

Appendix A. Search Strategies

Table A-1: MEDLINE search strategies updated (PubMed interface) December 11, 2013

Search terms	Results
Psychosocial interventions	
#1 attention deficit and disruptive behavior disorders[mh:noexp] OR conduct disorder[mh] OR (mental disorders[mh] AND aggression[mh]) OR externalizing behavior*[tiab] OR externalizing behaviour*[tiab] OR oppositional defian*[tiab] OR conduct disorder*[tiab] OR disruptive behavior disorder*[tiab] OR antisocial personality disorder[mh] OR conduct problems[tiab] OR antisocial behavior*[tiab]	23579
#2 therapy[sh] OR therapeutics[mh] OR teaching[mh] OR psychotherapy[mh] OR treatment outcome[mh] OR "Adolescent Transitions Program"[tiab] OR "Anger control training"[tiab] OR "Assertive training"[tiab] OR "Behavioral parent training"[tiab] OR "Brief Strategic Family Therapy"[tiab] OR "Collaborative Problem Solving"[tiab] OR "Coping Power"[tiab] OR "Early Risers Skills for Success"[tiab] OR "Skills for Success Program"[tiab] OR "First Step to Success"[tiab] OR "Functional Family Therapy"[tiab] OR "Helping the Noncompliant Child"[tiab] OR "Incredible Years"[tiab] OR "Interpersonal skills training"[tiab] OR "Multidimensional Family Therapy"[tiab] OR "Multidimensional Treatment Foster Care"[tiab] OR "Multisystemic Therapy"[tiab] OR "Multi-systemic Therapy"[tiab] OR "Parent Management Training"[tiab] OR "Parent-Child Interaction Therapy"[tiab] OR "Positive Parenting Program"[tiab] OR "Problem Solving Skills Training"[tiab] OR "Positive Behavioral Support System"[tiab] OR "Promoting Alternative Thinking Strategies"[tiab] OR "Second Step"[tiab] OR "Self-Control training"[tiab] OR "Teacher-Child Interaction Training"[tiab] OR "Teacher Child Interaction Training"[tiab]	6753849
#3 eng[la] AND (child[mh] OR adolescent[mh])	1775464
#4 newspaper article[pt] OR letter[pt] OR comment[pt] OR case reports[pt] OR review[pt] OR practice guideline[pt] OR news[pt] OR editorial[pt] OR historical article[pt] OR meta-analysis[pt] OR legal cases[pt] OR published erratum[pt] OR congresses[pt] OR jsubsetk	4996769
#5 (#1 AND #2 AND #3) NOT #4	3181
#6 (oppositional defian*[tiab] OR conduct disorder*[tiab] OR disruptive behavior disorder*[tiab] OR disruptive behaviour disorder*[tiab] OR conduct problem*[tiab] OR antisocial behavior*[tiab] OR antisocial behavior*[tiab] OR ((externaliz*[tiab] OR aggressi*[tiab]) AND (behavior*[tiab] OR behaviour*))) NOT medline[sb]	3745
#7 (therapy[tiab] OR effectiveness[tiab] OR efficacy[tiab] OR outcome[tiab] OR treatment*[tiab] OR randomized[tiab] OR "Adolescent Transitions Program"[tiab] OR "Anger control training"[tiab] OR "Assertive training"[tiab] OR "Behavioral parent training"[tiab] OR "Brief Strategic Family Therapy"[tiab] OR "Collaborative Problem Solving"[tiab] OR "Coping Power"[tiab] OR "Early Risers Skills for Success"[tiab] OR "Skills for Success Program"[tiab] OR "First Step to Success"[tiab] OR "Functional Family Therapy"[tiab] OR "Helping the Noncompliant Child"[tiab] OR "Incredible Years"[tiab] OR "Interpersonal skills training"[tiab] OR "Multidimensional Family Therapy"[tiab] OR "Multidimensional Treatment Foster Care"[tiab] OR "Multisystemic Therapy"[tiab] OR "Multi-systemic Therapy"[tiab] OR "Parent Management Training"[tiab] OR "Parent-Child Interaction Therapy"[tiab]	388791

Search terms		Results
	OR "Positive Parenting Program"[tiab] OR "Problem Solving Skills Training"[tiab] OR "Positive Behavioral Support System"[tiab] OR "Promoting Alternative Thinking Strategies"[tiab] OR "Second Step"[tiab] OR "Self-Control training"[tiab] OR "Teacher-Child Interaction Training"[tiab] OR "Teacher Child Interaction Training"[tiab]) NOT medline[sb]	
#8	(child*[tiab] OR youth*[tiab] OR adolescen*[tiab] OR teen*[tiab] OR preschool*[tiab] OR parent*[tiab] OR family[tiab] OR families[tiab] OR juvenile*[tiab] OR school-age*[tiab]) NOT medline[sb]	149580
#9	#6 AND #7 AND #8	564
#10	#5 OR #9 (Medline and non-indexed results)	3745
Pharmacologic interventions		
#11	attention deficit and disruptive behavior disorders[mh:noexp] OR conduct disorder[mh] OR (mental disorders[mh] AND aggression[mh]) OR externalizing behavior*[tiab] OR externalizing behaviour*[tiab] OR oppositional defian*[tiab] OR conduct disorder*[tiab] OR disruptive behavior disorder*[tiab] OR antisocial personality disorder[mh] OR conduct problems[tiab] OR antisocial behavior*[tiab]	23579
#12	"drug therapy" [Subheading] OR "Drug Therapy"[Mesh] OR "Antipsychotic Agents"[Mesh] OR "Antipsychotic Agents" [Pharmacological Action] OR "Adrenergic alpha-Agonists"[Mesh] OR "Adrenergic alpha-2 Receptor Agonists"[Mesh] OR "Anticonvulsants"[Mesh] OR "Anticonvulsants" [Pharmacological Action] OR "Serotonin Uptake Inhibitors"[Mesh] OR "Serotonin Uptake Inhibitors" [Pharmacological Action] OR "Central Nervous System Stimulants"[Mesh]	2353195
#13	eng[la] AND (child[mh] OR adolescent[mh])	1775464
#14	newspaper article[pt] OR letter[pt] OR comment[pt] OR case reports[pt] OR review[pt] OR practice guideline[pt] OR news[pt] OR editorial[pt] OR historical article[pt] OR meta-analysis[pt] OR legal cases[pt] OR published erratum[pt] OR congresses[pt] OR jsubsetk	4996769
#15	(#11 AND #12 AND #13) NOT #14	685
Pharmacologic or psychosocial interventions		
#16	#15 OR #10 (all results)	3781
#17	#10 NOT #15	3096

Key: [mh] Medical Subject Heading; [tiab] title/abstract word; [pt] publication type; [sh] subheading;

*Note: numbers do not tally as some articles are excluded in more than one category

After duplicates were removed, this search contributed 1678 records to the existing 2407 in the database, for a total of 4085 records.

Table A-2: MEDLINE search strategies updated (PubMed interface) January 13, 2014

	Search terms	Results
#1	<p>"aggressive behavior"[tiab] OR "aggressive behaviors"[tiab] OR "aggressive behavior"[tiab] OR "aggressive behaviours"[tiab] OR "aggressive children"[tiab] OR "aggressive child"[tiab] OR "aggressive adolescent"[tiab] OR "aggressive adolescents"[tiab] OR "adolescent aggression"[tiab] OR "child aggression"[tiab] OR "antisocial behavior"[tiab] OR "antisocial behaviors"[tiab] OR "antisocial behaviour"[tiab] OR "antisocial behaviours"[tiab] OR "aggressive disruptive"[tiab] OR "Attention Deficit and Disruptive Behavior Disorders"[Mesh:NoExp] OR "behavior disorder"[tiab] OR "behavior disorders"[tiab] OR "behaviour disorder"[tiab] OR "behaviour disorders"[tiab] OR "conduct disorder"[tiab] OR "conduct disorders"[tiab] OR "Conduct Disorder"[mesh] OR "conduct problems"[tiab] OR "disruptive behavior"[tiab] OR "disruptive behaviour"[tiab] OR "disruptive behaviors"[tiab] OR "disruptive behaviours"[tiab] OR "externalizing disorder" OR "externalizing disorders" OR "externalizing behavior"[tiab] OR "externalizing behaviors"[tiab] OR "externalizing behaviour"[tiab] OR "externalizing behaviours"[tiab] OR "externalizing problem behavior"[tiab] OR "externalizing problem behaviors"[tiab] OR "externalizing problem behaviour"[tiab] OR "externalizing problem behaviours"[tiab] OR "oppositional defiant"[tiab] OR "oppositional defiance"[tiab] OR oppositionality[tiab] OR ((Aggression[Mesh] OR aggression[tiab] OR bullying[tiab] OR noncompliant[tiab] OR defiance[tiab] OR defiant[tiab] OR disruptive[tiab] OR oppositional[tiab] OR antisocial[tiab] OR "Psychomotor Agitation"[mesh]) AND ("Child Behavior"[mesh] OR "Adolescent Behavior"[mesh] OR behavior[tiab] OR behaviour[tiab] OR behaviors[tiab] OR behaviours[tiab] OR conduct[tiab]))</p>	36627
#2	<p>"anger management"[tiab] OR "anger control"[tiab] OR "behavior management"[tiab] OR "behaviour management"[tiab] OR "behavioral management"[tiab] OR "behavioural management"[tiab] OR "behavioral support"[tiab] OR "behavioural support"[tiab] OR "cognitive therapy"[tiab] OR "cognitive behavior therapy"[tiab] OR "cognitive behaviour therapy"[tiab] OR "CBT"[tiab] OR "cognitive behavioral therapy"[tiab] OR "cognitive behavioural therapy"[tiab] OR "conflict management"[tiab] OR counseling[tiab] OR "coping power"[tiab] OR "Counseling"[Mesh] OR "drug therapy"[tiab] OR "early intervention"[tiab] OR "family therapy"[tiab] OR "multisystemic therapy"[tiab] OR "multi-systemic therapy"[tiab] OR "multidimensional treatment"[tiab] OR "multidimensional therapy"[tiab] OR "nonpharmacologic therapy"[tiab] OR "nondrug therapy"[tiab] OR "non-drug therapy"[tiab] OR "parent training"[tiab] OR "parent engagement"[tiab] OR "parent management"[tiab] OR "parenting skills"[tiab] OR "parenting intervention"[tiab] OR "parenting interventions"[tiab] OR "family training"[tiab] OR "family education"[tiab] OR "family intervention"[tiab] OR "family interventions"[tiab] OR "pharmacologic therapy"[tiab] OR "pharmacologic treatment"[tiab] OR "Problem Solving"[Mesh] OR "problem solving"[tiab] OR "Psychology, Applied"[Mesh] OR psychoeducation[tiab] OR "psychosocial therapy"[tiab] OR "psychosocial intervention"[tiab] OR "psychosocial interventions"[tiab] OR "psychosocial approach"[tiab] OR "psychosocial approaches"[tiab] OR "psychosocial treatment"[tiab] OR "psychosocial support"[tiab] OR "Psychotherapy"[Mesh] OR psychotherap*[tiab] OR "skills training"[tiab] OR "symptom management"[tiab] OR teaching[tiab] OR "Therapeutics"[Mesh:NoExp] OR treatment[tiab] OR therapy[tiab] OR training[tiab] OR "Treatment Outcome"[Mesh] OR "Adrenergic alpha-2 Receptor Agonists" [Pharmacological Action] OR "Adrenergic alpha-2 Receptor Agonists"[Mesh] OR "alpha-2 agonist"[tiab] OR "alpha-2 agonists"[tiab] OR "Antidepressive Agents"[Mesh] OR "Antidepressive Agents" [Pharmacological Action] OR antidepressant[tiab] OR antidepressants[tiab] OR "Antipsychotic Agents"[Mesh] OR "Antipsychotic Agents" [Pharmacological Action] OR antipsychotics[tiab] OR antipsychotic[tiab] OR "mood stabilizer"[tiab] OR "mood stabilizing"[tiab] OR "mood stabilizers"[tiab] OR psychostimulant[tiab] OR psychostimulants[tiab] OR "Serotonin Uptake Inhibitors"[Mesh] OR "SSRI"[tiab] OR "SSRIs"[tiab] OR "selective serotonin reuptake inhibitors"[tiab] OR "Serotonin Uptake Inhibitors" [Pharmacological Action] OR stimulants[tiab] OR "Central Nervous System</p>	4613496

