

# Medical Therapies for Children With Autism Spectrum Disorder – An Update



## **Medical Therapies for Children With Autism Spectrum Disorder—An Update**

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**None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.**

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The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of systematic reviews to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. These reviews provide comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies.

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## Key Informants

In designing the study questions, the EPC consulted several Key Informants who represent the end-users of research. The EPC sought the Key Informant input on the priority areas for research and synthesis. Key Informants are not involved in the analysis of the evidence or the writing of the report. Therefore, in the end, study questions, design, methodological approaches, and/or conclusions do not necessarily represent the views of individual Key Informants.

Key Informants must disclose any financial conflicts of interest greater than \$10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any conflicts of interest.

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In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

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## Peer Reviewers

Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

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# Medical Therapies for Children With Autism Spectrum Disorder—An Update

## Structured Abstract

**Objectives.** To evaluate the comparative effectiveness and safety of medical interventions (defined broadly as interventions involving the administration of external substances to the body or use of external nonbehavioral procedures to treat symptoms of autism spectrum disorder [ASD]) for children with ASD.

**Data sources.** We searched MEDLINE<sup>®</sup>, Embase<sup>®</sup>, the Cumulative Index of Nursing and Allied Health Literature, and PsycINFO<sup>®</sup> from January 2010 through September 2016.

**Review methods.** We included comparative studies of medical interventions that included at least 10 children with ASD. Two investigators independently screened studies and rated risk of bias. We extracted and summarized data qualitatively given significant heterogeneity. We also assessed strength of the evidence (SOE) and considered cumulative data from eligible studies included in our 2011 review of medical therapies and newly published studies.

**Results.** The 76 unique comparative studies (including 12 comparative studies addressed in the 2011 review) meeting our criteria included 72 randomized controlled trials (RCTs), 2 nonrandomized trials, and 2 retrospective cohort studies. Thirty-nine studies had low, 29 had moderate, and 8 had high risk of bias. Populations, treatment approaches, and outcomes assessed varied across studies. Relative to placebo, seven studies addressing risperidone or aripiprazole reported statistically significant improvements in challenging behavior in the short term (<6 months) but also clinically significant harms. Longer term effectiveness was reported in uncontrolled extensions. Three studies comparing risperidone and aripiprazole reported few significant differences in effects on weight gain between agents. RCTs addressing methylphenidate (n=2), atomoxetine (n=2), and guanfacine (n=1) reported significant improvements in hyperactivity, with frequent harms. Omega-3 fatty acids (4 RCTs) were not associated with changes in challenging behavior. N-acetylcysteine and tetrahydrobiopterin were not associated with improvements in social skills and symptom severity, respectively. Despite the number of RCTs with low or moderate risk of bias addressing nutritional supplements or specialized diets, evidence is insufficient for all clinical efficacy and harms outcomes because few, small studies addressed each diet or supplement. Similarly, although 14 RCTs with low or moderate risk of bias compared risperidone plus an adjunct medication with risperidone plus placebo, few addressed the same adjunct agents. Studies of hyperbaric oxygen therapy versus sham treatment using differing protocols reported conflicting results. Fourteen studies addressed other interventions, most evaluated in only one study, and typically reported some positive treatment effects on sleep, ASD symptoms, or language.

**Conclusions.** Risperidone and aripiprazole ameliorated challenging behaviors in the short term, but with clinically significant side effects (high SOE). Methylphenidate and atomoxetine were also associated with improvements in hyperactivity in small short-term RCTs (low SOE), with improvements maintained over 6 months for atomoxetine (low SOE for longer term effects). Methylphenidate was associated with clinically significant harms (low SOE), while atomoxetine



was associated with clinically moderate harms (low SOE). Omega-3 fatty acid supplementation, N-acetylcysteine, and tetrahydrobiopterin failed to show benefits (low SOE). Evidence for other interventions and outcomes studied was insufficient. While the conduct of studies has improved considerably over time (i.e., growing number of RCTs and use of standardized measures), data on longer term ( $\geq 6$  months) results and harms of most interventions are lacking. Similarly, more research is needed to understand characteristics of the child or treatment that modify outcomes, whether effectiveness of interventions generalizes across different settings such as the home or school, and how components of interventions may drive effects.

