at 1  $SD$  above the mean age (i.e., at 14.1 years old) indicated that students in M-CBT had significantly better outcomes and were more likely to be treatment responders than students in TAU [treatment responders (unstandardized  $B = 1.35$ ,  $SE = .64$ ,  $z = 2.12$ ,  $p = .03$ ;  $OR = 3.85$ ). Analyses of simple main effects at 1  $SD$  above the mean of baseline anxiety severity indicate that youth in M-CBT were significantly more likely to be treatment responders than youth in TAU ( $B = 1.70$ ,  $SE = .65$ ,  $z = 2.63$ ,  $p = .009$ ;  $OR = 5.46$ ). In contrast, at 1  $SD$  below the mean of baseline anxiety severity, youth in TAU were more likely than youth in M-CBT to be treatment responders ( $B = .84$ ,  $SE = .41$ ,  $z = 2.05$ ,  $p = .04$ ;  $OR = 2.31$ ). Finally, presence of GAD or SAD were not significant predictors or moderators of treatment responder status; however, SOP was both a predictor ( $B = -3.08$ ,  $SE = .88$ ,  $z = -3.50$ ,

**Table 3** Program effects on IE reports of child anxiety related outcome at post-treatment and 1 year follow-up

Outcome	Time Point	Actual % or Mean TAU		Program Main Effect B [95% CI]	Main Effect <i>p</i>
		%TAU	%CBT		
Responder (%yes)	Post	36.7	42.1	-.30[-.90, .31]	.34
	F12	57.1	47.7	.43[-.29, 1.16]	.24
No Anxiety Disorder <sup>1a</sup>	Post	35.0	34.9	-.13[-.72, .46]	.67
	F12	53.1	48.6	.15[-.58, .88]	.69
Loss of Primary disorder	Post	43.3	40.5	.15[-.42, .72]	.61
	F12	59.2	53.2	.27[-.42, .96]	.44
CGAS <sup>2b</sup>	Post	M 54.22	M 55.98	.99 [-1.42, 3.41]	.42
	F12	59.22	58.92	-1.01[-5.13, 3.10]	.63
CGI-S <sup>3c</sup>	Post	4.15	3.97	-.15[-.49, .19]	.38
	F12	3.41	3.61	.23[-.24, .71]	.34
SCARED-P	Post	21.72	20.25	-2.80[-5.59,-.01]	.05
	F12	15.12	17.74	.04[-.06,.13]	.44
SCARED-C	Post	23.65	22.82	.31[-3.42,4.05]	.87
	F12	20.54	19.63	.03[-.09,.14]	.65
Service Use	Post	1.73	1.72	.19[-.54, .92]	.61
	F12	1.66	1.61	.38[-.50, 1.25]	.40

<sup>a</sup>No Anxiety Disorder = loss of all study entry anxiety diagnosis; <sup>b</sup>CGAS Children's Global Assessment Scale; <sup>c</sup>CGI-S Clinical Global Impression Severity Scale SCARED Screen for Child Anxiety Related Emotional Disorders

$p < .001$ ) and moderator ( $B = 3.0$ ,  $SE = .89$ ,  $z = 3.37$ ,  $p = .001$ ) of treatment response. Specifically, regardless of treatment condition, youth with versus without SOP at baseline, were less likely to be a treatment responder ( $OR = .05$ ) at posttest, but not follow-up. However, among youth with SOP, those who received M-CBT were significantly more likely to be treatment responders than those receiving in TAU ( $B = 2.08$ ,  $SE = .83$ ,  $z = 2.50$ ,  $p = .01$ ;  $OR = 8.00$ ). In contrast, among youth without SOP, those in TAU were significantly more likely to be treatment responders than youth in M-CBT at posttreatment only ( $B = .92$ ,  $SE = .45$ ,  $z = 2.03$ ,  $p = .04$ ;  $OR = 2.50$ ).

