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EVIDENCE BASE UPDATE

Evidence Base Update on the Treatment of Early Childhood Anxiety and Related Problems

Jonathan S. Comer, Natalie Hong, Bridget Poznanski, Karina Silva, and Maria Wilson

Mental Health Interventions and Technology (MINT) Program, Center for Children and Families, Florida International University

The controlled evaluation of treatments for early childhood anxiety and related problems has been a relatively recent area of investigation, and accordingly, trials examining early childhood anxiety treatment have not been well represented in existing systematic reviews of youth anxiety treatments. This Evidence Base Update provides the first systematic review of evidence supporting interventions specifically for the treatment of early childhood anxiety and related problems. Thirty articles testing 38 treatments in samples with mean age < 7.9 years (N = 2,228 children) met inclusion criteria. We applied Southam-Gerow and Prinstein's (2014) review criteria, which classifies families of treatments according to one of five levels of empirical support—Well-Established, Probably Efficacious, Possibly Efficacious, Experimental, and of Questionable Efficacy. We found family-based cognitive-behavioral therapy (CBT) to be a Well-Established treatment, and Group Parent CBT and Group Parent CBT + Group Child CBT to both be Probably Efficacious treatments. In contrast, play therapy and attachment-based therapy are still only Experimental treatments for early childhood anxiety, relaxation training has Questionable Efficacy, and there is no evidence to date to speak to the efficacy of individual child CBT and/or medication in younger anxious children. All 3 currently supported interventions for early childhood anxiety entail exposure-based CBT with significant parental involvement. This conclusion meaningfully differs from conclusions for treating anxiety in older childhood that highlight the well-established efficacy of individual child CBT and/or medication and that question whether parental involvement in treatment enhances outcomes.

Anxiety disorders are among the most common and impairing mental health problems affecting young children. Up to 9% of preschoolers and early grade-schoolers in community settings, and up to 20% of preschoolers in pediatric primary care settings, already meet full diagnostic criteria for at least one anxiety disorder (Egger & Angold, 2006; Egger et al., 2006; Franz et al., 2013; Lavigne et al., 1996; Wichstrom et al., 2012). Such early-onset (i.e., those presenting younger than 8 years of age) anxiety disorders and related problems, such as obsessive-compulsive disorder (OCD) and traumatic stress disorders, are associated with considerable functional impairment and contemporaneous problems with emotion regulation, family functioning, sleep hygiene, and social development (e.g., Chou, DeSerisy, Garcia, Freeman, & Comer, 2017; De Young, Kenardy, & Cobham, 2011; Dougherty et al., 2013; Towe-Goodman, Franz, Copeland, Angold, & Egger, 2014). Earlier onset of anxiety and related problems is associated with more intractable symptom trajectories and worse outcomes across time (Carpenter, Puliafico, Kurtz, Pincus, & Comer, 2014; Ramsawh, Weisberg, Dyck, Stout, & Keller, 2011). When left untreated, anxiety problems persist into adulthood and are linked with comorbid depression, substance misuse, suicidal ideation and attempts, and overall reduced quality of life (Bentley et al., 2016; Comer et al., 2011; Copeland, Angold, Shanahan, & Costello, 2014; Tang et al., 2017). Accordingly, effective treatment for early-onset anxiety and related problems is critical.

The past 50 years have witnessed extraordinary advances in the development and identification of evidence-based practices for the treatment of childhood anxiety disorders. According to several systematic reviews of the youth anxiety treatment

Correspondence should be sent to Jonathan S. Comer, Center for Children and Families, Florida International University, 11200 S.W. 8th Street, Miami, FL 33199. E-mail: jocomer@fiu.edu

literature (Higa-McMillan, Francis, Rith-Najarian, & Chorpita, 2016; Silverman, Pina, & Viswesvaran, 2008), the most research-supported and well-established treatments are cognitive-behavioral in nature, and to varying extents incorporate child exposure to feared stimuli, modeling, psychoeducation about anxiety, thought challenging and cognitive restructuring, somatic management skills training, and contingent reinforcement. Extensive support has been documented for such youth cognitive-behavioral therapies (CBTs) across a variety of formats (Kendall, Hudson, Gosch, Flannery-Schroeder, & Suveg, 2008; Ollendick, Ryan, & Capriola-Hall, 2018; Silverman et al., 1999) and when implemented concurrently with selective serotonin reuptake inhibitor (SSRI) medication management (Albano et al., 2018; Walkup et al., 2008). Moreover, individual child CBT (i.e., CBT in which the therapist works directly with the child, with minimal parental involvement) has received extensive support as a first line treatment for child and adolescent anxiety, and several systematic reviews have concluded that parental involvement in child anxiety treatment may not significantly enhance outcomes over gains associated with individual child CBT (see Barmish & Kendall, 2005; Breinholst, Esbjorn, Reinholdt-Dunne, & Stallard, 2012; In-Albon & Schneider, 2007; Reynolds, Wilson, Austin, & Hooper, 2012; Silverman et al., 2008).