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# Executive Summary

## Introduction

Autism spectrum disorder (ASD) is a neurodevelopmental disorder broadly defined by impaired social communication as well as restricted or repetitive patterns of behavior and interest. As defined by the *Diagnostic and Statistical Manual of Mental Disorders*, Fifth edition (DSM-5), specific features of ASD include deficits in social and emotional reciprocity (e.g., atypical social approaches, conversational impairment, atypical sharing of interests, attention, and affect); deficits in nonverbal communication (e.g., poorly integrated verbal and nonverbal communication, atypical body-language and gesture use, deficits in use and understanding of nonverbal communication), and deficits in maintaining appropriate relationships (e.g., challenges with peer interest, vulnerabilities forming friendships, difficulties adjusting behavior to suit social contexts) as well as restricted and repetitive patterns of behavior such as stereotyped speech, motor movements, or use of objects; excessive adherence to routine or insistence on sameness; intense interest patterns; and atypical sensory interests or responses. Symptoms of the disorder impair and limit everyday functioning and are thought to be evident in early childhood; although they may not be fully evident until later ages. Although not core symptoms, many children with ASD may also have significant cognitive and language impairments.

## Treatment of ASD

The manifestation and severity of symptoms of ASD differ widely, and treatments include a range of behavioral, psychosocial, educational, medical, and complementary approaches<sup>1-4</sup> that vary by a child's age and developmental status. The goals of treatment for ASD typically focus on improving core deficits in communication, social interactions, or restricted behaviors, as changing these fundamental deficits may help children develop greater functional skills and independence.<sup>5</sup> Treatment frequently is complicated by symptoms or comorbidities that may warrant targeted intervention. Individual goals for treatment vary for different children and may include combinations of approaches such as behavioral and medical therapies; parents may also pursue complementary and alternative medicine therapies.

The antipsychotics risperidone (Risperdal) and aripiprazole (Abilify) have been specifically approved by the U.S. Food and Drug Administration (FDA) for treatment of irritability and challenging behaviors in ASD. Many other medications are used off-label to manage behavioral symptoms such as anxiety and hyperactivity. In addition, devices such as hyperbaric oxygen chambers may be used to treat symptoms of ASD.

## Scope and Key Questions (KQs)

### Scope of the Review

This review updates findings reported in the 2011 AHRQ review *Therapies for Children with ASD*<sup>6</sup> with a focus on studies of medical interventions. We defined medical interventions broadly as interventions involving the administration of external substances to the body or use of external, nonbehavioral procedures to treat symptoms of ASD, which includes pharmacologic agents, diet therapies, vitamins and supplements, chelating agents, electroconvulsive therapy, transcranial magnetic stimulation and hyperbaric oxygen, among other modalities. We used this broad definition, developed with input from our clinical experts, in order to capture the landscape

of medically-related interventions used to treat children with ASD. A companion review updating findings related to interventions targeting sensory challenges is available on the AHRQ Effective Health Care Web site.

## **Key Questions**

We developed KQs in consultation with Key Informants and Task Order Officers. KQs were posted for review to the AHRQ Effective Health Care Web site.

KQs were as follows:

**KQ1: Among children ages 2-12 with ASD, what is the comparative effectiveness (benefits and harms) of medical treatments?**

- a. What are the effects on core symptoms (e.g., deficits in social communication and interaction; restricted, repetitive patterns of behavior, interests, or activities including hyper- or hypo- reactivity to sensory input or unusual interest in sensory aspects of the environment) in the short term (<6 months)?
- b. What are the effects on commonly associated symptoms (e.g., motor, medical, mood/anxiety, irritability, and hyperactivity) in the short term (<6 months)?
- c. What are the longer term effects ( $\geq 6$  months) on core symptoms (e.g., social deficits, communication deficits, and repetitive behaviors)?
- d. What are the longer term effects ( $\geq 6$  months) on commonly associated symptoms (e.g., motor, medical, mood/anxiety, irritability, and hyperactivity)?