Search terms	Results
Stimulants"[Mesh] OR "Central Nervous System Stimulants" [Pharmacological Action] OR "Sympatholytics"[Mesh] OR "Sympatholytics" [Pharmacological Action] OR sympatholytic[tiab] OR sympatholytics[tiab]	
#3 #1 AND #2 AND english[la] AND (child[mh] OR adolescent[mh] OR child*[tiab] OR teen*[tiab] OR adolescent*[tiab] OR adolescence[tiab] OR pediatric[tiab] OR paediatric*[tiab])	6076
#4 newspaper article[pt] OR letter[pt] OR comment[pt] OR case reports[pt] OR review[pt] OR practice guideline[pt] OR news[pt] OR editorial[pt] OR historical article[pt] OR meta-analysis[pt] OR legal cases[pt] OR published erratum[pt] OR congresses[pt] OR jsubsetk	5028324
#5 #3 NOT #4	4695

Key: [mh] Medical Subject Heading; [tiab] title/abstract word; [pt] publication type; [sh] subheading;

*Note: numbers do not tally as some articles are excluded in more than one category

This search, less the duplicates, contributed 2716 citations for a total of 6801 records for initial screening

Table A-3: PsycINFO (via ProQuest Interface) Search Results November 26, 2013

Search terms	Results
PsycInfo- psychosocial	
#1 SU.EXACT("Conduct Disorder") OR SU.EXACT("Oppositional Defiant Disorder") OR SU.EXACT("Antisocial Personality Disorder") OR (disruptive behavior disorder OR disruptive behavior disorders)	11181
#2 SU.EXACT.EXPLODE("Treatment") OR SU.EXACT.EXPLODE("Medicinal Herbs and Plants") OR SU.EXACT.EXPLODE("Dietary Supplements") OR SU.EXACT.EXPLODE("Nutrition") OR SU.EXACT.EXPLODE("Vitamins") OR SU.EXACT("Drug Therapy") OR SU.EXACT.EXPLODE("Behavior Therapy")	573194
#3 #1 and #2	2580
#4 #3, limited children and adolescents	1558
#5 #3, limited to 2003-2013 publication date	1323
#6 #3 limited to peer reviewed, scholarly journals	1719
#7 #3 limited to research methodology (Empirical Study OR Quantitative Study OR Treatment Outcome/Clinical Trial OR Longitudinal Study OR Followup Study OR Retrospective Study OR Prospective Study OR Field Study)	1200
#8 #3 AND #4 AND #5 AND #6 AND #7	412
PsycInfo- pharmacologic	

Search terms		Results
#9	SU.EXACT("Conduct Disorder") OR SU.EXACT("Oppositional Defiant Disorder") OR SU.EXACT("Antisocial Personality Disorder") OR (disruptive behavior disorder OR disruptive behavior disorders)	11181
#10	(SU.EXACT.EXPLODE("Adrenergic Blocking Drugs") OR SU.EXACT.EXPLODE("Adrenergic Drugs")) OR (SU.EXACT.EXPLODE("Anticonvulsive Drugs") OR SU.EXACT.EXPLODE("Antidepressant Drugs")) OR (SU.EXACT.EXPLODE("Drug Augmentation") OR SU.EXACT.EXPLODE("Drug Therapy")) OR SU.EXACT.EXPLODE("Neuroleptic Drugs") OR antipsychotic	142032
#11	#9 AND #10	643
#12	#11, limited to children and adolescents	436
#13	#11, limited to 2003-2013	384
#14	#11, limited to peer reviewed, scholarly journals	540
#15	#11, limited to research methodology ((Empirical Study OR Quantitative Study OR Treatment Outcome/Clinical Trial OR Longitudinal Study OR Followup Study OR Retrospective Study OR Prospective Study OR Field Study)	398
#16	#11 AND #12 AND #13 AND #14 AND #15	170
PsycInfo- psychosocial and pharmacologic interventions		
#17	#8 OR #16	425

Table A-4: Embase search strategy (OvidSP interface, includes MEDLINE results) April 18, 2014

Search terms		Search results
#1	conduct disorder/ or behavior disorder/ or disruptive behavior/ or oppositional defiant disorder/ or aggression/ or intermittent explosive disorder/ or disruptive mood dysregulation disorder.mp	80970
#2	exp antidepressant agent/ or exp neuroleptic agent/ or exp serotonin uptake inhibitor/ or exp central stimulant agent/ or exp adrenergic receptor blocking agent/ or exp alpha 2 adrenergic receptor stimulating agent/	811935
#3	#1 AND #2	13405
#4	#3 NOT (review or conference paper or conference abstract or editorial or letter or note or short survey).pt. or case report/ or practice guideline/ or systematic review/ or meta analysis/	5115
#5	#4 limit to (human and english language and exclude medline journals and yr="1994 - Current" and (infant <to one year> or child <unspecified age> or preschool child <1 to 6 years> or school child <7 to 12 years> or adolescent <13 to 17 years>))	70

Key: [mh] Medical Subject Heading; [la] language; [tiab] title/abstract word; [pt] publication type; [sh] subheading

Appendix B. Literature Screening Forms

Abstract Review Form

First Author, Year: _____ Endnote Reference ID #: _____ Abstractor Initials: ___ ___ ___

Primary Inclusion/Exclusion Criteria				
X-1	1. Reports original research (i.e., not commentaries, literature reviews, or systematic reviews) <i>NOTE: If the publication appears relevant to the topic, consider whether it should be retained for "review for references" (see check boxes below the form). These publications will be flagged for review, but not promoted for full text screening.</i>	Yes	No	Cannot Determine
X-2	2. Measures the relationship between a psychosocial or pharmacologic intervention and an outcome (i.e., not a descriptive study).	Yes	No	Cannot Determine
X-3	3. Population is children (youth). <i>NOTE: If the intervention targets parent/caregiver, the study must report at least one child outcome.</i>	Yes	No	Cannot Determine
X-4	4. Population has a disruptive behavior disorder which a. meets standardized disease classification or criteria for diagnosis of a disruptive behavior disorder (includes oppositional-defiant disorder and conduct disorder); OR b. is characterized by maladaptive behavior(s) assessed using a standardized behavior checklist, tool or measure.	Yes	No	Cannot Determine
X-5	5. Study is conducted in a healthcare setting. <i>NOTE: Do not include studies conducted exclusively in the juvenile justice system or school setting; do not include systems-level, universal, or preventive interventions; do not include studies conducted exclusively in hospitalized (i.e. inpatient) participants.</i>	Yes	No	Cannot Determine
X-6	6. The study includes an alternate treatment or intervention for comparison to measure effectiveness.	Yes	No	Cannot Determine

Retain for:

Background/Discussion Review of references Harms data Other_____

COMMENTS:

Full Text Review Form

First Author, Year: _____ Endnote Reference ID #: _____ Abstractor Initials: _____

<p><i>If response to item #1-6 is "No" the form is complete. Consider whether the reference should be retained for background, review of references, team review, harms, or other reason, and then submit the form to move to the next reference.</i></p>			
X-1	<p>1. Reports original research (i.e., not commentaries, literature reviews, or systematic reviews) <i>NOTE: If the publication appears relevant to the topic, consider whether it should be retained for "review for references" (see check boxes below the form). These publications will be flagged for review, but not promoted for full text screening.</i></p>	Yes	No
X-2	<p>2. The study measures the relationship between a psychosocial or pharmacologic intervention and an outcome (i.e., not a descriptive study). If "Yes", check one:</p> <ul style="list-style-type: none"> <input type="radio"/> Randomized controlled trial <input type="radio"/> Nonrandomized controlled trial <input type="radio"/> Prospective cohort with concurrent control group <input type="radio"/> Retrospective cohort (groups NOT defined by outcome) <input type="radio"/> Other _____ 	Yes	No
X-3	<p>3. The study population is children (youth). <i>NOTE: If the intervention targets parent/caregiver, the study must report at least one child outcome.</i></p>	Yes	No
X-4	<p>4. The study population has a disruptive behavior disorder which:</p> <ul style="list-style-type: none"> a) meets standardized disease classification or criteria for diagnosis of a disruptive behavior disorder (includes oppositional-defiant disorder and conduct disorder); OR b) is characterized by maladaptive behavior(s) assessed using a standardized behavior checklist, tool or measure. <p>If "No", target population described as children with ADHD?</p> <ul style="list-style-type: none"> <input type="radio"/> Yes <input type="radio"/> No 	Yes	No
X-5	<p>5. The study is conducted in a healthcare setting. <i>NOTE: Do not include studies conducted exclusively in the juvenile justice system or school setting; do not include systems-level, or universal interventions; do not include studies conducted exclusively in hospitalized (i.e. inpatient) participants.</i></p>	Yes	No
X-6	<p>6. The study includes an alternate treatment or intervention for comparison to measure effectiveness. If "Yes", check one:</p> <ul style="list-style-type: none"> <input type="radio"/> Compares two or more psychosocial interventions <input type="radio"/> Compares two or more pharmacologic interventions <input type="radio"/> Compares one or more psychosocial interventions with one or more pharmacologic interventions <input type="radio"/> Compares one or more combined psychosocial and pharmacologic interventions with another intervention <input type="radio"/> Compares one or more psychosocial interventions with an inactive control (e.g., waitlist) <input type="radio"/> Compares one or more psychosocial interventions with usual care <input type="radio"/> Compares one or more pharmacologic interventions with a control (e.g., placebo, untreated) <input type="radio"/> Compares one or more combined psychosocial and pharmacologic interventions with a control 	Yes	No
X-7	<p>7. The study reports an outcome of interest for the population (youth) with disruptive behavior.</p>	Yes	No
X-8	<p>8. Addresses Key Question (s)</p>	Yes	No