Important to note, the controlled evaluation of treatments for *early* childhood anxiety has been a relatively recent area of investigation, and accordingly, trials examining the treatment of early childhood anxiety have not been well represented in existing systematic reviews of youth anxiety treatments. Indeed, published conclusions about preferred practices and supported treatments for the management of youth anxiety and related problems have relied overwhelmingly on evidence drawn from trials evaluating the treatment of anxiety in middle childhood and/or adolescence. For example, none of the studies included in In-Albon and Schneider's (2007) review, only one of the studies included in Barmish and Kendall's (2005) review (i.e., Shortt, Barrett, & Fox, 2001), only one of the studies included in Silverman et al. (2008) review (i.e., Shortt et al., 2001), and only three of the studies included in Higa-McMillan et al. (2016) review (i.e., Cartwright-Hatton et al., 2011; Hirshfeld-Becker et al., 2010; Shortt et al., 2001) included samples with an average participant age younger than 8 years. Although some of these reviews comment that supporting evidence may differ for younger anxious children, to date there has not been a systematic review exclusively focusing on the evidence base of treatments for early childhood anxiety, nor has there been a review comprehensively classifying the level of support for alternative treatments in this younger child population. Recent years have witnessed a very rapid rise in the number of controlled trials evaluating the treatment of early childhood anxiety and related problems (e.g., Cartwright-Hatton et al., 2011; Comer et al., 2017; Donovan & March, 2014; Hirshfeld-Becker et al., 2010), yet, in the absence of a systematic review directly evaluating clinical trials of younger anxious children, it remains unclear how far broad conclusions about the evidence base of youth anxiety treatments (e.g., Higa-McMillan et al., 2016) can be applied to anxious early child populations.

The optimal treatment of early childhood anxiety may differ from established practices with older youth. Preschoolers and early grade-schoolers are considerably more reliant on their parents for basic life skills, organization, executive functioning, task engagement, and emotional support, and as such there may be a particularly important role for parents in the treatment of younger anxious children. Increasing research suggests that parenting factors (e.g., parental overprotection, anxiety accommodation, modeling of parental anxiety) may be particularly central to the development and/or maintenance of child anxiety at earlier stages of development (e.g., Kerns, Pincus, McLaughlin, & Comer, 2017), and thus, family-based treatment approaches may be particularly helpful when treating younger populations.

In addition, many of the programs found to effectively treat anxiety in middle childhood and adolescence rely heavily on cognitive strategies and tasks that may be beyond the developmental capacities of younger children (Carpenter et al., 2014; Comer et al., 2012; Pincus, Santucci, Ehrenreich, & Eyberg, 2008). Treatments that place greater emphasis on child's information processing and abstract thinking may be misguided and less successful in the management of early childhood anxiety. Treatment tasks centrally focusing on recognizing physiological symptoms of anxiety and identifying and adjusting maladaptive cognitions in anxiety-provoking situations may require metacognitive and receptive and expressive language abilities that are beyond the developmental capacities of preschoolers and early grade-schoolers (Cornacchio, Sanchez, Chou, & Comer, 2017). Similarly, the perspective-taking skills needed for a child to engage in treatment tasks that require reflection about how others might differentially construe feared situations may also be too advanced for earlier developmental stages (Cornacchio et al., 2017).

Indeed, the very large body of literature on the treatment of early childhood disruptive behavior problems underscores the importance of direct parental involvement when treating preschoolers and early grade-schoolers. Such treatments indirectly target child symptoms by placing greater emphasis on the primary context of child development (e.g., parent–child interactions), and placing less emphasis on directly engaging younger children in cognitive tasks that may be beyond their developmental abilities (Comer, Chow, Chan, Cooper-Vince, & Wilson, 2013; Kaminski & Claussen, 2017). Moreover, despite the very strong support for multimodal CBT + SSRI medication treatment strategies for managing anxiety in middle childhood and adolescence (Albano et al., 2018; Taylor et al., 2018; Walkup et al., 2008), consensus child psychiatry guidelines urge caution when considering psychotropic medications for very young children (Gleason et al., 2007).

This article presents a systematic review of the empirical literature on the treatment of early childhood anxiety and

related problems (social anxiety, separation anxiety, generalized anxiety, phobias, selective mutism, obsessive-compulsive and related problems, traumatic stress disorders), with an exclusive focus on evaluations in samples of children with a mean age younger or at 7.9 years. As part of the *Journal of Clinical Child and Adolescent Psychology* Evidence Base Updates series, we applied Southam-Gerow and Prinstein (2014) review criteria (see Table 1), which classifies families of treatments (rather than brand-name protocols) according to one of five levels of empirical support—Level 1: Well-Established, Level 2: Probably Efficacious, Level 3: Possibly Efficacious, Level 4: Experimental, and Level 5: of Questionable Efficacy.

METHODS

Literature Search

Several strategies were used to identify relevant studies for this Evidence Base Update. First, all articles included in the Higa-McMillan et al. (2016) Evidence Base Update on the treatment of child anxiety were examined to identify any included publications that studied a sample with a mean age at or younger than 7.9 years. Second, a computerized search was conducted in PsycINFO using keywords for anxiety and related problems (e.g., fear, worry, anxiety, behavior inhibition, OCD, traumatic stress, etc.), crossed with keywords for early childhood (e.g., *preschool, Pre-K, kindergarten, infant, toddler, elementary*), crossed with keywords for intervention (e.g., *treatment, services, prevention*; a full list of search keywords is available upon request). Third, focused searches of work from known experts in the treatment of early childhood anxiety were conducted to identify any relevant articles that might have eluded the previous search procedures. Finally, a backward reference search examined reference sections of articles identified via the aforementioned search procedures for inadvertently missed articles.

Identification of Eligible Studies

The preceding search procedures identified an initial sample of 1,423 article. These articles were further scrutinized to confirm that they were (a) published in peer-reviewed outlets, (b) included a sample with a mean age of 7.9 years or younger, (c) presented a treatment that primarily targeted anxiety-related problems (e.g., social anxiety/behavioral inhibition, separation anxiety, worry, generalized anxiety obsessive-compulsive and related problems, and/or traumatic stress), and (d) presented anxiety-related outcomes. A resulting 370 articles were further examined, and studies using one of the following designs were considered eligible for inclusion: (a) between-groups randomized clinical trials (RCTs), (b) between-groups quasi-experimental (nonrandomized) designs, (c) open trials with $N > 5$ that included pre-versus postquantitative analyses on pooled data across subjects, and (d) multiple baseline trials. Case studies and case series with $N < 5$ were excluded. A final 30 articles were retained for inclusion in this Evidence Base Update of the treatment of early childhood anxiety and related problems.