**KQ2: Among children ages 2-12 with ASD, what are the modifiers of outcome for different medical treatments?**

- a. Is the effectiveness of the therapies reviewed affected by the frequency, duration, intensity, or dose of the intervention?
- b. Is the effectiveness of the therapies reviewed affected by co-interventions or prior treatment, or the training and/or experience of the individual providing the therapy?
- c. What characteristics (e.g., age, symptom severity), if any, of the child modify the effectiveness of the therapies reviewed?
- d. What characteristics, if any, of the family modify the effectiveness of the therapies reviewed?

**KQ3: What is the time to effect of medical interventions?**

KQ4: What is the evidence that effects measured at the end of the treatment phase predict long-term functional outcomes of medical interventions?

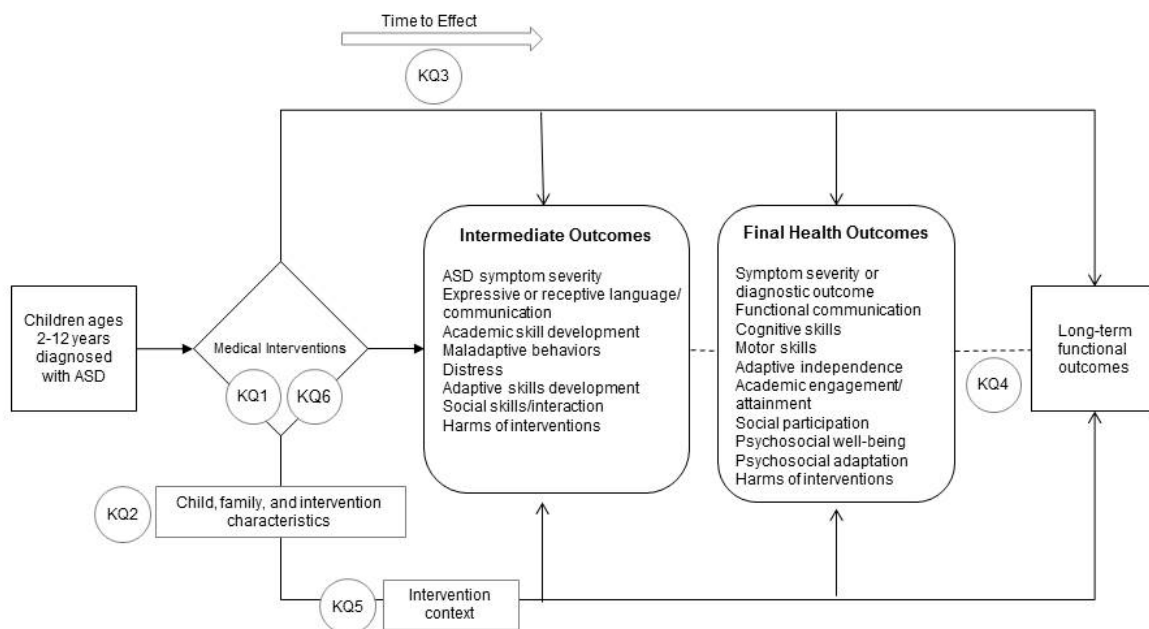
KQ5: Is the effectiveness of medical interventions maintained across environments or contexts (e.g., people, places, materials)?

KQ6: What evidence supports specific components of treatment with medical interventions as driving outcomes, either within a single treatment or across treatments?

## Analytic Framework

The analytic framework (Figure A) illustrates the population, interventions, and outcomes that guided the literature search and synthesis.

Figure A. Analytic framework



ASD=autism spectrum disorder; KQ=Key Question

## Methods

### Topic Surveillance

The topic for a 2011 report on therapies for children with ASD<sup>6</sup> was nominated by Autism Speaks in a public process using the Effective Health Care Web site. AHRQ published an update addressing behavioral interventions in 2014.<sup>7</sup> We conducted a surveillance process to assess the need to update the earlier report by contacting topic experts about the relevance of the KQs and new evidence that may address them. In consultation with clinical experts and stakeholders, and based on our preliminary scan of the literature and surveillance findings, we focused the review update on medical approaches and approaches to address sensory challenges (reported in a separate update). These areas reflect both areas of clinical relevance and sufficient newly published literature for a review update.