<p>In children under 18 years of age treated for disruptive behaviors:</p> <p>____ (KQ1) are any psychosocial interventions more effective for improving short-term and long-term psychosocial outcomes than no treatment or other psychosocial interventions?</p> <p>____ (KQ2) are alpha-agonists, anticonvulsants, beta-blockers, central nervous system stimulants, first-generation antipsychotics, second-generation (atypical) antipsychotics, and selective serotonin reuptake inhibitors more effective for improving short-term and long-term psychosocial outcomes than placebo or other pharmacologic interventions?</p> <p>____ (KQ3) what is the relative effectiveness of psychosocial interventions compared with the pharmacologic interventions listed in Key Question 2 for improving short-term and long-term psychosocial outcomes?</p> <p>____ (KQ4) are combined psychosocial and pharmacologic interventions more effective for improving short-term and long-term psychosocial outcomes than individual interventions?</p> <p>____ (KQ5) what are the harms of treatment associated with either psychosocial or pharmacologic interventions?</p> <p>Do interventions intended to address disruptive behaviors and identified in Key Questions 1-4 vary in effectiveness based on:</p> <p>____ (KQ6a) patient characteristics, including gender, age, race/ethnic minority, family history of disruptive behavior disorders, family history of mental health disorders, history of trauma, and socioeconomic status?</p> <p>____ (KQ6b) characteristics of the disorder, including specific disruptive behavior or disruptive behavior disorder (e.g., oppositional defiant disorder, conduct disorder, aggression), concomitant psychopathology (e.g., attention deficit hyperactivity disorder or substance abuse), related personality traits and symptom clusters, presence of co-morbidities, age of onset, and duration?</p> <p>____ (KQ6c) treatment history of the patient?</p> <p>____ (KQ6d) characteristics of the treatment, including duration, delivery, timing, and dose?</p>		
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Retain for:

- Background/Discussion
 Review of references
 Team Review
 Harms
 Other

COMMENTS:

Appendix C. Risk of Bias Assessment

The Cochrane Collaboration tool is used to assess risk of bias for randomized controlled trials. Bias is assessed as a judgment (high, low, or unclear) for individual elements from five domains (selection, performance, attrition, reporting, and other).

Table C-1. Cochrane Risk of Bias Tool

Risk of Bias Assessment for Ref ID: _____						
Domain	Description	High Risk of Bias	Low Risk of Bias	Unclear Risk of Bias	Reviewer Assessment	Reviewer Comments
<i>Selection bias</i> Random sequence generation	Described the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups	Selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence	Random sequence generation method should produce comparable groups	Not described in sufficient detail	High Low Unclear	
<i>Selection bias</i> Allocation concealment	Described the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen before or during enrollment	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment	Intervention allocations likely could not have been foreseen in before or during enrollment	Not described in sufficient detail	High Low Unclear	
<i>Reporting bias</i> Selective reporting	Stated how the possibility of selective outcome reporting was examined by the authors and what was found	Reporting bias due to selective outcome reporting	Selective outcome reporting bias not detected	Insufficient information to permit judgment†	High Low Unclear	
<i>Other bias</i> Other sources of bias	Any important concerns about bias not addressed above*	Bias due to problems not covered elsewhere in the table	No other bias detected	There may be a risk of bias, but there is either insufficient information to assess whether an important risk of bias exists or	High Low Unclear	

Risk of Bias Assessment for Ref ID: _____

Domain	Description	High Risk of Bias	Low Risk of Bias	Unclear Risk of Bias	Reviewer Assessment	Reviewer Comments
				insufficient rationale or evidence that an identified problem will introduce bias		

* If particular questions/entries were pre-specified in the study's protocol, responses should be provided for each question/entry.

Risk of Bias Assessment for Ref ID: _____ (continued)

Assess each main or class of outcomes for each of the following. Indicate the specific outcome.

Outcome:

Domain	Description	High Risk of Bias	Low Risk of Bias	Unclear Risk of Bias	Reviewer Assessment	Reviewer Comments
<i>Performance bias</i> Blinding (participants and personnel)	Described all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective.	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.	Blinding was likely effective.	Not described in sufficient detail	High Low Unclear	
<i>Detection bias</i> Blinding (outcome assessment)	Described all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provided any information relating to whether the intended blinding was effective.	Detection bias due to knowledge of the allocated interventions by outcome assessors.	Blinding was likely effective.	Not described in sufficient detail	High Low Unclear	
<i>Attrition bias</i> Incomplete outcome data	Described the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. Stated whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for	Attrition bias due to amount, nature or handling of incomplete outcome data.	Handling of incomplete outcome data was complete and unlikely to have produced bias	Insufficient reporting of attrition/exclusions to permit judgment (e.g., number randomized not stated, no reasons for missing data provided)	High Low Unclear	

attrition/exclusions
where reported.

* If particular questions/entries were pre-specified in the study's protocol, responses should be provided for each question/entry.

Table C-2. Criteria for Judging Risk of Bias in the ‘Cochrane Risk of Bias’ Assessment Tool*

Bias	Judgment	Criteria
RANDOM SEQUENCE GENERATION	‘Low risk’ of bias.	<p>The investigators describe a random component in the sequence generation process such as:</p> <ul style="list-style-type: none"> • Referring to a random number table; • Using a computer random number generator; • Coin tossing; • Shuffling cards or envelopes; • Throwing dice; • Drawing of lots; • Minimization*. <p>*Minimization may be implemented without a random element, and this is considered to be equivalent to being random.</p>
	Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.	<p>The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example:</p> <ul style="list-style-type: none"> • Sequence generated by odd or even date of birth; • Sequence generated by some rule based on date (or day) of admission; • Sequence generated by some rule based on hospital or clinic record number. <p>Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example:</p> <ul style="list-style-type: none"> • Allocation by judgement of the clinician; • Allocation by preference of the participant; • Allocation based on the results of a laboratory test or a series of tests; • Allocation by availability of the intervention.
	‘Unclear risk’ of bias.	Insufficient information about the sequence generation process to permit judgement of ‘Low risk’ or ‘High risk’.
ALLOCATION CONCEALMENT	‘Low risk’ of bias.	<p>Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation:</p> <ul style="list-style-type: none"> • Central allocation (including telephone, web-based and pharmacy-controlled randomization); • Sequentially numbered drug containers of identical appearance; • Sequentially numbered, opaque, sealed envelopes.
	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.	<p>Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on:</p> <ul style="list-style-type: none"> • Using an open random allocation schedule (e.g. a list of random numbers); • Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered); • Alternation or rotation; • Date of birth; • Case record number; • Any other explicitly unconcealed procedure.
	‘Unclear risk’ of bias.	Insufficient information to permit judgement of ‘Low risk’ or ‘High risk’. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.
SELECTIVE REPORTING	‘Low risk’ of bias.	<p>Any of the following:</p> <ul style="list-style-type: none"> • The study protocol is available and all of the study’s pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; • The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
	Reporting bias due to selective outcome reporting.	<p>Any one of the following:</p> <ul style="list-style-type: none"> • Not all of the study’s pre-specified primary outcomes have been reported; • One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified;

Bias	Judgment	Criteria
		<ul style="list-style-type: none"> One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
	'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. It is likely that the majority of studies will fall into this category.
OTHER BIAS Bias due to problems not covered elsewhere in the table.	'Low risk' of bias.	The study appears to be free of other sources of bias.
	'High risk' of bias.	There is at least one important risk of bias. For example, the study: <ul style="list-style-type: none"> Had a potential source of bias related to the specific study design used; or Has been claimed to have been fraudulent; or Had some other problem.
	'Unclear risk' of bias.	There may be a risk of bias, but there is either: <ul style="list-style-type: none"> Insufficient information to assess whether an important risk of bias exists; or Insufficient rationale or evidence that an identified problem will introduce bias.
BLINDING OF PARTICIPANTS AND PERSONNEL Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.	'Low risk' of bias.	Any one of the following: <ul style="list-style-type: none"> No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
	'High risk' of bias.	Any one of the following: <ul style="list-style-type: none"> No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.
	'Unclear risk' of bias.	Any one of the following: <ul style="list-style-type: none"> Insufficient information to permit judgment of 'Low risk' or 'High risk'; The study did not address this outcome.
BLINDING OF OUTCOME ASSESSMENT Detection bias due to knowledge of the allocated interventions by outcome assessors.	'Low risk' of bias.	Any one of the following: <ul style="list-style-type: none"> No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
	'High risk' of bias.	Any one of the following: <ul style="list-style-type: none"> No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; Blinding of outcome assessment, but likely that the blinding could have been broken and the outcome measurement is likely to be influenced by lack of blinding.
	'Unclear risk' of bias.	Any one of the following: <ul style="list-style-type: none"> Insufficient information to permit judgment of 'Low risk' or 'High risk'; The study did not address this outcome.
INCOMPLETE OUTCOME DATA Attrition bias due to amount, nature, or handling of incomplete outcome data.	'Low risk' of bias.	Any one of the following: <ul style="list-style-type: none"> No missing outcome data; Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size;

Bias	Judgment	Criteria
		<ul style="list-style-type: none"> • Missing data have been imputed using appropriate methods.
	'High risk' of bias.	Any one of the following: <ul style="list-style-type: none"> • Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; • 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization; • Potentially inappropriate application of simple imputation.
	'Unclear risk' of bias.	Any one of the following: <ul style="list-style-type: none"> • Insufficient reporting of attrition/exclusions to permit judgement of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided); • The study did not address this outcome.

* Adapted from the Cochrane Collaboration

Table C-3. Risk of Bias Assessment for Cohort Studies

Cohort Study Assessment Form

Ref ID: _____

Reviewer: _____

		No	Yes	Comments
Questions to Assess the Risk of Bias				
Q1	Do the inclusion/exclusion criteria vary across the comparison groups of the study?			
Q2	Does the strategy for recruiting participants into the study differ across groups?			
Q3	Is the selection of the comparison group inappropriate, after taking into account feasibility and ethical considerations?			
Q4	Was the outcome assessor not blinded to the intervention or exposure status of participants?			
Q5	Were valid and reliable measures, implemented consistently across all study participants used to assess inclusion/exclusion criteria, intervention/exposure outcomes, participant health benefits and harms, and confounding?			
Q6	Was the length of followup different across study groups?			
Q7	In cases of high loss to followup (or differential loss to followup), was the impact assessed (e.g., through sensitivity analysis or other adjustment method)?			
Questions to Assess Confounding				
Q8	Any attempt to balance the allocation between the groups or match groups (e.g., through stratification, matching, propensity scores)?			
Q9	Were the important confounding variables taken into account in the design and/or analysis (e.g., through matching, stratification, interaction terms, multivariate analysis, or other statistical adjustment such as instrumental variables)?			
Questions to Assess Precision				
Q10	Are the statistical methods used to assess the primary benefit outcomes inadequate?			
Q11	Are the statistical methods used to assess the main harm or adverse event outcomes inadequate?			

Based on cohort questions from: Viswanathan M, Berkman ND, Dryden DM, et al. Assessing Risk of Bias and Confounding in Observational Studies of Interventions or Exposures: Further Development of the RTI Item Bank [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2013 Aug. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK154461/>

Assessment of Overall Risk of Bias for Individual Studies

There are three categories for describing the overall risk of bias for included studies: low risk of bias; moderate risk of bias; and high risk of bias.