Treatment Family Categorization

Following recent trends moving away from a focus on brand-name therapies (Chorpita, Daleiden, Ebesutani, Young, & Becker et al., 2011), and consistent with Southam-Gerow and Prinstein (2014) guidelines for evaluating the evidence base of treatments in clinical child and adolescent psychology, we grouped tested interventions into broader treatment families that share theoretical principles of change and formats of delivery. Such "generic" groupings of broad treatment families optimize the public health relevance and utility of an evidence base review and are more consistent with stakeholder recommendations (Southam-Gerow & Prinstein, 2014; Wiltsey-Stirman & Comer, 2019).

Across the eligible studies, six broad categories of treatment approaches for early childhood anxiety and related problems emerged: (a) Family-Based CBT, (b) Group Parent CBT, (c) Group Parent CBT + Group Child CBT, (d) Relaxation Training, (e) Play Therapy, and (f) Attachment-Based Therapy (without CBT components). The coding team did not identify a single eligible study with mean age at or younger than 7.9 years that evaluated individual child CBT and/or medication treatment for child anxiety or related problems.

An evaluated treatment was categorized as a Family-Based CBT if (a) parents attended most of the sessions, (b) treatment focused on the acquisition of parent and/or child skills and strategies for managing child anxiety, (c) treatment provided psychoeducation about the nature of anxiety, (d) treatment worked to identify and modify reinforcing factors that might be maintaining child anxiety, (e) treatment assigned child exposure to feared stimuli, and (f) between-session homework exercises were assigned to maximize continued engagement with and generalizability of treatment content. Given the somewhat less cognitive nature of child anxiety often seen at earlier stages of development (Cornacchio et al., 2017), we did not require a treatment to focus on children's anxious thoughts and/or incorporate cognitive restructuring for a treatment to be categorized as a Family-Based CBT.

An evaluated treatment was categorized as a Group Parent CBT if (a) treatment was delivered in a group format, in which parents of different children were treated together; (b) parents attended all treatments sessions; (c) children did not attend any sessions; (d) treatment focused on the acquisition of parent and/or child skills and strategies for managing child anxiety; (e) treatment provided

TABLE 1
Review criteria for *Journal of Clinical Child and Adolescent Psychology* Evidence Base Updates (Southam-Gerow & Prinstein; 2014)

	Methods criteria
	M.1. Group design: Study involved a randomized controlled design
	M.2. Independent variable defined: Treatment manuals or logical equivalent were used for the treatment
	M.3. Population clarified: Conducted with a population, treated for specified problems, for whom inclusion criteria have been clearly delineated
	M.4. Outcomes assessed: Reliable and valid outcome assessment measures gauging the problems targeted (at a minimum) were used
	M.5. Analysis adequacy: Appropriate data analyses were used and sample size was sufficient to detect expected effects
	Evidence Criteria
Level 1: ***Well-Established Treatments***	1.1 Efficacy demonstrated for the treatment by showing the treatment to be either: 1.1.a Statistically significantly superior to pill or psychological placebo or to another active treatment OR 1.1.b Equivalent (or not significantly different) to an already well-established treatment in experiments AND 1.1.c In at least two (2) independent research settings and by two (2) independent investigatory teams demonstrating efficacy AND 1.2 All five (5) of the Methods Criteria
	Evidence Criteria
Level 2: ***Probably Efficacious Treatments***	2.1 There must be at least two good experiments showing the treatment is superior (statistically significantly) to a waitlist control group OR 2.2 One (or more) experiments meeting the Well-Established Treatment level except for criterion 1.1c (i.e., Level 2 treatments will not involve independent investigatory teams) AND 2.3 All five (5) of the Methods Criteria
	Evidence Criteria
Level 3: ***Possibly Efficacious Treatments***	3.1 At least one good randomized controlled trial showing the treatment to be superior to a waitlist or no-treatment control group AND 3.2 All five (5) of the Methods Criteria OR 3.3 Two or more clinical studies showing the treatment to be efficacious, with two or more meeting the last four (of five) Methods Criteria, but none being randomized controlled trials
	Evidence Criteria
Level 4: ***Experimental Treatments***	4.1 Not yet tested in a randomized controlled trial OR 4.2 Tested in one or more clinical studies but not sufficient to meet Level 3 criteria
	Evidence Criteria
Level 5: ***Treatments of Questionable Efficacy***	5.1 Tested in good group-design experiments and found to be inferior to other treatment group and/or wait-list control group, that is, only evidence available from experimental studies suggests the treatment produces no beneficial effect

psychoeducation about the nature of anxiety; (f) treatment worked to identify and modify reinforcing factors that might be maintaining child anxiety; (g) treatment assigned child exposure to feared stimuli; and (h) between-session homework exercises were assigned to maximize continued engagement with and generalizability of treatment content.

An evaluated treatment was categorized as a Group Parent CBT + Group Child CBT if (a) treatment was delivered in a group format, in which families of different children were treated together; (b) treatment included parent-only group sessions *and* child-only group sessions; (c) treatment focused on the acquisition of parent and/or child skills and strategies for managing child anxiety; (d) treatment provided psychoeducation about the nature of anxiety; (e) treatment worked to identify and modify reinforcing factors that might be maintaining child anxiety; (f) treatment assigned child exposure to feared stimuli; and (g) between-session homework exercises were assigned to maximize continued engagement with and generalizability of treatment content.

An evaluated treatment was categorized as Relaxation Training if (a) treatment centrally focused on progressive muscle relaxation and verbally cued guided imagery to attain a relaxation response, (b) treatment did not target identification and modification of reinforcing factors that might be maintaining child anxiety, and (c) treatment did not assign child exposure to feared stimuli.