### Literature Search Strategy

To ensure comprehensive retrieval of relevant studies of medical therapies for children with ASD, we used four key databases: the MEDLINE<sup>®</sup> medical literature database via the PubMed<sup>®</sup> interface; EMBASE (Excerpta Medica Database); the Cumulative Index of Nursing and Allied Health Literature (CINAHL); and PsycINFO<sup>®</sup>. Search strategies applied a combination of controlled terms and key words. We last conducted searches for the review in September 2016.

We hand searched the reference lists of recent systematic reviews or meta-analyses of studies addressing therapies for ASD. The investigative team also scanned the reference lists of studies included after the full-text review phase for additional potentially relevant studies.

### Inclusion Criteria

Table A lists our inclusion criteria. We focused the review on children between 2 and 12 years of age. We chose to limit the age range to this span because a) diagnosis of ASD earlier than age 2 is less established and b) adolescents likely have substantially different challenges and would warrant different interventions than children in the preschool, elementary, and middle school age groups.

**Table A. Inclusion criteria**

Category	Criteria
Study population	Children ages 2-12 with ASD (mean age plus standard deviation is $\leq$ 12 years and 11 months)
Publication languages	English only
Admissible evidence (study design and other criteria)	Admissible designs Randomized controlled trials, prospective and retrospective cohort studies with comparison groups, and nonrandomized controlled trials  Other criteria Original research studies published from 2010—present and not addressed in prior reviews  Studies must have relevant population and $\geq$ 20 participants with ASD (non-RCTs) or at least 10 total participants (RCTs)  Studies must address one or more of the following for ASD: -Outcomes of interest -Treatment modality of interest



Category	Criteria
	-Predictors or drivers of treatment outcomes (e.g., biomarkers, clinical changes) -Maintenance of outcomes across environments or contexts -Sufficiently detailed methods and results to enable data extraction -Reporting of outcome data by target population or intervention

ASD = autism spectrum disorder; RCT = randomized controlled trial

## Study Selection

Two reviewers independently assessed each abstract and the full text of studies proceeding to full text review. A senior reviewer adjudicated disagreements in full text review .

## Data Extraction and Synthesis

Data were initially extracted by one team member and reviewed for accuracy by a second. We summarized data for KQs qualitatively using summary tables as studies were too heterogeneous to allow for meta-analyses.

## Risk-of-Bias Assessment of Individual Studies

We evaluated the overall methodologic risk of bias of individual studies using the ASD-specific assessment approach developed and used in our prior reviews of interventions for ASD and informed by the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.<sup>8</sup> Two senior investigators assessed each included study independently with disagreements resolved through discussion. Appendix D of the main report includes ratings for each study.

## Strength of the Body of Evidence

Two senior investigators graded the strength of the evidence (SOE) for key intervention/outcome pairs using methods based on the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.<sup>8</sup> We assessed the domains of study limitations (low, medium, high level of limitation), consistency (inconsistency not present, inconsistency present, unknown), directness (direct, indirect), precision (precise, imprecise), and reporting bias (detected, unsuspected). The full team reviewed the final SOE designations. The possible grades were:

- High: High confidence that the evidence reflects the true effect. Further research is unlikely to change estimates.
- Moderate: Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- Low: Low confidence that the evidence reflects the true effect. Further research is likely to change confidence in the estimate of effect and is also likely to change the estimate.
- Insufficient: Evidence is either unavailable or does not permit a conclusion.<sup>9</sup>

## Applicability

We assessed the applicability of findings reported in the included literature addressing our KQs to the general population of children with ASD by determining the population, intervention, comparator, and setting in each study and developing an overview of these elements for each intervention category. We anticipated that areas in which applicability would be especially important to describe would include ASD severity, comorbidities, age at treatment, and

intervention characteristics such provider, dosing/intensity, and setting. Applicability tables are in Appendix E of the full report.

## Results

We identified 6583 nonduplicative titles or abstracts with potential relevance, with 554 proceeding to full text review. We excluded 469 studies at full text review. We included 68 unique studies (85 publications) in the review. In addition to these 68 studies published since the completion of our original review of therapies for children with ASD in 2011, we include 12 comparative studies addressed in the 2011 review that also addressed an agent reported on in the current review. Four studies included in the 2011 review now include followup analyses published since the completion of that report; thus we describe a total of 76 studies in the review.