Randomized Controlled Trials (Cochrane Risk of Bias Tool)

Threshold for Overall Study Risk of Bias

- **Low:** low risk of bias for all domains.
- **Moderate:** unclear risk of bias for one or more domains and no known important limitation that could invalidate its results.
- **High:** high risk of bias for one or more domains.

Tool includes seven items in six domains:

- Selection Bias (*2 items*)
- Reporting bias (*1 item*)
- Other bias (*1 item*)
- Performance bias (*1 item*)
- Detection bias (*1 item*)
- Attrition bias (*1 item*)

Cohort Studies (Cohort Assessment Form - RTI Bank)

Threshold for Overall Study Risk of Bias

- **Low:** all positive ratings
- **Moderate:** two or fewer negative ratings
- **High:** more than two negative ratings

Form includes eleven items in three domains:

- Risk of Bias (*7 items*)
- Confounding (*2 items*)
- Precision (*2 items*)

Table C-4. Quality Assessment Form for Systematic Reviews (AMSTAR)

1. Was a <i>a priori</i> design provided?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
2. Was there duplicate study selection and data extraction?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
3. Was a comprehensive literature search performed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
5. Was a list of studies (included and excluded) provided?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
6. Were the characteristics of the included studies provided?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
7. Was the scientific quality of the included studies assessed and documented?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
9. Were the methods used to combine the findings of studies appropriate?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable

10. Was the likelihood of publication bias assessed?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable
11. Was the conflict of interest included?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Can't answer <input type="checkbox"/> Not applicable

Table C-5 Risk of bias summary for KQ1 RCTs

Citation	AgeCat	Random Sequence Generation	Allocation Conceal	Selective Reporting	Other Bias	Outcome(s)	Blinding (pts, personnel)	Blinding (outcome assess)	Incomplete Outcome Data	Low	High	Unclear	Overall Score
Perrin et al., 2013 ¹	PRE-K	L	U	L	U	ECBI	H	H	L	3	2	2	Moderate
Jones, et al., 2013 ²	PRE-K	U	U	L	L	ECBI problem, ECBI intensity	U	U	H	2	1	4	High
Somech et al., 2012 ³	PRE-K	L	U	U	L	ECBI Intensity	U	U	L	3	0	4	Moderate
Cummings et al., 2008 ⁴	PRE-K	L	L	U	H	CBCL,ECBI	H	H	H	2	4	1	High
Lavigne, et al., 2008 ⁵	PRE-K	U	U	U	H	ECBI, CBCL	U	U	U	0	1	6	High
Hutchings et al., 2007 ⁶	PRE-K	L	L	L	L	ECBI	H	L	L	6	1	0	Moderate
Markie-Dadds, et al., 2006 ⁷	PRE-K	U	U	U	U	ECBI Intensity, ECBI Problem, PDR	U	U	L	1	0	6	Moderate
McGilloway, et al., 2012 ⁸	PRE-K	L	L	U	H	ECBI	L	L	L	5	1	1	Low

Citation	AgeCat	Random Sequence Generation	Allocation Conceal	Selective Reporting	Other Bias	Outcome(s)	Blinding (pts, personnel)	Blinding (outcome assess)	Incomplete Outcome Data	Low	High	Unclear	Overall Score
Markie-Dadds, et al., 2006 ⁹	PRE-K	L	U	U	U	ECBI Intensity, ECBI Problem, PDR	H	H	H	1	3	3	Moderate
Sanders et al., 2000 ¹⁰	PRE-K	U	U	U	L	ECBI, PDR, PS, PSOC, ADAS, PPC, PASS	H	H	H	1	3	3	Moderate
Connell, et al., 1997 ¹¹	PRE-K	L	U	U	U	ECBI (intensity), ECBI (problem), PDRC	H	U	L	2	1	4	High
Sanders, et al., 2012 ¹²	PRE-K	L	u	U	H	ECBI intensity, ECBI problem, SDQ	H	U	L	2	2	3	High
Jouriles, et al., 2001 ¹³	PRE-K	U	U	U	H	CBCL, direct observation	U	U	U	0	1	6	High
Bagner, et al., 2010 ¹⁴	PRE-K	L	U	U	L	CBCL (externalizing), CBCL (aggression), ECBI (intensity), ECBI (problem)	H	H	H	2	3	2	High
McCabe, et al., 2009 ¹⁵	PRE-K	L	U	U	L	ECBI, CBCL, ARSMA-II	L	L	L	5	0	2	Low
Schuhmann et al., 1998 ¹⁶	PRE-K	L	L	U	L	DPICS	U	L	H	4	1	2	Moderate

Citation	AgeCat	Random Sequence Generation	Allocation Conceal	Selective Reporting	Other Bias	Outcome(s)	Blinding (pts, personnel)	Blinding (outcome assess)	Incomplete Outcome Data	Low	High	Unclear	Overall Score
Eyberg et al., 1995 ¹⁷	PRE-K	U	U	U	L	ECBI intensity, ECBI problem	H	U	H	1	2	4	High
Nixon, et al., 2003 ¹⁸	PRE-K	U	U	U	L	ECBI Intensity, DPICS	U	H	L	2	1	4	Moderate
van Manen et al., 2004 ¹⁹	SCHOOL	U	L	U	U	CBCL, TOPS, TRA, SCRS, SCST	U	U	H	1	1	5	Moderate
Kjobli, et al., 2012 ²⁰	SCHOOL	L	U	U	U	ECBI, CBCL	H	H	L	2	2	3	High
Axberg, et al., 2012 ²¹	SCHOOL	U	U	U	H	ECBI	H	H	L	1	3	3	High
McGrath, et al., 2011 ²²	SCHOOL	L	L	L	L	K-SADS	U	L	L	6	0	1	Low
Kling, et al., 2010 ²³	SCHOOL	U	U	U	L	PDR, ECB1, ECBIP	U	U	L	2	0	5	Moderate
Ogden et al., 2008 ²⁴	SCHOOL	L	L	U	L	CBCL, SSRS, PDR	U	U	L	4	0	3	Moderate

Citation	AgeCat	Random Sequence Generation	Allocation Conceal	Selective Reporting	Other Bias	Outcome(s)	Blinding (pts, personnel)	Blinding (outcome assess)	Incomplete Outcome Data	Low	High	Unclear	Overall Score
Gardner, et al., 2006 ²⁵	SCHOOL	L	L	U	U	ECBI	U	U	L	3	0	4	Moderate
Webster-Stratton et al., 1994 ²⁶	SCHOOL	U	U	U	L	CBCL, ECBI, DPICS	U	U	U	1	0	6	Moderate
Hutchings, et al., 2002 ²⁷	SCHOOL	U	U	U	U	ECBI	U	U	L	1	0	6	Moderate
Scott et al., 2010 ²⁸	SCHOOL	L	L	L	U	PACS, ECBI	L	L	L	6	0	1	Low
Larsson, et al., 2009 ²⁹	SCHOOL	U	U	U	L	ECBI, CBCL, KSADS-PL	U	U	L	2	0	5	Moderate
van de Wiel et al., 2007 ³⁰	SCHOOL	U	U	U	U	CBCL, CBCL,TRF	U	U	L	1	0	6	Moderate
Drugli, et al., 2006 ³¹	SCHOOL	U	U	U	H	ECBI, CBCL, KSANS	H	H	L	1	3	3	Moderate
Webster-Stratton et al., 2004 ³²	SCHOOL	U	U	U	L	ECBI, CBCL	U	U	U	1	0	6	Moderate

Citation	AgeCat	Random Sequence Generation	Allocation Conceal	Selective Reporting	Other Bias	Outcome(s)	Blinding (pts, personnel)	Blinding (outcome assess)	Incomplete Outcome Data	Low	High	Unclear	Overall Score
Cabiya et al., 2008 ³³	SCHOOL	U	U	U	H	BSBI, CDI	U	L	H	1	2	4	High
Webster-Stratton et al., 1997 ³⁴	SCHOOL	U	U	U	L	CBCL,EBCI Intensity, PDR	U	U	L	2	0	5	Moderate
Boylan, et al., 2013 ³⁵	SCHOOL	U	U	U	U	ChIPS, P-ChIPS, CDRS-R, MRS, MSI	U	L	L	2	0	5	Moderate
Augimeri et al., 2007 ³⁶	SCHOOL	U	U	U	H	CBCL	U	U	L	1	1	5	Moderate
Kolko, et al., 2001 ³⁷	SCHOOL	L	U	U	L	FHS, CP w, fire, CFI, SUFA	U	U	L	3	0	4	Moderate
Kolko, et al., 2010 ³⁸	SCHOOL	L	U	U	L	PSC-17; SDQ	U	H	L	3	1	3	Moderate
Kolko, et al., 2009 ³⁹	SCHOOL	L	U	U	L	KSADS, TRE, CBCL	U	U	L	3	0	4	Moderate
Greene, et al., 2004 ⁴⁰	SCHOOL	U	U	U	U	PCRI, PSI.ODBRS, CGI, KSADS-E	U	U	L	1	0	6	Moderate

Citation	AgeCat	Random Sequence Generation	Allocation Conceal	Selective Reporting	Other Bias	Outcome(s)	Blinding (pts, personnel)	Blinding (outcome assess)	Incomplete Outcome Data	Low	High	Unclear	Overall Score
Jouriles, et al., 2009 ⁴¹	SCHOOL	L	H	U	L	CBCL-EXT, ECBI	H	H	U	2	3	2	High
Rohde et al., 2004 ⁴²	TEEN	L	L	H	H	Conduct Disorder, BDI-II, HDRS, CBCL, CGAS, SAS-R	L	L	U	4	2	1	High
Weiss et al., 2013 ⁴³	TEEN	U	U	U	L	CBCL	U	U	L	2	0	5	Moderate
Butler, et al., 2011 ⁴⁴	TEEN	L	L	U	L	arrest records	U	L	L	5	0	2	Low
Asscher et al., 2013 ⁴⁵	TEEN	L	U	L	U	CBCL - parents + YSR	U	H	L	3	1	3	High
Borduin et al., 1995 ⁴⁶	TEEN	L	U	U	U	symptom checklist, RPBX, FACES II	U	U	H	1	1	5	Moderate
Sundell et al., 2008 ⁴⁷	TEEN	L	L	L	L	CBCL	U	U	L	5	0	2	Low
Shechtman, et al., 2006 ⁴⁸	TEEN	U	U	U	U	CBCL, CCNES	U	U	L	1	0	6	Moderate

Citation	AgeCat	Random Sequence Generation	Allocation Conceal	Selective Reporting	Other Bias	Outcome(s)	Blinding (pts, personnel)	Blinding (outcome assess)	Incomplete Outcome Data	Low	High	Unclear	Overall Score
Santisteban et al., 2003 ⁴⁹	TEEN	U	U	U	L	RBPC	U	U	H	1	1	5	High
Nickel, et al., 2006 ⁵⁰	TEEN	L	L	L	L	ARBS, STAXI, SF-36	L	L	L	7	0	0	Low
Nickel, et al., 2005 ⁵¹	TEEN	L	L	L	L	ARBS, STAXI	L	L	L	7	0	0	Low
Nickel, et al., 2006 ⁵²	TEEN	L	L	U	U	Salivary, STAXI	U	L	L	4	0	3	Moderate