An evaluated treatment was categorized as Play Therapy if (a) treatment was nondirective, (b) treatment focused on allowing children to express their feelings freely through

play, (c) treatment did not focus on the acquisition of parent and/or child skills and strategies for managing child anxiety, (d) treatment did not work to identify and modify reinforcing factors that might be maintaining child anxiety, and (e) treatment did not assign child exposure to feared stimuli.

Finally, an evaluated treatment was categorized as an Attachment-Based Therapy if (a) treatment was structured and directive (which differs from nondirective play therapy), (b) treatment centered around structured parent–child play activities intended to improve attachment and promote parental acceptance and nurturance, and (c) treatment did not assign child exposure to feared stimuli.

Study Coding

All treatment conditions included across eligible studies were included for coding. For example, if a study evaluated two active treatments and a waitlist control (i.e., three conditions: Treatment A, Treatment B, and waitlist control), we coded the outcome of (a) comparisons between Treatment A and Treatment B, (b) comparisons between Treatment A and waitlist control, and (c) comparisons between Treatment B and waitlist control. Only anxiety-related symptoms and/or diagnoses were included as outcomes (i.e., fear, worry, anxiety, social anxiety, behavior inhibition, separation anxiety, generalized anxiety, phobias, OCD and related problems, tics, traumatic stress). When determining the evidence base levels of treatment families, we did not include other outcomes that may have also been included in a given study (e.g., functional impairment, quality of life, academic outcomes, etc.).

Within each study, for each comparison between treatment conditions (e.g., Condition 1 vs. Condition 2), we categorized the outcome according to one of three options: (a) Condition 1 superior to Condition 2, (b) Condition 2 superior to Condition 1, or (c) Condition 1 and Condition 2 performed equally well. Consistent with prior Evidence Base Updates in this series (e.g., Kaminski & Claussen, 2017), in a given study, for a treatment to be classified as superior to another condition, the treatment had to show significantly greater improvements than the comparison condition on at least 50% of all anxiety-related outcomes included in the study. For example, if a Family-Based CBT was compared to a waitlist control, and four anxiety-related outcomes were included (e.g., observed child behavioral inhibition, parent-report of child social anxiety, separation anxiety, and worry), Family-Based CBT would be classified as superior to waitlist control only if Family-Based CBT showed significantly greater improvements than waitlist control on at least two of the anxiety-related outcomes. If, in contrast, Family-Based CBT only showed significantly greater improvement than waitlist control on one anxiety-related outcome in the study, and on the other three outcomes differences between Family-Based CBT and waitlist control did not reach statistical significance, for that study Family-Based CBT would be classified as performing comparably to waitlist control.

For studies that did not include between-groups comparisons (e.g., multiple baseline trials, open trials), we categorized a treatment as showing significant improvements if 50% or more of anxiety-related outcomes showed significant improvements from pretreatment/baseline to posttreatment.

Each study was coded by two coders, and discrepancies were resolved by the first author.

Classifying Treatment Families into Evidence Base Levels

Consistent with the other articles in the *Journal of Clinical Child and Adolescent Psychology* Evidence Base Updates series, we applied Southam-Gerow and Prinstein (2014) review criteria (see Table 1) to studies, which classifies families of treatments according to levels of empirical support. Southam-Gerow and Prinstein's review criteria expand on prior criteria sets for classifying the evidence base of treatments (Chambless & Hollon, 1998; Chambless & Ollendick, 2001; Chorpita et al., 2011; Silverman & Hinshaw, 2008) to (a) focus on families of treatments (rather than on brand-name treatment protocols), (b) provide additional methodological criteria, and (c) define five levels of empirical support for treatment families (including a new level indicating that a treatment family has been found to be inferior to other treatments and/or control conditions). Table 1 presents the specific criteria sets for each of Southam-Gerow and Prinstein's five levels of empirical support—Well-Established; Probably Efficacious; Possibly Efficacious; Experimental; and Questionable Efficacy—as well as the methodological criteria of studies that must be met for classification of a treatment family into the higher evidence base levels.

Specifically, families of treatments classified as Well-Established must have (a) been evaluated by at least two independent research teams across different settings; (b) had evaluations that satisfied five specified methods criteria (i.e., used randomized between-groups designs, used treatment manuals or logical equivalents, treated a clearly specified population, used reliable and valid outcomes measures, and applied appropriate data analyses in adequately sized samples); and (c) had evaluations in which the treatment outperformed a pill placebo, psychological placebo, or other active treatment, or demonstrated equivalence to an already well-established treatment. Families of treatments classified as Probably Efficacious must have (a) outperformed a waitlist control in at least two evaluations meeting the five methods criteria, or (b) met the Well-Established criteria except that evaluations were not

conducted by independent research teams. Families of treatments classified as Possibly Efficacious must have (a) outperformed a waitlist control in at least one evaluation meeting the five methods criteria, or (b) been shown to be efficacious in multiple evaluations that satisfy all of the methods criteria with except that the treatment has not been evaluated in a randomized between-groups design. Families of treatments classified as Experimental are those that have been tested in one or more clinical studies, but either (a) have not yet been tested in a randomized controlled trial, or (b) do not qualify for Level 3 (Possibly Efficacious) status. Finally, treatments classified as having Questionable Efficacy are those that have been found to be statistically inferior to other treatment groups and/or waitlist control groups in randomized between-groups designs.

RESULTS

Preliminary Findings

Thirty articles testing 38 treatments and evaluating treatment outcomes in 2,228 children younger than 8 years of age met inclusion criteria for this Evidence Base Update of the treatment of early childhood anxiety and related problems (see Table 2). Of these studies, 22 entailed between-groups controlled designs. Table 3 presents a summary of the treatment families categorized into each evidence base level based on this literature.