## Discussion

This study compared the effectiveness of M-CBT to TAU, delivered by school-based clinicians, for students with anxiety disorders. The study addressed several methodological limitations in the treatment efficacy literature by using non-CBT experts in the school setting and an active therapeutic control condition. Overall, findings indicated that at post-treatment and at a 1 year follow-up, youth in both treatment groups showed significant but similar levels of clinical and functional improvement across several outcome measures (within treatment effect sizes using Cohen's  $d$  was over .9 for continuous outcome measures). One exception was that parents of youth receiving CBT, compared to TAU, reported greater reduction

in child anxiety at post treatment (Cohen's  $d = .29$ ). An examination of potential moderators revealed that at post-treatment only, older students, those with more severe anxiety, and those with social anxiety disorder at baseline showed greater clinical improvement in M-CBT compared to TAU. On the one hand, these findings are encouraging in that that school-based M-CBT delivered by novice clinicians with minimal training (and low doses of CBT) resulted in better outcomes than TAU for specific subgroups of students with anxiety. On the other hand, findings reveal concerning disparities between the implementation of M-CBT and rates of clinical improvement relative to those reported in outpatient treatment efficacy trials and signal an urgent need for research on improving the implementation of high quality evidenced-based treatments in school settings for youth with anxiety disorders.

In the current study, 37% and 42% of youth were classified as post-treatment responders in TAU and CBT respectively. These rates were not statistically different from each other but were nearly 20% lower than those found using the same measure/definition in one of the landmark studies of CBT for pediatric anxiety disorders (CAMS; Walkup et al., 2008), which reported a 60% responder rate for CBT (treatment was administered in university settings by highly trained CBT clinicians). However, when compared to school-based treatment studies for anxiety disorders in which treatment was delivered by school clinicians, with more intensive training and supervision, rates were similar. For instance, Masia-Warner et al. (2016), using a more lenient criterion for responder status (i.e.,



CGI-I of 1, 2, or 3) reported that 65% of youth receiving C-SASS were classified as treatment responders (versus 18% for the control condition SFL). Using this same criterion (CGI of 1, 2, or 3), we found that 82% receiving M-CBT were classified as treatment responders (and 80% of youth receiving TAU).

With respect to diagnostic changes, there were no treatment group differences at post-treatment (e.g., 43% and 41% respectively of TAU and M-CBT no longer met criteria for their primary disorder and 35% and 34% in TAU and CBT respectively no longer met criteria for any study entry anxiety disorder). These rates were similar to those found in our pilot study (50% in M-CBT and 46% in TAU; Ginsburg et al., 2012) and also in line with Masia-Warner et al. (2016) who reported that at post-treatment, approximately 21% of youth receiving C-SASS (versus 7% of the control condition; SFL) no longer met diagnostic criteria for SOP.

The current study also examined changes in anxiety severity and global functioning. Youth in both conditions showed significant reductions in anxiety severity and improvements in global functioning at post-treatment but few treatment group differences. This pattern of change is consistent with evidence showing CBT reduces anxiety and improves global functioning (James et al., 2013; Walkup et al., 2008). Thus, youth receiving some form of treatment will likely experience symptomatic relief and engage more fully in their daily life. However, the absence of robust treatment group differences raises questions about the superiority of CBT over TAU as implemented in this study.

Findings with respect to clinical improvement at the 1 year follow-up revealed that youth in both conditions maintained the gains from baseline—with no differences between conditions. The maintenance of clinical gains replicates many published efficacy and effectiveness trials (see Gibby, Casline, & Ginsburg, 2017 for a review) and suggests that receiving a brief course of psychosocial treatment, CBT or TAU, has benefits that persist over a 1 year period of time. This is encouraging given that many youth transitioned to new schools before the 1 year assessment (e.g., elementary to middle school) or advanced to new grades, which is known to trigger a spike in anxiety (Grills-Taquechel, Norton, & Ollendick, 2010).

Taken together, these results indicate a need for closer examination and enhancement of practices for disseminating CBT for anxiety to school-based clinicians (e.g., higher doses of training and supervision). Potential reasons for the lower response rates in the current study compared to efficacy trials reflect the challenges of dissemination into schools and include limited therapist training (1 day) and supervision, students failing to get a full course of CBT (an average of nine 26 min sessions versus 12–16 1 h sessions in efficacy trials), clinician challenges with implementing CBT correctly using all essential CBT elements, and greater clinical complexity of youth enrolled in the study (i.e., minimal exclusion criteria

and a more diverse sample with respect to income, race/ethnicity). Moreover, the majority of youth in this study had a diagnosis of GAD and/or SOP—both of which may have been more difficult to treat. Similar to published studies, our own analysis indicated that a baseline diagnosis of SOP was predictive poorer post-treatment clinical improvement (though those receiving CBT relative to TAU had better outcomes). With respect to GAD, identifying appropriate exposure tasks and implementing cognitive restructuring (which focuses more on uncertainty rather than disputing or challenging specific unrealistic thoughts) might have been more difficult for non-CBT experts to implement. This is supported by the low rates of clinician adherence to using exposure.