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Table C-6. Risk of bias assessment for nonrandomized controlled studies (KQ1)

Author, Year	Inclusion/exclusion criteria across groups	Recruitment strategy across groups	Selection of the comparison group	Outcome assessor blinding	Valid & reliable measures across study participants	Length of followup different across groups	Assessment of impact of high loss to followup	Balancing allocation between groups/matching groups	Accounting for confounding factors	Adequacy of statistical methods to assess primary outcomes	Adequacy of statistical methods to assess harms or adverse events outcomes	Rating
van der Put et al., 2013 ¹	+	+	-	-	-	-	NA	-	-	+	NA	Poor
Koegl et al., 2008 ²	+	-	+	-	+	+	-	+	+	+	NA	Poor
Posthumus et al., 2012 ³	+	+	+	-	+	+	NA	+	+	+	NA	Fair
Lipman et al., 2008 ⁴	+	+	+	-	+	+	-	-	+	+	NA	Poor
Costin et al., 2004 ⁵	+	+	+	-	+	+	-	-	-	-	NA	Poor
Coughlin 2009 ⁶	+	+	+	-	+	+	-	-	-	+	NA	Poor
Shapiro et al., 2012 ⁷	+	+	+	-	+	-	+	-	+	+	NA	Poor
Foster et al, 2007 ⁸	+	+	+	-	+	-	-	NA	-	+	NA	Poor

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Table C-7. Risk of bias assessment for randomized controlled trials (KQ2)

Citation (Family)	Pharm	Random Sequence Generation	Allocation Conceal	Selective Reporting	Other Bias	Outcome(s)	Blinding (pts/ personnel)	Blinding (outcome assess)	Incomplete Outcome Data	Low	High	Unclear	Overall Score
Dittmann et al., 2011 ¹ (B-P)	Atomoxetine	L	L	U	L	ECBI, SNAP	U	U	H	3	1	3	Moderate
Connor et al., 2010 ²	Guanfacine	L	L	L	L	CPRS	U	U	L	5	0	2	Moderate
Saxena et al., 2010 ³	Divalproex	H	U	L	H	CGI; OAS	H	H	H	1	5	1	High
Blader et al., 2009 ⁴	Divalproex	L	U	L	U	OAS	U	H	L	3	2	2	Moderate
Dell'Agnello et al., 2009 ⁵	Atomoxetine	U	U	L	L	SWAR-IV, CGI-S, CPRS-S, SCARED, HRQOL	U	U	L	3	0	4	High
Connor et al., 2008 ⁶	Quetiapine	U	U	L	U	CGI-S; OAS; CPRS-CP	L	L	L	4	1	2	Moderate
Armenteros et al., 2007 ⁷	Risperidone	U	U	L	U	CAS; CGI	L	L	L	4	1	2	Moderate
Spencer et al., 2006 ⁸ (I-P)	Amphetamine	U	U	L	L	SNAP	U	U	L	3	0	4	High

Reyes et al., 2006 ⁹	Risperidone	U	U	L	U	CGI; CGAS	U	U	H	1	2	4	High
Steiner et al., 2003 ¹⁰ (K-P)	Divalproex	U	U	L	U	CGI	U	L	L	3	1	3	Moderate
Donovan et al., 2000 ¹¹	Divalproex	U	U	L	L	OAS	L	L	L	3	0	4	Moderate
Findling et al., 2000 ¹²	Risperidone	L	L	L	U	CBCL; CPRS	L	L	L	6	1	0	Low
Klein et al., 1997 ¹³	Methylphenidate	H	H	L	U	CTRS; IOWA	H	H	L	2	4	1	High

Table C-8. Risk of bias assessment for nonrandomized controlled studies (KQ2)

Author, Year	Inclusion/exclusion criteria across groups	Recruitment strategy across groups	Selection of the comparison group	Outcome assessor blinding	Valid & reliable measures across study participants	Length of followup different across groups	Assessment of impact of high loss to followup	Balancing allocation between groups/matching groups	Accounting for confounding factors	Adequacy of statistical methods to assess primary outcomes	Adequacy of statistical methods to assess harms or adverse events outcomes	Rating
Bastiaens et al., 2009 ¹⁴	+	+	+	-	+	+	+	-	-	-	-	Poor

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Appendix D. Meta-analytic Methods

We developed a meta-analysis to address Key Question 1, which concerns the comparative effectiveness of psychosocial interventions for improving psychosocial outcomes for children treated for disruptive behaviors. We employed Bayesian multivariate, mixed treatment (network) meta-analytic methods (Lumley 2002, Lu and Ades 2004, Wei and Higgins 2013) to use both direct and indirect evidence for comparing a large suite of treatments. Of the 16 instruments used to measure treatment outcomes, we included studies that employed one or more of the four most prevalent instruments:

- Eyeberg Child Behavior Inventory (ECBI), Intensity Subscale
- ECBI, Problem Subscale
- Child Behavior Checklist (CBC), Externalizing (T-score)
- CBC, Externalizing (raw score)

Studies were included in the meta-analysis if they reported baseline and end-of-treatment (EOT) means and standard deviations from one of the four metrics listed above. In total, 26 studies were used to fit the model. The baseline was subtracted from the EOT mean and used as the response measure $d_i = y_i^{(eot)} - y_i^{(b)}$. The response expected values m were modeled jointly as a multivariate normal likelihood, with any unmeasured outcomes treated as missing data; this allowed for the covariance among measures to be accounted for and estimated.

$$\begin{pmatrix} m_1 \\ m_2 \\ m_3 \\ m_4 \end{pmatrix}_i \sim \text{MVN}(\mu, \Sigma)$$

To accommodate the large suite of interventions employed by the constituent studies, we classified each intervention according to the treatment components that comprised them. Specifically, the treatment arms of each study were classified as one of the following types:

- Child-only treatment
- Parent-only treatment
- Multiple treatment

Thus, a given treatment arm was specified by a vector of indicator variables.

$$X_i = \begin{bmatrix} x_c \\ x_p \\ x_f \end{bmatrix}_i$$

Those not identified by any of these three classes were considered either control or treatment-as-usual arms, encoded by a zero vector. Recognizing that these treatment categories are broad, encompassing a range of specific interventions, each component was modeled as a random effect.

$$\begin{aligned}\beta_j^{(c)} &\sim N(\mu_\beta^{(c)}, \tau_\beta^{(c)}) \\ \beta_j^{(p)} &\sim N(\mu_\beta^{(p)}, \tau_\beta^{(p)}) \\ \beta_j^{(t)} &\sim N(\mu_\beta^{(t)}, \tau_\beta^{(t)})\end{aligned}$$

This allowed for variation in treatment effect within each class, due to factors not explicitly modeled here. All measurement instruments shared the same study arm treatment effect in our model, but the effect was scaled by the standard deviation of the outcome variable.

The age of subjects in each study arm was included in the model as a categorical covariate, broadly grouped into either pre-kindergarten, pre-teen child or teenage categories. The pre-teen child was used as the baseline value because it was the most prevalent among studies. The age covariate was combined additively with the intervention component effects and control/treatment-as-usual means to model the observed treatment differences relative to baseline. Though we considered age-by-treatment interactions, there was not enough balance among the age and treatment combinations to include them in the final model. We also considered including the study age distribution as a covariate, but this was ultimately left out of the final model based on poor deviance information criterion (DIC) scores.

Outcome means, treatment effects and the age covariate were combined to calculate expected response (treatment difference) in an additive linear model.

$$\theta_i = m_{[i]k} + X_i\beta + \alpha X_{age}$$

The likelihood of the observed differences was specified as a Gaussian distribution, with the observed standard error of the treatment effect (the sum of the baseline and EOT standard deviations) as the standard deviation of the estimates.

$$d_i \sim N(\theta_i, \hat{\sigma}_i^2)$$

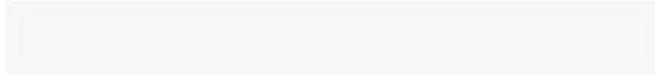
All unknown parameters were given weakly-informative prior distributions and estimated using Markov chain Monte Carlo (MCMC, Brooks et al. 2011) methods via the PyMC 2.3 software package (Patil et al. 2010). The model was run for 100,000 iterations, with the first 90,000 samples conservatively discarded as burn-in, leaving 10,000 for inference.

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Appendix E. Outcome Measures Used in the Meta-analysis of Intervention Effects

The Bayesian multivariate, mixed treatment (network) meta-analysis used data from a subset of RCTs identified as addressing KQ1 that measured parent-reported child disruptive behavior using one of the following outcome measures: 1) ECBI Intensity subscale; 2) ECBI Problem subscale; 3) CBCL externalizing subscale reported as a T-score. These three measures were the most prevalent in the literature.

The Eyberg Child Behavior Inventory (ECBI)^{1,2} is an inventory used in the assessment of disruptive behaviors in children ages 2 through 16 that occur in the home and in school. The ECBI is completed by parents and assesses behaviors on two scales: an Intensity Scale, which indicates how often the behaviors occur, and a Problem Scale, which identifies the specific behaviors that are cause problems for the parent. The Intensity Scale uses a frequency of occurrence rating: from *Never* (1) to *Always* (7). The sum of the Intensity Scale item ratings ranges from 36 to 252. The Problem Scale consists of a "Yes" or "No" problem identification rating for each item. The count of the "Yes" responses yields a problem score with a range from 0 to 36. The clinical cutoffs are 127 and 11 on the Intensity and Problem scales, respectively.

The Child Behavior Checklist (CBCL)³ is part of the Achenbach System of Empirically Based Assessments (ASEBA). The target population for the CBCL is children between the ages of 6 and 18. The pre-2001 version was intended for children ages 4 to 18 years. A version of the CBCL is also available for children ages 1 ½ to 5 years of age. The CBCL obtains reports from parents, other close relatives, and/or guardians regarding children's competencies and behavioral/emotional problems. Parents provide information for 20 competence items covering their child's activities, social relations, and school performance. The CBCL/6-18 has 118 items that describe specific behavioral and emotional problems, plus two open-ended items for reporting additional problems. Parents rate their child for how true each item is now or within the past 6 months using the following scale: 0 = not true (as far as you know); 1 = somewhat or sometimes true; 2 = very true or often true. Responses to items are aggregated to generate a total score, externalizing subscale score, internalizing subscale score, empirically-based syndrome scales, and/or DSM-oriented scales.