The 76 studies included in the review comprised 72 randomized controlled trials (RCTs), 2 nonrandomized trials, and 2 retrospective cohort studies. Studies addressed the following categories:

- **Antipsychotics:** 11 RCTs and one retrospective cohort study (n=1055 children) with low (n=7) and moderate (n=5) risk of bias.
- **Medications to treat attention deficit hyperactivity disorder (ADHD):** Five RCTs (n=265 children) with low (n=4) and moderate (n=1) risk of bias.
- **Combination medical and behavioral treatments:** Three RCTs and two nonrandomized trials (n=419 children) with low (n=2), moderate (n=1) and high (n=2) risk of bias.
- **Nutritional supplements and dietary interventions:** 19 RCTs (n=732 children) with low (n=4), moderate (n=10), and high (n=5) risk of bias.
- **Risperidone adjuncts:** 14 RCTs (n =561 children) with low (n=12) and moderate (n=2) risk of bias.
- **Hyperbaric oxygen therapy:** Three RCTs (n=150 children) with low (n=2) and moderate (n=1) risk of bias.
- **N-acetylcysteine:** Two RCTs (n=123 children) with low and moderate risk of bias.
- **Tetrahydrobiopterin:** Two RCTs (n=56 children) with low and moderate risk of bias.
- **Other interventions:** 13 RCTs and 1 retrospective cohort study (n=829 children) with low (n=6), moderate (n=7), and high (n=1) risk of bias. We categorized studies as “other” if we could not assess strength of evidence for interventions and outcomes reported (i.e., insufficient strength of evidence) and the studies did not fall under a broader category of intervention such as diet or nutritional supplements.

Overall, 39 studies had low, 29 had moderate, and 8 had high risk of bias. Despite the high number of low and moderate risk of bias studies, few studies addressed the same interventions or outcomes, and most studies included few participants, evaluated only in the short term (<6 months). Thus, evidence for many agents remains insufficient. Because few studies addressed subquestions under Key Questions (KQ) 1 and 2, we present results in the aggregate under each of these KQ.

### KQ1. Benefits and Harms of Medical Treatments

**Antipsychotics.** Studies of antipsychotics addressed either risperidone or aripiprazole and reported significant improvements in measures of challenging behavior in the short term (<6 months) in children receiving the medications compared with those receiving placebo. Harms of

these agents, including extrapyramidal symptoms and weight gain, were also clinically significant. Studies reporting longer term followup (up to 21 months for risperidone) reported continued effectiveness in most children but did not include control groups.

**Medications to treat ADHD.** RCTs of methylphenidate, atomoxetine, and guanfacine reported improvements in hyperactivity and other challenging behaviors with treatment compared with placebo. Clinically significant side effects were associated with methylphenidate including aggressive behavior and appetite changes. Harms reported with atomoxetine and guanfacine included irritability, gastrointestinal symptoms, drowsiness, and decreased appetite.

**Studies of combined medical and behavioral treatments.** In three of the five studies of combined medical and behavioral treatments, the addition of a behavioral therapy (e.g., cognitive behavioral therapy, parent training) did not increase effectiveness over medical therapy alone. In two small trials, bumetanide plus applied behavior analysis improved symptom severity more than applied behavioral analysis alone and stem cell transplantation plus rehabilitation therapy improved symptom severity, lethargy, and stereotypy more than umbilical cord blood cell transplant plus rehabilitation therapy or rehabilitation therapy alone.

**Diet and nutritional supplements.** Omega-3 fatty acid supplementation did not affect challenging behaviors and was not associated with clinically significant harms. Seven studies addressed variations of the gluten-free diet, but studies addressed different outcomes and different approaches to restricted and control diets. Similarly, a number of RCTs with low or moderate risk of bias addressed other agents, but studies were small and few addressed the same agent or outcomes.

**Risperidone adjuncts.** Study medications added to risperidone included celecoxib, minocycline, *Ginkgo biloba*, memantine, topiramate, riluzole, buspirone, N-acetylcysteine (addressed in 2 studies), amantadine, pioglitazone, pentoxifylline, galantamine, and piracetam. Most studies (12 of 14) reported improvements in irritability measured on the Aberrant Behavior Checklist (ABC) in the adjunct groups compared with placebo plus risperidone.