The effectiveness of TAU in the current study was notably strong and may be attributed to several factors. For instance, it may be that clinicians felt more comfortable using their preferred treatment strategies. Aspects of TAU were also necessarily altered as study procedures required the use of weekly assessments to monitor anxiety severity (via session summary forms) and imposed a treatment structure (e.g., a designated number of sessions to be completed before the post-treatment evaluation as opposed to the generally open-ended treatment provided in schools). Routine assessment has been shown to enhance clinical outcomes (Bickman, Kelley, Breda, de Andrade, & Riemer, 2011; Stein, Kogan, Hutchison, Magee, & Sorbero, 2010). TAU clinicians were also provided with a detailed diagnostic report which may have influenced their case conceptualization and use of treatment strategies. Some of the TAU sessions did include CBT structure elements (e.g. agenda setting and homework) which may have increased the effectiveness of TAU.

Additional research is needed to understand under what conditions CBT, TAU, or other treatment strategies are optimal for specific youth. Our findings suggest that older youth, those with high baseline anxiety severity, and those with social phobia experienced greater clinical gains in M-CBT compared to TAU. One reason may be that the structure and skill-based ingredients of CBT were particularly helpful for more anxious students, though additional research is needed to test this hypothesis. Students with social phobia may have had greater opportunity to engage in real time social exposures and older students may have benefitted more from M-CBT because of increased autonomy and ability to practice new skills on their own. Research shows that younger students benefit more from parental involvement (Manassis et al., 2014). Younger students, who spend more time with parents, may also be more affected by parental behaviors (e.g., accommodation) that maintain anxiety. Parental involvement in the current study was minimal. Thus, increasing parental involvement in school-based studies for younger students may enhance CBT outcomes. Regardless, these findings may be used to inform the selection of treatments based on child characteristics in this setting.

The current study, while addressing previous limitations, had several methodological shortcomings and the findings should be interpreted accordingly. Randomization was conducted only at the school/clinician level and not at the child level, raising potential biases such as systematic differences in youth in each condition. This possibility is heightened by the higher student enrollment rates in M-CBT versus TAU as clinicians assigned to TAU were often disappointed about their assigned condition which may have lowered their motivation to enroll students. Moreover, the unequal and smaller than anticipated sample sizes may have lowered statistical power to find a treatment group difference (i.e., power was less than .50 to detect a small effect of  $d = .25$ ).

In summary, M-CBT was superior to TAU at post treatment based on parent report of child anxiety. M-CBT was also superior at post treatment for older youth, those with social phobia, and those with higher anxiety severity. No treatment group differences or moderators emerged at the 1 year follow-up. In light of lower levels of clinical effectiveness of M-CBT compared to those reported in efficacy trials, an important implication is the need to improve the implementation quality (e.g., training, treatment dosage) of CBT. Indeed given the need and benefits of providing treatment in schools, efforts to improve the outcomes for youth with anxiety disorders receiving any type of treatment should be a high priority.

**Acknowledgments** We are grateful for the hard work and support of many research assistants and school personnel throughout the course of the study. The authors would also like to thank all the clinicians, students, and parents who participated in the study. We are especially grateful to Jennifer Nail, Sarah Williams, Amy Hale, Elizabeth Casline, Michela Muggeo, Jamie LoCurto, Brian Padilla, and many students and fellows for their assistance with implementing this study.

**Funding** The research reported here was supported by the Institute of Education Sciences, U.S. Department of Education, through Grant R324A120405 to Dr. Ginsburg. The opinions expressed are those of the authors and do not represent views of the Institute or the U.S. Department of Education.

## Compliance with Ethical Standards

**Conflict of Interest** The authors declare that they have no conflicts of interest.

**Ethical Approval** All procedures performed in this study involving human participants were in accordance with the ethical standards of the University of Connecticut institutional review board and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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