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Appendix F. Applicability Tables

Table F-1. Applicability of evidence psychosocial interventions

Domain	Description of applicability of evidence
Population	The population studied included children from ages 1.5 - 18 years, inclusive, and 72% male . The inclusion criteria varied from strict diagnostic criteria for a disruptive behavior disorder (typically ODD) to more vague assessments of disruptive behaviors typically operationalized as above a clinical cutoff on a well-validated parent-report measure.
Intervention	Psychosocial interventions for disruptive behaviors included interventions with a either a child, parent, or family component (single component interventions) and multicomponent interventions that included more than one of those individual components. Within each of these broad categories, individual interventions were heterogenous.
Comparators	The studies compared active treatment either to treatment as usual or to a wait list control group.
Outcomes	Parent report of child disruptive behaviors was by far the most commonly reported outcomes. The CBCL externalizing subscale, ECBI Intensity subscale, ECBI Problem subscale, and SDQ were the most commonly used parent-reported measures. Child self-report, teacher report, and direct observations of child disruptive behaviors were also reported. Measures of functional outcomes were far less common.
Setting	The vast majority of studies were in the outpatient setting and generally carried out at academic medical centers in the United States. Several studies were conducted at specialty centers including a psychiatric day treatment program and domestic violence shelter.

Table F-2. Applicability of evidence antipsychotic medications

Domain	Description of applicability of evidence
Population	The population studied included children from ages 6-17, inclusive, and 83% male . The inclusion criteria varied from strict diagnostic criteria of ODD and CD to more vague assessments of aggressive behavior “severe enough to warrant pharmacotherapy.” One study {1508} studied aggression in patients with ADHD exclusively.
Intervention	The intervention medications, Aripiprazole, Quetiapine, Risperidone and Ziprasidone are not FDA approved for treatment of disruptive behavior in children, but are used routinely in clinical practice in the US.
Comparators	Only one of the studies (5102) studied two medications head-to-head. The other studies compared the active medication to placebo.
Outcomes	The most common measures were the OAS and CGI. The OAS specifically addresses aggressive behavior symptoms and the CGI addresses improvement of symptoms compared to baseline.
Setting	The studies were all in the outpatient setting and generally carried out at academic medical centers in the US, with one (5102) at a community outpatient clinic..

Notes: Abbreviations: ADHD – Attention Deficit Hyperactivity Disorder; CD – Conduct Disorder; CGI – Clinical Global Impression; OAS – Ongoing Abuse Screen; ODD – Oppositional Defiant Disorder

Table F-3. Applicability of evidence for antiepileptic medications

Domain	Description of applicability of evidence
Population	The population studied included children from ages 6-18, inclusive, and 90% male .
Intervention	The intervention, valproic acid, is not FDA approved for disruptive behaviors in children, but is used in clinical practice in the US.

Comparators	Valproic acid compared to placebo or to low dose valproic acid.
Outcomes	The most common measures were the OAS and CGI. The OAS specifically addresses aggressive behavior symptoms and the CGI addresses improvement of symptoms compared to baseline.
Setting	The largest of the three studies (2016,N=58) analyzed patients from a correctional facility, which indicates a higher acuity of disruptive behaviors. The other studies were conducted in outpatient clinics.

Table F-4. Applicability of evidence for Non-stimulant Medications

Domain	Description of applicability of evidence
Population	The population studied included school-aged children and adolescents, ages 6-17 years, and mostly male (69%-92%). Inclusion criteria included specifically children with ADHD and co-morbid ODD based on strict diagnostic criteria of ODD/CD.
Intervention	The intervention medications include the selective norepinephrine reuptake inhibitor atomoxetine and Guanfacine extended release, a selective central alpha2A-adrenergic receptor agonist; both of which are approved for the treatment of ADHD, but are not FDA approved for treatment of disruptive behavior in children.
Comparators	All studies compared the active medication to placebo. One study (665) had three arms that compared fast to slow titration of atomoxetine with target dose in both arms of 1.2mg/kg/d..
Outcomes	Primary outcomes were the change from baseline in the Swanson, Nolan, and Pelham Rating Scale-Revised (SNAP-IV) ODD subscore, or the oppositional subscale of the Conners Parent Rating Scale-Revised: Long Form (CPRS-R: L) measured at 8-9 weeks of treatment.
Setting	The studies were all in the outpatient setting at centers in the US, Germany, and Italy.

Table F-5. Applicability of evidence for ADHD stimulant medications

Domain	Description of applicability of evidence
Population	The population studied included school-aged children and adolescents, 6-17 years; and mostly male (69-90%). Patient population had ODD symptoms based on strict diagnostic criteria; and majority also had co-morbid ADHD (66% to 79%)
Intervention	The intervention medications included methylphenidate and mixed amphetamine salts extended release (MAS XR); both of which are approved for treatment of ADHD; but are not FDA approved for disruptive behaviors in children.
Comparators	All studies compared the active medication to placebo. One study (1650) compared four different doses of MAS XR (10 mg, 20 mg, 30 mg, and 40 mg/d) to placebo.
Outcomes	Primary outcomes were the ODD subscore of the SNAP-IV and parent and teacher ratings of CD symptoms based on the Conners Teacher Rating Scale, and subscales of the Quay revised behavior problem checklist, measured after 4-5 weeks of treatment.
Setting	The two studies were conducted in the outpatient setting at centers in the US.

Appendix G. Reasons for Exclusion

Exclusion Code	Exclusion Reason	Count
X-1	Not original research	53
X-2	Does not measure the relationship between a psychosocial or pharmacologic intervention and an outcome	135
X-2a	Not an eligible study design	6
X-3	Not youth	29
X-4	No standardized disruptive behavior disorder classification or symptom assessment meeting a clinical threshold cutoff	248
X-5	Not conducted in an outpatient healthcare setting	147
X-6	Does not include an alternate treatment or control group for comparison to measure effectiveness	208
X-7	Does not report an outcome of interest for the population (youth) with disruptive behavior.	97
X-8	Does not address a Key Question	130
X-9	Duplicate	1
X-10	Unavailable	16
X-11	Older than 20 years	197
X-12	Non-english	5

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Appendix H. Pharmacologic Approval Status, Harms, and Indications

The harms data provided in this section were gathered from analyzing available gray literature (i.e. package inserts and FDA review packages). FDA approval packages were limited to those available on the FDA website that contained a “Medical Review” section of the document. Upon further analysis, approval packages that did not assess pediatric safety data were not included. Table 1 includes the pediatric indication for medications referenced in the clinical studies included in this review. Medications that have not been approved as safe and effective in pediatric patients; therefore are only FDA approved in adults are referenced in Table 2. Notable boxed warnings, contraindications, and warnings/precautions that would be relevant to consider in the pediatric population were included. As a result, the data provided in this chart is not an all-inclusive list of these package insert sections. For complete data please see the corresponding package insert.

Updated: September 28, 2014

Table H-1: FDA Approved Pediatric Medications Included in Literature Review

Drug	FDA Approved Pediatric Indication	Boxed Warning	Contraindications	Warnings/ Precautions
Guanfacine ²	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications	---	---	<ul style="list-style-type: none"> ● Dose-dependent decreases in blood pressure and heart rate. ● Somnolence and sedation
Divalproex sodium ³	<ul style="list-style-type: none"> ● Treatment of manic episodes associated with bipolar disorder ● Monotherapy and adjunctive therapy of 	<ul style="list-style-type: none"> ● Hepatotoxicity, including fatalities, usually during the first 6 months of treatment. Children under the 	<ul style="list-style-type: none"> ● Hepatic disease or significant hepatic dysfunction, ● Known mitochondrial disorders caused by mutations in mitochondrial DNA polymerase 	<ul style="list-style-type: none"> ● Suicidal behavior or ideation ● Thrombocytopenia; monitor platelet counts and coagulation test. ● Hyperammonemia and hyperammonemic encephalopathy; measure ammonia level if unexplained lethargy and vomiting or changes in mental status, and also with concomitant topiramate use; consider discontinuation of therapy. ● Hypothermia

Drug	FDA Approved Pediatric Indication	Boxed Warning	Contraindications	Warnings/ Precautions
	<p>complex partial seizures and simple and complex absence seizures; adjunctive therapy in patients with multiple seizure types that include absence seizures</p> <ul style="list-style-type: none"> ● Prophylaxis of migraine headaches 	<p>age of two years and patients with mitochondrial disorders are at higher risk.</p> <ul style="list-style-type: none"> ● Pancreatitis, including fatal hemorrhagic cases. 	<p>γ (POLG),</p> <ul style="list-style-type: none"> ● Suspected POLG-related disorder in children under two years of age, ● Urea cycle disorders. 	
Aripiprazole ⁴	<ul style="list-style-type: none"> ● Treatment of schizophrenia : Adolescents (ages 13-17) ● Acute treatment of manic or mixed episodes associated with bipolar I disorder as monotherapy and as an adjunct to lithium or valproate: Pediatric Patients (ages 10-17) ● Treatment of irritability associated with autistic disorder: Pediatric Patients (ages 6-17 years) 	<ul style="list-style-type: none"> ● Children, adolescents, and young adults are at increased risk of suicidal thinking and behavior when taking this medication. 	---	<ul style="list-style-type: none"> ● Neuroleptic Malignant Syndrome: Manage with immediate discontinuation and close monitoring. ● Tardive Dyskinesia: Discontinue if clinically appropriate. ● Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that include hyperglycemia/diabetes mellitus, dyslipidemia, and body weight gain ● Orthostatic Hypotension: Use with caution in patients with known cardiovascular or cerebrovascular disease ● Leukopenia, Neutropenia, and Agranulocytosis: Patients with a history of a clinically significant low white blood cell count (WBC) or a drug-induced leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and discontinuation of aripiprazole should be considered at the first sign of a clinically significant decline in WBC in the absence of other causative factors. ● Seizures/Convulsions: Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold. ● Potential for Cognitive and Motor Impairment: Use caution when operating machinery. ● Suicide: The possibility of a suicide attempt is inherent in schizophrenia and bipolar disorder.

Drug	FDA Approved Pediatric Indication	Boxed Warning	Contraindications	Warnings/ Precautions
Atomoxetine ⁵	Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD)	Increased risk of suicidal ideation in children or adolescents	<ul style="list-style-type: none"> ● Atomoxetine use within 2 weeks after discontinuing MAOI or other drugs that affect brain monoamine concentrations. ● Pheochromocytoma or history thereof ● Severe Cardiovascular Disorders that might deteriorate with clinically important increases in HR and BP. 	<ul style="list-style-type: none"> ● Severe Liver Injury – Should be discontinued and not restarted in patients with jaundice or laboratory evidence of liver injury. ● Serious Cardiovascular Events – Sudden death, stroke and myocardial infarction have been reported in association with atomoxetine treatment. Patients should have a careful history and physical exam to assess for presence of cardiovascular disease. Atomoxetine generally should not be used in children or adolescents with known serious structural cardiac abnormalities, cardiomyopathy, serious heart rhythm abnormalities, or other serious cardiac problems that may place them at increased vulnerability to its noradrenergic effects. ● Emergent Cardiovascular Symptoms – Patients should undergo prompt cardiac evaluation. ● Effects on Blood Pressure and Heart Rate – Increase in blood pressure and heart rate; orthostasis and syncope may occur. Use with caution in patients with hypertension, tachycardia, or cardiovascular or cerebrovascular disease. ● Emergent Psychotic or Manic Symptoms – Consider discontinuing treatment if such new symptoms occur. ● Bipolar Disorder – Screen patients to avoid possible induction of a mixed/manic episode. ● Aggressive behavior or hostility should be monitored. ● Effects on Urine Outflow – Urinary hesitancy and retention may occur. ● Priapism – Prompt medical attention is required in the event of suspected priapism. ● Growth – Height and weight should be monitored in pediatric patients. ● Concomitant Use of Potent CYP2D6 Inhibitors or Use in patients known to be CYP2D6 PMs – Dose adjustment of atomoxetine may be necessary.
Amphetamine-Dextroamphetamine ⁶	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) and Narcolepsy	<ul style="list-style-type: none"> ● Administration of amphetamine for prolonged periods of time may 	<ul style="list-style-type: none"> ● Advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe 	<ul style="list-style-type: none"> ● Serious Cardiovascular Events: Sudden Death and Pre Existing Structural Cardiac Abnormalities or Other Serious Heart Problems <ul style="list-style-type: none"> ○ Sudden death has been reported in association with CNS stimulant treatment at usual doses in children