Level 1: Well-Established Treatment Families

Family-based CBT

Family-Based CBT was the only intervention to meet criteria for categorization as a Well-Established treatment family. Fifteen RCTs and four nonrandomized designs supported the strong efficacy of Family-based CBT, with several studies including multiple comparison conditions. Specifically, five RCTs found Family-Based CBT to be superior to another active treatment, six RCTs found Family-Based CBT to perform comparably to alternative active treatments, seven RCTs found Family-Based CBT to be superior to waitlist control, and four nonrandomized studies found significant pretreatment-to-posttreatment improvements in anxiety-related problems following Family-Based CBT. In total, 22 Family-Based CBTs were tested.

The tested Family-Based CBTs targeted the full range of early child anxiety and related problems, including elevated/mixed anxiety symptoms (k = 12), separation anxiety (k = 10), social anxiety/behavioral inhibition (k = 8), worry/fear/generalized anxiety (k = 7), phobias (k = 6), selective mutism (k = 2), traumatic stress (k = 4), and OCD (k = 6). Comparably positive results were found across these diverse treatment outcomes.

By definition, parents participated in most sessions of the Family-Based CBTs tested. The majority of Family-Based CBTs also had the child participate (k = 18), although a small number of Family-Based CBTs (k = 4) did not directly involve the child in treatment. Across Family-Based CBTs, there was variability in the extent to which treatment focused on parental and/or parenting changes as key to reducing child anxiety. Specifically, more than half of the Family-Based CBTs addressed patterns of parental overprotection and family accommodation of child anxiety symptoms (k = 13), more than half focused on the quality of the parent–child relationship (k = 12), and some focused on parents' own anxiety as well as the child's (k = 6; e.g., Freeman et al., 2008; Morgan et al., 2016, Morgan et al., 2017; Shortt et al., 2001). There were no discernable differences in outcomes across Family-Based CBTs that did or did not include such content.

Exposure to feared stimuli was central to all Family-Based CBTs tested. Most of the tested Family-Based CBTs included child exposure activities in session (k = 15), and all Family-Based CBTs assigned child exposure exercises to be completed outside of treatment. Notably, all five Family-Based CBTs that were found to be superior to active treatment comparisons included child exposure activities in session (e.g., Freeman et al., 2008; Kahn, Ronen, Apter, & Sadeh, 2017).

Several of the tested Family-Based CBTs leveraged technology (e.g., computers, Internet) to expand the reach of care (k = 6). Of these programs, one entailed a telemental health approach in which videoconferencing was used to remotely conduct real-time sessions with a live therapist (Comer et al., 2017), and five entailed largely self-administered participation in the Family-Based CBT with minimal clinician support (e.g., Donovan & March, 2014; Infantino, Donovan, & March, 2016; Morgan et al., 2016, Morgan et al., 2017). Notably, the telemental health Family-Based CBT using videoconferencing to provide real-time services (Comer et al., 2017) was one of the tested Family-Based CBTs that showed comparable outcomes to an active treatment comparison.

Level 2: Probably Efficacious Treatment Families

Two interventions met criteria for categorization as Probably Efficacious treatment families: Group Parent CBT and Group Parent CBT + Group Child CBT.

Group parent CBT

Four RCTs and one nonrandomized study supported the efficacy of Group Parent CBT, with one study including two comparison conditions. Specifically, one RCT found Group Parent CBT to perform comparably to an alternative active treatment (i.e., Group Parent CBT + Group Child CBT), three RCTs found Group Parent CBT to be superior

TABLE 2
Overview of Studies Included in This Evidence Base Update on the Treatment of Early Childhood Anxiety and Related Problems

Study	*Design*	N	M *Age, Years*	*Treatment Tested*	*Treatment Family*[a]	*Summary of Outcomes*[b]
Barrett et al. (2015)	Open Trial	31	5.7	Fun FRIENDS Program	Group Parent CBT + Group Child CBT	Significant improvements
Bergman et al. (2013)	Waitlist-controlled RCT	21	5.4	Integrated behavior therapy for selective mutism	Family-Based CBT	Superior to waitlist
Cartwright-Hatton et al. (2011)	Waitlist-controlled RCT	74	6.6	Timid to Tiger	Group Parent CBT	Superior to waitlist
Comer et al. (2012)	Multiple baseline trial	9	5.4	The CALM Program	Family-Based CBT	Significant improvements
Comer et al. (2017)	RCT (comparing active treatments)	22	6.7	Family-Based CBT (Internet-delivered)	Family-Based CBT	Comparable to other Family-Based CBT
				Family-Based CBT (clinic)	Family-Based CBT	Comparable to other Family-Based CBT
Chronis-Tuscano et al. (2015)	Waitlist-controlled RCT	41	4.4	Turtle Program	Group Parent CBT + Group Child CBT	Superior to waitlist
Deblinger et al. (2011)	RCT (comparing active treatments)	210	7.7	Trauma-Focused CBT with Trauma Narrative	Family-Based CBT	Comparable to other Family-Based CBT
				Trauma-Focused CBT without Trauma Narrative	Family-Based CBT	Comparable to other Family-Based CBT
Donovan and March (2014)	Waitlist-controlled RCT	52	4.1	Brave Online	Family-Based CBT	Superior to waitlist
Freeman et al. (2008)	RCT (comparing active treatments)	42	7.1	Family-Based CBT for young children with OCD	Family-Based CBT	Superior to relaxation training
				Family-based Relaxation Training	Relaxation Training	Inferior to Family-Based CBT
Freeman et al. (2014)	RCT (comparing active treatments)	127	7.2	Family-Based CBT for young children with OCD	Family-Based CBT	Superior to relaxation training
				Family-based Relaxation Training	Relaxation Training	Inferior to Family-Based CBT
Hirshfeld-Becker et al. (2008)	Open series	9	5.8	Being Brave	Family-Based CBT	Significant improvements
Hirshfeld-Becker et al. (2010)	Waitlist-controlled RCT	64	5.4	Being Brave	Family-Based CBT	Superior to waitlist
Infantino et al. (2016)	Waitlist-controlled RCT	24	7.5	Turnaround	Family-Based CBT	Superior to waitlist
Lewin et al. (2014)	RCT (comparing active treatments)	31	5.8	Family-based exposure and response prevention	Family-Based CBT	Superior to treatment as usual
Kahn et al. (2017)	RCT (comparing active treatments)	90	5.1	CBT + Parent Involved Play	Family-Based CBT	Superior to Play Therapy
				Triadic Expressive Play Therapy	Play Therapy	Inferior to Family-Based CBT
Kennedy et al. (2009)	Waitlist-controlled RCT	71	3.9	Modified Cool Kids Program	Group Parent CBT	Superior to waitlist
Monga et al. (2009)	Open Trial	32	6.5	Taming Sneaky Fears	Group Parent CBT + Group Child CBT	Significant improvements
Morgan et al. (2017)	RCT (comparing active treatments)	51	5.8	Cool Little Kids Online	Family-Based CBT	Comparable to other Family-Based CBT
				Cool Little Kids Online + Clinician Support	Family-Based CBT	Comparable to other Family-Based CBT
Morgan et al. (2017)	Waitlist-controlled RCT	433	4.8	Cool Little Kids Online	Family-Based CBT	Superior to waitlist
Pincus et al. (2008)	Open Trial	10	6.2	Modified PCIT for Separation Anxiety	Family-Based CBT	Significant improvements
Rapee et al. (2010)	RCT (with monitoring control condition)	146	3.9	Parent Intervention Program	Group Parent CBT	Superior to monitoring condition
Rudy et al. (2016)	RCT (comparing active treatments)	22	5.4	Parent-Led Exposure Therapy	Family-Based CBT	Superior to treatment as usual
Ruocco et al. (2016)	Quasi-Experimental Waitlist-controlled Trial	134	6.8	Get Lost Mr. Scary Programme	Group Parent CBT + Group Child CBT	Superior to waitlist
Salloum et al. (2014)	Open Series	9	4.7	Step One of Stepped Care Trauma-Focused CBT	Family-Based CBT	Significant improvements
Scheeringa et al. (2011)	Waitlist-controlled RCT	64	6.2	Trauma-Focused CBT	Family-Based CBT	Superior to waitlist

(*Continued*)

TABLE 2
(Continued)

Study	*Design*	N	M *Age, Years*	*Treatment Tested*	*Treatment Family*[a]	*Summary of Outcomes*[b]
Schneider et al. (2011)	Waitlist-controlled RCT	43	6.2	Trennungsangstprogramm fur Familien (separation Anxiety Family Therapy)	Family-Based CBT	Superior to waitlist
Shortt et al. (2001)	Waitlist-controlled RCT	71	7.5	FRIENDS Program	Group Parent CBT + Group Child CBT	Superior to waitlist
van der Sluis et al. (2012)	Open Trial	26	5.6	Confident Kids	Group Parent CBT	Significant improvements
Waters et al. (2009)	RCT (with active comparison group and waitlist control)	80	6.8	Take Action Program (parents only)	Group Parent CBT	Superior to waitlist; comparable to Group Parent CBT + Group Child CBT
				Take Action Program (Parents + Children)	Group Parent CBT + Group Child CBT	Superior to waitlist; comparable to Group Parent CBT
Wettig et al. (2011)	Open Trial	22	4.1	Theraplay	Attachment-Based Therapy	Significant improvements
	Open Trial	167	4.5	Theraplay	Attachment-Based Therapy	Significant improvements

Note: RCT = randomized clinical trial; CBT = cognitive-behavioral therapy; CALM = Counseling for Anger and Lifeskills Management; OCD = obsessive compulsive disorder; PCIT = parent-child interaction therapy.

[a]See Methods section (Treatment Family Categorization) for definitions of each Treatment Family.

[b]See Methods section (Study Coding) for description of how Summary of Outcomes was determined for each study.

TABLE 3
Summary of Levels of Evidence for Interventions Evaluated in the Treatment of Early Childhood Anxiety and Related Problems

Level 1: Well-Established	*Level 2: Probably Efficacious*	*Level 3: Possibly Efficacious*	*Level 4: Experimental*	*Level 5: Questionable Efficacy*
Family-Based CBT	Group Parent CBT Group Parent CBT + Group Child CBT	(None currently identified)	Play Therapy Attachment-Based Therapy	Relaxation Training

Note: Criteria for determining categorization at each level of evidence based on Southam-Gerow and Prinstein (2014); see Table 1. CBT = cognitive-behavioral therapy.

to waitlist control, one RCT found Group Parent CBT to be superior to a symptom monitoring control condition, and one nonrandomized study found significant pre-to-post improvements in anxiety-related problems following Group Parent CBT. The tested Group Parent CBTs targeted elevated/mixed anxiety symptoms (k = 5) and/or social anxiety/behavioral inhibition (k = 4).

By definition, parents participated in all sessions of the Group Parent CBTs tested. All of the Group Parent CBTs addressed patterns of parental overprotection and family accommodation of child anxiety symptoms (k = 5), all but one focused on the quality of the parent-child relationship (k = 5), and all but one focused on parents' own anxiety as well as the child's (k = 4). Child exposure to feared stimuli was central to all Group Parent CBTs tested, although given that children did not directly participate in Group Parent CBT, all exposure exercises were assigned for parents to complete with their children outside of treatment.