Drug	FDA Approved Pediatric Indication	Boxed Warning	Contraindications	Warnings/ Precautions
		<p>lead to drug dependence due to the high risk of abuse and must be avoided</p> <ul style="list-style-type: none"> ● Misuse of amphetamine may cause sudden death and serious cardiovascular adverse events. 	<p>hypertension, hyperthyroidism, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, glaucoma.</p> <ul style="list-style-type: none"> ● Agitated states. ● Patients with a history of drug abuse. ● During or within 14 days following the administration of monoamine oxidase inhibitors (hypertensive crises may result). 	<p>and adolescents with structural cardiac abnormalities or other serious heart problems.</p> <ul style="list-style-type: none"> ○ Hypertension and Other Cardiovascular Conditions: Stimulant medications cause a modest increase in average blood pressure (about 2-4 mmHg) and average heart rate (about 3-6 bpm), and individuals may have larger increases. ○ Assessing Cardiovascular Status in Patients being Treated with Stimulant Medications: Children, adolescents, or adults who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such disease (e.g., electrocardiogram and echocardiogram). ● Psychiatric Adverse Events <ul style="list-style-type: none"> ○ Preexisting Psychosis: Administration of stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder. ○ Bipolar Disorder: Particular care should be taken in using stimulants to treat ADHD in patients with comorbid bipolar disorder because of concern for possible induction of a mixed/manic episode in such patients. ○ Emergence of New Psychotic or Manic Symptoms: Treatment emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or mania in children and adolescents without a prior history of psychotic illness or mania can be caused by stimulants at usual doses. ○ Aggression: Aggressive behavior or hostility is often observed in children and adolescents with ADHD, and has been reported in clinical trials and the post-marketing experience of some medications indicated for the treatment of ADHD. ○ Long-Term Suppression of Growth:

Drug	FDA Approved Pediatric Indication	Boxed Warning	Contraindications	Warnings/ Precautions
				<p>Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or non-medication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of growth rebound during this period of development.</p> <ul style="list-style-type: none"> ○ Seizures: there is some clinical evidence that stimulants may lower the convulsive threshold in patients with prior history of seizures, in patients with prior EEG abnormalities in absence of seizures, and, very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. ○ Visual disturbances: Difficulties with accommodation and blurring of vision have been reported with stimulant treatment. ● Should be used with caution in patients who use other sympathomimetic drugs. ● Amphetamines have been reported to exacerbate motor and phonic tics and Tourette’s syndrome. ● Amphetamines may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or vehicles; the patient should therefore be cautioned accordingly.
Methylphenidate ⁷	Attention Deficit Disorders (previously known as Minimal Brain Dysfunction in Children). Other terms being used to describe	---	<ul style="list-style-type: none"> ● Marked anxiety, tension, and agitation since the drug may aggravate these symptoms. ● Glaucoma ● Motor tics or with a family history or 	<ul style="list-style-type: none"> ● Serious Cardiovascular Events: <ul style="list-style-type: none"> ○ Sudden Death and Preexisting Structural Cardiac Abnormalities or Other Serious Heart Problems - Sudden death has been reported in association with CNS stimulant treatment at usual doses in children and adolescents with structural cardiac abnormalities or other serious heart problems.

Drug	FDA Approved Pediatric Indication	Boxed Warning	Contraindications	Warnings/ Precautions
	<p>the behavioral syndrome below include: Hyperkinetic Child Syndrome, Minimal Brain Damage, Minimal Cerebral Dysfunction, Minor Cerebral Dysfunction.</p>		<p>diagnosis of Tourette’s syndrome.</p> <ul style="list-style-type: none"> ● Treatment with monoamine oxidase inhibitors, and also within a minimum of 14 days following discontinuation of a monoamine oxidase inhibitor (hypertensive crises may result). 	<ul style="list-style-type: none"> ○ Hypertension and Other Cardiovascular Conditions Stimulant medications cause a modest increase in average blood pressure (about 2-4 mmHg) and average heart rate (about 3-6 bpm), and individuals may have larger increases. ○ Assessing Cardiovascular Status in Patients being Treated with Stimulant Medications Children, adolescents, or adults who are being considered for treatment with stimulant medications should have a careful history (including assessment for a family history of sudden death or ventricular arrhythmia) and physical exam to assess for the presence of cardiac disease, and should receive further cardiac evaluation if findings suggest such disease (e.g., electrocardiogram and echocardiogram). ● Psychiatric Adverse Events <ul style="list-style-type: none"> ○ Pre-existing Psychosis: Administration of stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychotic disorder. ○ Bipolar Disorder: Particular care should be taken in using stimulants to treat ADHD in patients with comorbid bipolar disorder because of concern for possible induction of a mixed/ manic episode in such patients. ○ Emergence of New Psychotic or Manic Symptoms: Treatment emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or mania in children and adolescents without a prior history of psychotic illness or mania can be caused by stimulants at usual doses. ○ Aggression: Aggressive behavior or hostility is often observed in children and adolescents with ADHD, and has been reported in clinical trials and the post-marketing experience of some medications indicated for the treatment of ADHD. ● Long-term suppression of growth: Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or non-medication

Drug	FDA Approved Pediatric Indication	Boxed Warning	Contraindications	Warnings/ Precautions
				<p>treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and non-medication treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate (on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of growth rebound during this period of development.</p> <ul style="list-style-type: none"> ● Seizures: There is some clinical evidence that stimulants may lower the convulsive threshold in patients with prior history of seizures, in patients with prior EEG abnormalities in absence of seizures, and, very rarely, in patients without a history of seizures and no prior EEG evidence of seizures. ● Priapism: Prolonged and painful erections, sometimes requiring surgical intervention, have been reported with methylphenidate products in both pediatric and adult patients. ● Peripheral Vasculopathy, Including Raynaud’s Phenomenon: Stimulants, including methylphenidate, used to treat ADHD are associated with peripheral vasculopathy, including Raynaud’s phenomenon. ● Visual Disturbance: Difficulties with accommodation and blurring of vision have been reported with stimulant treatment. ● Use in Children Under Six Years of Age: should not be used in children under 6 years, since safety and efficacy in this age group have not been established. ● Drug Dependence methylphenidate should be given cautiously to patients with a history of drug dependence or alcoholism. Chronic abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during withdrawal from abusive use, since severe depression may occur. Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder that may require

Drug	FDA Approved Pediatric Indication	Boxed Warning	Contraindications	Warnings/ Precautions
				<p>follow-up.</p> <ul style="list-style-type: none"> ● Patients with an element of agitation may react adversely; discontinue therapy if necessary. ● Periodic CBC, differential, and platelet counts are advised during prolonged therapy. ● Drug treatment is not indicated in all cases of this behavioral syndrome and should be considered only in light of the complete history and evaluation of the child. The decision to prescribe should depend on the physician's assessment of the chronicity and severity of the child's symptoms and their appropriateness for his/her age. Prescription should not depend solely on the presence of 1 or more of the behavioral characteristics. When these symptoms are associated with acute stress reactions, treatment with methylphenidate is usually not indicated.
Quetiapine ⁸	<ul style="list-style-type: none"> ● Schizophrenia ● Bipolar I disorder manic episodes ● Bipolar disorder, depressive episodes 	Suicidal Thoughts and Behaviors: Increased risk of suicidal thoughts and behavior in children, adolescents and young adults taking antidepressants.	---	<ul style="list-style-type: none"> ● Neuroleptic Malignant Syndrome (NMS): Manage with immediate discontinuation and close monitoring ● Metabolic Changes: Atypical antipsychotics have been associated with metabolic changes. These metabolic changes include hyperglycemia, dyslipidemia, and weight gain. ● Tardive Dyskinesia: Discontinue if clinically appropriate. ● Hypotension: Use with caution in patients with known cardiovascular or cerebrovascular disease. ● Increased Blood Pressure in Children and Adolescents: Monitor blood pressure at the beginning of, and periodically during treatment in children and adolescents ● Leukopenia, Neutropenia and Agranulocytosis: Monitor complete blood count frequently during the first few months of treatment in patients with a preexisting low white cell count or a history of leukopenia/neutropenia and discontinue at the first sign of a decline in WBC in absence of other causative factors. ● Cataracts: Lens changes have been observed in patients during long-term quetiapine treatment. Lens examination is recommended when starting treatment and at 6-month intervals during chronic

Drug	FDA Approved Pediatric Indication	Boxed Warning	Contraindications	Warnings/ Precautions
				<p>treatment.</p> <ul style="list-style-type: none"> ● Hypothyroidism: In controlled trials in children and adolescent patients with schizophrenia or bipolar mania, the incidence of shifts for thyroid function values at any time for quetiapine treated patients and placebo-treated patients for elevated TSH was 2.9% (8/280) vs. 0.7% (1/138), respectively and for decreased total thyroxine was 2.8% (8/289) vs. 0% (0/145, respectively). ● Hyperprolactinemia: In controlled trials in children and adolescent patients with bipolar mania or schizophrenia, the incidence of shifts in prolactin levels to a value (>20 µg/L males; > 26 µg/L females at any time) was 13.4% (18/134) for quetiapine compared to 4% (3/75) for placebo in males and 8.7% (9/104) for quetiapine compared to 0% (0/39) for placebo in females. ● Potential for Cognitive and Motor Impairment - Since quetiapine has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about performing activities requiring mental alertness.
Risperidone ⁹	<ul style="list-style-type: none"> ● Treatment of schizophrenia a. Efficacy was established in 2 short-term trials in adolescents (ages 13 to 17 years) ● Treatment (monotherapy) of acute manic or mixed episodes associated with Bipolar I Disorder. Efficacy was established in one short-term trial in children and 	---	---	<ul style="list-style-type: none"> ● Neuroleptic Malignant Syndrome: Manage with immediate discontinuation and close monitoring. ● Tardive dyskinesia: Consider discontinuing if clinically indicated. ● Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/ cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and weight gain. ● Hyperprolactinemia: Prolactin elevations occur and persist during chronic administration. ● Orthostatic hypotension: For patients at risk, consider a lower starting dose and slower titration. ● Leukopenia, Neutropenia, and Agranulocytosis: Perform complete blood counts in patients with a history of clinically significant low white blood cell count (WBC). Consider discontinuing if a clinically significant decline in WBC occurs in the absence of other causative factors.

Drug	FDA Approved Pediatric Indication	Boxed Warning	Contraindications	Warnings/ Precautions
	adolescents (ages 10 to 17 years) <ul style="list-style-type: none"> • Treatment of irritability associated with autistic disorder, including symptoms of aggression towards others, deliberate self-injuriousness, temper tantrums, and quickly changing moods. Efficacy was established in 3 short-term trials in children and adolescents (ages 5 to 17 years) 			<ul style="list-style-type: none"> • Potential for cognitive and motor impairment: Use caution when operating machinery. • Seizures: Use cautiously in patients with a history of seizures or with conditions that lower the seizure threshold.

Table H-2: FDA Approved Adult Medications (Prescribed OfG- Label in Pediatric Patients) Included in Literature Review

Drug	FDA Approved Adult Indication	Boxed Warning	Contraindications	Warnings/ Precautions
Ziprasidone ¹⁰	<ul style="list-style-type: none"> • Treatment of schizophrenia. • Acute treatment as monotherapy of manic or mixed episodes associated with bipolar I disorder • Maintenance treatment of bipolar I 	---	<ul style="list-style-type: none"> • Do not use in patients with a known history of QT prolongation. • Do not use in patients with recent acute myocardial infarction • Do not use in patients with uncompensated heart failure 	<ul style="list-style-type: none"> • QT Interval Prolongation: should be avoided in patients with bradycardia, hypokalemia or hypomagnesemia, congenital prolongation of the QT interval, or in combination with other drugs that have demonstrated QT prolongation • Neuroleptic Malignant Syndrome (NMS): Potentially fatal symptom complex has been reported with antipsychotic drugs. Manage with immediate discontinuation of drug and close monitoring. • Tardive Dyskinesia - May develop acutely

Drug	FDA Approved Adult Indication	Boxed Warning	Contraindications	Warnings/ Precautions
	<p>disorder as an adjunct to lithium or valproate.</p> <ul style="list-style-type: none"> ● Acute treatment of agitation in schizophrenic patients. 		<ul style="list-style-type: none"> ● Do not use in combination with other drugs that have demonstrated QT prolongation. 	<p>or chronically</p> <ul style="list-style-type: none"> ● Metabolic Changes: Atypical antipsychotic drugs have been associated with metabolic changes that may increase cardiovascular/cerebrovascular risk. These metabolic changes include hyperglycemia, dyslipidemia, and weight gain. ● Rash: Discontinue in patients who develop a rash without an identified cause ● Orthostatic Hypotension: Use with caution in patients with known cardiovascular or cerebrovascular disease ● Leukopenia, Neutropenia, and Agranulocytosis has been reported with antipsychotics. Patients with a pre-existing low white blood cell count (WBC) or a history of leukopenia/neutropenia should have their complete blood count (CBC) monitored frequently during the first few months of therapy and should discontinue at the first sign of a decline in WBC in the absence of other causative factors. ● Seizures: Use cautiously in patients with a history of seizures or with conditions that lower seizure threshold ● Potential for Cognitive and Motor impairment: Patients should use caution when operating machinery ● Suicide Closely supervise high-risk patients

Table H-3: Serious Adverse Events Reported Across Medications*

	Guanfacine	Divalproex	Aripiprazole	Atomoxetine	Amphetamine / Dextroamphetamine	Methylphenidate	Quetiapine	Risperidone	Ziprasidone
Suicide attempt			•					•	•
Suicidal ideation			•	•					
QT prolongation	•			•			•	•	•
Death	•			•	•	•		•	
Stroke				•	•				
Myocardial Infarction	•			•	•				•
Orthostatic hypotension	•		•					•	•
Angioedema			•	•	•			•	•
Cardiac arrest	•								
Neuroleptic malignant syndrome			•			•	•	•	•
Steven-Johnson syndrome					•		•		
Mania/hypomania	•				•	•		•	•
Extrapyramidal symptoms/disorder			•				•	•	•
Tardive dyskinesia		•	•				•	•	•
Abnormal LFTs				•					
Respiratory system disorders								•	•
Pancreatitis		•					•	•	

	Guanfacine	Divalproex	Aripiprazole	Atomoxetine	Amphetamine / Dextroamphetamine	Methylphenidate	Quetiapine	Risperidone	Ziprasidone
Seizures/convulsions	•		•	•	•	•		•	•
Syncope	•			•			•		•

*These events were gathered from all available harms data including: clinical trial data and post-marketing experience

Table H-4: Selected Adverse Events Observed Across Medications*

	Guanfacine	Divalproex Sodium	Aripiprazole	Atomoxetine	Amphetamine-Dextroamphetamine	Methylphenidate	Quetiapine	Risperidone	Ziprasidone
Somnolence	•	•	•	•			•	•	•
Weight Loss		•		•	•	•			
Weight Gain	•	•	•				•	•	•
Tachycardia	•	•		•	•	•	•		•
Decrease alkaline phosphatase				•					
Hyperprolactinemia							•	•	
Aggression	•		•	•	•	•	•		
Hypotension	•	•					•	•	

	Guanfacine	Divalproex Sodium	Aripiprazole	Atomoxetine	Amphetamine-Dextroamphetamine	Methylphenidate	Quetiapine	Risperidone	Ziprasidone
Hypertension	•	•		•	•	•			
Decreased heart rate	•								
Increased heart rate				•	•	•	•	•	
Dyslipidemia			•				•	•	•
Hyperglycemia			•				•	•	•
Leukopenia			•	•		•	•	•	•
Neutropenia			•				•	•	•

*These events were gathered from all available harms data including: clinical trial data and post-marketing experience

References:

1. Prozac [package insert]. Indianapolis, IN: Eli Lilly and Company; 2014.
2. Intuniv [package insert]. Wayne, PA: Shire US Inc.; 2013.
3. Depakote [package insert]. North Chicago, IL: AbbVie Inc.; July 2013.
4. Abilify [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; 2013.
5. Strattera [package insert]. Indianapolis, IN: Eli Lilly and Company; 2014.
6. Adderall [package insert]. Pomona, NY: Barr Laboratories; 2007.
7. Ritalin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2013.
8. Seroquel [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2013.
9. Risperdal [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; 2014.
10. Geodon [package insert]. New York, NY: Pfizer; October 2012.
11. Prozac Medical Review - Pediatric Indication. Silver Spring, MD: Food and Drug Administration Center for Drug Evaluation and Research; 2003.

12. Intuniv Medical Review - Original Approval. Silver Spring, MD: Food and Drug Administration Center for Drug Evaluation and Research; 2009.
13. Abilify Medical Review - Schizophrenia in Pediatric Patients. Silver Spring, MD: Food and Drug Administration Center for Drug Evaluation and Research; 2007.
14. Strattera Medical Review - Original Approval. Silver Spring, MD: Food and Drug Administration Center for Drug Evaluation and Research; 2002.
15. Seroquel Medical Review - QT Prolongation Review. Silver Spring, MD: Food and Drug Administration Center for Drug Evaluation and Research; 2011.
16. Risperdal Medical Review - Pediatric Approval. Silver Spring, MD: Food and Drug Administration Center for Drug Evaluation and Research; 2007.

Table H-5 Pharmacologic agents considered for DBD review

Drug Class		
Individual agent (proprietary name)		
Alpha-agonists <ul style="list-style-type: none"> • Clonidine • Guanfacine (Intuniv®) 	First-generation antipsychotics <ul style="list-style-type: none"> • Chlorpromazine • Fluphenazine • Haloperidol • Loxapine • Perphenazine • Prochlorperazine • Thiothixene • Thioridazine • Trifluoperazine 	Selective serotonin reuptake inhibitors (SSRI) <ul style="list-style-type: none"> • Fluoxetine • Sertraline • Citalopram • Escitalopram • Paroxetine • Fluvoxamine
Anticonvulsants <ul style="list-style-type: none"> • Carbamazepine (Tegretol®) • Oxcarbazepine (Trileptal®) • Divalproex sodium (Depakote®) • Lamotrigine (Lamictal®) • Valproate/ Valproic acid 	Second-generation (atypical) antipsychotics <ul style="list-style-type: none"> • Aripiprazole (Abilify®) • Asenapine (Saphris®) • Clozapine (Clozaril®) • Iloperidone (Fanapt®) • Lurasidone (Latuda®) • Olanzapine (Zyprexa®) • Olanzapine/Fluoxetine (Symbyax®) • Paliperidone (Invega®) • Quetiapine (Seroquel®) • Risperidone (Risperdal®) • Ziprasidone (Geodon®) 	Other (e.g., antihistamines, benzodiazepines, mood stabilizers, non-SSRI antidepressants) <ul style="list-style-type: none"> • Lithium • Atomoxetine (Strattera®) • Naltrexone • Hydroxyzine • Clonazepam (Klonopin®) • Levetiracetam (Keppra®) • Lorazepam (Ativan®) • Bupropion
Beta-blockers <ul style="list-style-type: none"> • Propranolol • Metoprolol • Pindolol • Nadolol 		
Central nervous system (CNS) stimulants <ul style="list-style-type: none"> • Amphetamine-Dextroamphetamine (Adderall®) • Methylphenidate (Ritalin®) • Lisdexamfetamine (Vyvanse®) 		

Table H-6. FDA approval status for drugs included in the DBD review

Generic Name (Trade Name)	Indications	Age Group for Which Approved
Amphetamine Salts (Adderall)	Attention Deficit Hyperactivity Disorder (ADHD)	Children (3 +)
	Narcolepsy	Children (6 +)

Aripiprazole (Abilify)	Schizophrenia	Adults and adolescents (13–17 years)
	Bipolar disorder (manic/mixed) monotherapy or adjunctive to lithium or valproate	Adults and children (10–17 years)
	Adjunctive treatment of major depressive disorder	Adults
	Irritability Associated with autistic disorder	Children (6–17 years)
	Acute treatment of agitation	Adults
Atomoxetine (Strattera)	Attention Deficit Hyperactivity Disorder (ADHD)	Adults and children (6-18)
Divalproex (Depakote)	Bipolar Disorder (manic episodes)	Adults and children (10 +)
	Seizures	
	Migraine Headaches	
Guanfacine (Intuniv)	Attention Deficit Hyperactivity Disorder (ADHD) and adjunctive therapy to stimulant medications	Children and adolescents (6-17)
Methylphenidate (Ritalin)	Attention Deficit Disorders (ADD)	Children and adults (6 + years)
Quetiapine (Seroquel)	Schizophrenia	Adults and adolescents (13–17 years)
	Bipolar disorder (acute manic)	Adults, children, and adolescents (10–17 years)
	Bipolar disorder (depression)	Adults
	Bipolar disorder (maintenance)	
	Adjunctive therapy for major depressive disorder	
Risperidone (Risperdal)	Schizophrenia	Adults and adolescents (13–17 years)
	Bipolar disorder (manic/mixed)	Adults and adolescents (10–17 years)
	Irritability associated with autism	Children (5–16 years)
Valproate/Valproic Acid (Depacon)	Epilepsy	Children and adults (10 + years)
Ziprasidone (Geodon)	Schizophrenia	Adults

	Bipolar disorder (manic/mixed)	
	Bipolar disorder (maintenance)	
	Acute agitation in patients with schizophrenia	