Group parent CBT + group child CBT

Three RCTs and three nonrandomized designs supported the efficacy of Group Parent CBT + Group Child CBT, with one study including two comparison conditions. Specifically, one RCT found Group Parent CBT + Group Child CBT to perform comparably to an alternative active treatment (i.e., Group Parent CBT), three RCTs found Group Parent CBT + Group Child CBT to be superior to waitlist control, one between-groups quasi-experimental design found Group Parent CBT + Group Child CBT to be superior to a control, and two nonrandomized studies found significant pre-to-post improvements in anxiety-related problems following Group Parent CBT + Group Child CBT. The tested Group Parent CBT + Group Child CBTs targeted a range of early child anxiety problems, including elevated/mixed anxiety symptoms (k = 2), separation anxiety (k = 2), social anxiety/behavioral inhibition (k = 5), worry/fear/generalized anxiety (k = 2), and phobias (k = 1).

One Group Parent CBT + Group Child CBTs addressed patterns of parental overprotection and family accommodation of child anxiety symptoms (k = 2), two focused on the quality of the parent–child relationship (k = 5), and three focused on parents' own anxiety as well as the child's (k = 3). Child exposure to feared stimuli was central to all Group Parent CBT + Group Child CBTs tested; all included both in-session exposures as well as assigned exposure exercises to be completed outside of treatment.

Level 3: Possibly Efficacious Treatment Families

No treatment families met the Southam-Gerow and Prinstein (2014) criteria for Possibly Efficacious classification.

Level 4: Experimental Treatment Families

Across eligible studies, two interventions met criteria for categorization as Experimental (Level 4) treatment families: Play Therapy and Attachment-Based Therapy.

Play therapy

One RCT evaluated nondirective Play Therapy relative to Family-Based CBT (Kahn et al., 2017). Although Family-Based CBT was found to be superior to Play Therapy in this study, it should be noted that Play Therapy was nonetheless still associated with significant decreases in child fear. Additional well-controlled trials with positive outcomes are needed for Play Therapy to be considered for classification at a level higher than Experimental.

Attachment-based therapy

Two nonrandomized open trials (reported in a single article) evaluated structured and directive Attachment-Based Therapy (Wettig, Franke, & O'Connor, 2011). These studies found Attachment-Based Therapy to be associated with reductions in shyness, although well-controlled trials with positive outcomes are needed for structured Attachment-Based Therapy to be considered for classification at a level higher than Experimental.

Level 5: Treatment Families of Questionable Efficacy

Relaxation training

Relaxation Training was the only intervention to meet criteria for categorization as being of Questionable Efficacy. Two RCTs compared Relaxation Training to Family-Based CBT (Freeman et al., 2008; 2014), and both found Relaxation Training to be inferior to Family-Based CBT. Specifically, in these studies Family-Based CBT was associated with almost double to triple the response rate relative to Relaxation Training. Notably, both of these studies targeted early child OCD, and thus it is possible that the questionable efficacy of Relaxation Training is restricted to the treatment of early child OCD.

Other Considerations

Treatment outcomes across interventions did not appear to vary as a function of child age or whether the child was male or female.

Twelve of the included RCTs included additional follow-up evaluations beyond a sole focus on acute posttreatment outcomes. The time points of these follow-up evaluations ranged from 4 weeks (Schneider et al., 2011) to 3 months (Infantino et al., 2016; Lewin et al., 2014; Morgan et al., 2017) to 6 months (Bergman, Gonzalez, Piacentini, & Keller, 2013; Comer et al., 2017; Donovan & March, 2014; Scheeringa, Weems, Cohen, Amaya-Jackson, & Guthrie, 2011) to 1-year posttreatment (Cartwright-Hatton et al., 2011; Hirshfeld-Becker et al., 2010; Shortt et al., 2001; Waters, Ford, Wharton, & Cobham, 2009), and indicated that treatment gains were maintained across time, and in some cases even improved. Maintained treatment gains were found in evaluations of Family-Based CBT, Group Parent CBT, and Group Parent CBT + Group Child CBT and did not vary as a function of the domain of anxiety-related problem(s) targeted. None of the eligible studies evaluated outcomes beyond 1-year following treatment.

Ten of the eligible RCTs assessed treatment satisfaction. Very high satisfaction was associated with Family-Based CBT (e.g., Bergman et al., 2013; Comer et al., 2017; Kahn et al., 2017; Lewin et al., 2014; Shortt et al., 2001), Group Parent CBT (Waters et al., 2009), and Group Parent CBT + Group Child CBT (Waters et al., 2009). One RCT (Kahn et al., 2017) found satisfaction with Play Therapy to be significantly poorer than satisfaction with Family-Based CBT. In two studies (Donovan & March, 2014; Infantino et al., 2016), self-administered Family-Based CBTs leveraging technology showed acceptable, but somewhat lower, satisfaction relative to ratings consistently reported for clinic-based programs. Further, engagement was somewhat modest in one trial evaluating self-administered Family-Based CBT without clinician support (Morgan et al., 2017). In contrast, the one telemental health Family-Based CBT tested using videoconferencing to provide real-time services was associated with very high consumer satisfaction and treatment engagement that was comparable to that seen in clinic-based Family CBT (Comer et al., 2017).

DISCUSSION

Although the past 50 years have witnessed tremendous advances in the development and identification of evidence-based practices for the treatment of anxiety disorders in middle childhood and adolescence (Higa-McMillan et al., 2016; Silverman et al., 2008), it has only been within the past two decades that researchers have specifically evaluated the treatment of *early* childhood anxiety in rigorous controlled trials. This Evidence Base Update provides the first systematic review of the evidence supporting various interventions for the treatment of anxiety and related problems in children younger than 8. When classifying treatments in accordance with the Southam-Gerow and Prinstein (2014) criteria for Evidence Base Updates, Family-Based CBT—in which parents are highly involved in an exposure-based treatment focused on identifying and modifying anxiety-reinforcing factors—emerged

as the only Well-Established intervention option for early childhood anxiety and related problems. In addition, two other exposure-based intervention strategies—Group Parent CBT and Group Parent CBT + Group Child CBT—emerged as Probably Efficacious treatment options for early childhood anxiety and related problems. In contrast, Play Therapy and Attachment-Based Therapy were classified as only Experimental, Relaxation Training was classified as being of Questionable Efficacy, and there was no evidence found for individual child CBT and/or medication interventions for early childhood anxiety.

This review highlights how the growing body of evidence for treating early childhood anxiety and related problems yields a different set of recommendations from consensus guidelines for treating anxiety in middle childhood and adolescence. Whereas Higa-McMillan et al. (2016) Evidence Base Update on treating anxiety in older children classified both individual child CBT and CBT + Medication among the best-supported and most Well-Established intervention strategies, at this point, there is no evidence supporting the efficacy of individual child CBT and/or medication in the treatment of early childhood anxiety and related problems. Similarly, although several systematic reviews of research on treating older child anxiety have concluded that parental involvement may not meaningfully enhance outcomes over gains associated with individual child CBT (see Barmish & Kendall, 2005; Breinholst et al., 2012; In-Albon & Schneider, 2007; Reynolds et al., 2012; Silverman et al., 2008), it is noteworthy that all three interventions currently showing empirical support in the treatment of early childhood anxiety entail substantial parental involvement. Given the strong support for both Family-Based CBTs and Group CBTs involving parents—including a large number of CBTs that do not even directly involve children in treatment (e.g., Cartwright-Hatton et al., 2011; Donovan & March, 2014; Kennedy, Rapee, & Edwards, 2009; Rapee, Kennedy, Ingram, Edwards, & Sweeney, 2010; Waters et al., 2009)—research might do well to empirically question the extent to which direct child involvement is critical for effectively treating early childhood anxiety and related problems.

Despite clear support for parental involvement in the treatment of early childhood anxiety and related problems, it is not yet clear what the exact nature of that parental involvement should entail. More than half of the supported Family-Based CBTs and all of the supported Group Parent CBTs covered patterns of parental overprotection and family accommodation of child anxiety, whereas a large number of supported CBTs also worked to improve the quality of parent–child interactions (e.g., Chronis-Tuscano et al., 2015; Comer et al., 2012; Pincus et al., 2008), and many supported CBTs also targeted parents' own anxiety (e.g., Hirshfeld-Becker et al., 2010; Morgan et al., 2016, Morgan et al., 2017; Shortt et al., 2001). At present, it is not clear whether variations in the specific focus of parental involvement are associated with differential outcomes, as this has not been directly tested. It may be that the impact of working to reduce patterns of family accommodation, improve the quality of parent–child interactions, and/or decrease parental anxiety varies as a function of the extent to which these family factors are clinically relevant for a particular family. Research is also needed to examine the extent to which the benefits associated with parental involvement in CBT for early childhood anxiety is a due to parental modeling, parental encouragement of child exposure exercises outside of session, parental reinforcement of child participation in treatment, and/or a "transfer of control," in which therapist expertise and skills are communicated to the parent (s) who, in turn, communicate(s) them to the child (Breinholst et al., 2012; Ginsburg, Silverman, & Kurtines, 1995).

The empirical literature examining the treatment of early childhood anxiety and related problems has thus far yielded relatively consistent evidence supporting exposure-based CBT with heavy parental involvement (whether in a group or individual family format), but this literature is still relatively modest compared to the much larger empirical literature examining the treatment of anxiety for older children. Continued research efforts are needed to (a) replicate these findings in subsequent controlled evaluations, (b) consider the extent to which child involvement is essential for the effective treatment of early childhood anxiety, (c) examine the extent to which technology can be used to extend the reach of supported care, (d) elucidate the mechanisms through which supported treatments take effect, (e) evaluate potential moderators of treatment response that can identify which children differentially benefit most from alternative supported options, and (f) determine the generalizability of treatment effects across diverse patients, providers, and settings.

Moreover, although almost half of the RCTs included in this Evidence Base Update included follow-up evaluations beyond acute posttreatment assessments, the longest term follow-up evaluations in the included studies were conducted 1-year posttreatment. Longer term follow-up evaluations are needed to speak to the endurance of gains associated with supported treatments for early childhood anxiety and to consider whether effective treatment of early childhood anxiety is also associated with the secondary prevention of subsequent problems in later adolescence and young adulthood, such as depression, substance misuse, and suicidal ideation.

CONCLUSIONS

Several of the grand theories of clinical psychology were founded, in large part, on anxiety-related single case studies or demonstrations with very young children (e.g., Little Hans: Freud, 1909; Little Albert: Watson & Rayner, 1920) but only in the past two decades have rigorous controlled evaluations been conducted to inform best practices for treating early

childhood anxiety and related problems. Our review of the empirical literature concluded that Family-Based CBT is a Well-Established treatment for early childhood anxiety, and Group Parent CBT and Group Parent CBT + Group Child CBT are both Probably Efficacious treatments. In contrast, Play Therapy and Attachment-Based Therapy are still only Experimental treatments for early childhood anxiety, Relaxation Training has Questionable Efficacy, and there is no evidence to date to speak to the efficacy of individual child CBT and/or medication in anxious early child patient populations.

More research is needed to expand upon this growing empirical literature, but a relatively consistent set of conclusions has already emerged about the evidence-based treatment of early childhood anxiety and related problems. Across clinical trials to date, all three supported interventions entail exposure-based CBT with significant parental involvement. These supported treatments each directly target the contexts, functions, and reinforcements of early child anxiety, and many place relatively less emphasis on the more abstract and sophisticated cognitive content that characterizes evidence-based treatment for anxiety in middle childhood and adolescence. The present conclusions for treating early childhood anxiety meaningfully differ from evidence-based conclusions for treating anxiety in older childhood that highlight the Well-Established efficacy of individual child CBT and medication strategies and that question whether parental involvement in treatment enhances outcomes. At this stage, only Family-Based CBT and Group Parent CBT (with or without parallel Group Child CBT) have shown support in the treatment of early childhood anxiety and related problems.

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