**Hyperbaric oxygen therapy.** Three RCTs of hyperbaric oxygen used different doses and reported inconsistent outcomes and harms.

**N-acetylcysteine.** N-acetylcysteine had no effect on social skills outcomes in two small RCTs. Harms of this agent were not clinically significant.

**Tetrahydrobiopterin.** Tetrahydrobiopterin had no effect on symptom severity and was not associated with clinically significant harms.

**Other medical interventions.** Few studies addressed the same agent or outcomes. Studies of donepezil, melatonin, bumetanide, citalopram, amantadine, divalproex, prednisolone, and transcranial stimulation reported some positive effects on outcomes including symptom severity, language, and sleep. Studies of oxytocin and mecamylamine reported no statistically significant effects. Harms reported in studies comparing these interventions were diverse, and their clinical significance is difficult to determine.

## **KQ2. Modifiers of Treatment Outcomes**

Few studies reported modifiers, and few were likely adequately powered to detect effects. In one subanalysis, higher baseline irritability was associated with greater improvement in irritability than was low severity in improvement with risperidone. Greater weight gain was associated with less irritability improvement in the risperidone group. In another study of risperidone, younger age and better communication skills were associated with greater gains in communication but not with gains in daily living skills or socialization.

Studies of stimulants identified no significant phenotypic predictors of effects (e.g., baseline cognitive skills, age, IQ), but one genetic analysis identified seven genetic variations that predicted response to methylphenidate. Modifiers reported in studies of other agents were varied and included cognitive skills, age, and symptom severity. No characteristics had consistent effects.

## **KQ3. Time to Effect of Interventions**

While several studies reported changes in the number of children responding to a given agent over time, studies typically did not provide data to determine the initiation of effects.

## **KQ4. Evidence that Effects Measured at the End of Treatment Predict Long-Term Functional Outcomes**

Few studies had longer term followup and those with more than 6 months of treatment or followup typically did not report functional outcomes. In one study, risperidone use was not associated with changes in IQ: changes from baseline to the end of study in class assignment (e.g., special education, regular classroom) were not significant.

## **KQ5. Effectiveness Across Environments or Contexts**

Seven studies reported teacher ratings of outcome measures that provide some information to address this KQ, but the limited results preclude conclusions. One RCT of omega-3 fatty acids reported no significant group differences in teacher ratings of challenging behaviors (parents also rated few measures as improved), while another RCT of docosahexaenoic acid (DHA) supplementation versus placebo reported improvement in parent-rated social skills in children receiving placebo vs. those receiving DHA, while teachers rated communication as more improved in the treatment group compared with placebo. An RCT of challenge foods introduced to a gluten-free diet reported no statistically significant changes in behavior as rated by parents or teachers on the Connors scale. An RCT of levetiracetam vs. placebo reported no significant group differences on any parent- or teacher- rated measures but also noted that teachers, but not parents, rated children in the placebo arm as more improved on irritability compared with the levetiracetam group.

RCTs of methylphenidate reported general agreement between parent and teacher ratings of hyperactivity. In one RCT, both parents and teachers considered hyperactivity and impulsive behavior to be significantly improved in the treatment group compared with placebo, but teachers (vs. parents) reported no significant group differences in inattention or oppositional behavior. Finally, one RCT of atomoxetine reported significant teacher-rated improvements in hyperactivity in the atomoxetine group compared with placebo but teacher ratings of cognitive problems/inattention, oppositional behavior, or overall ADHD symptoms did not differ between

groups. In another RCT comparing atomoxetine alone, atomoxetine + parent training, placebo alone, and placebo + parent training, parents, but not teachers, rated children in active treatment groups as significantly improved on measures of ADHD, inattention, hyperactivity, and oppositional behavior.

## **KQ6. Drivers of Treatment Outcomes**

We did not identify any studies that provided data to address this KQ.

## **Discussion**

### **State of the Literature**

We identified a total of 76 unique comparative studies, primarily (n=72) RCTs, addressing medical interventions. Most studies were small (median 40 total participants/study) and addressed variable agents. Most studies had placebo comparators, while five compared a pharmaceutical agent to behavioral treatment or combined pharmaceutical and behavioral treatment. Studies were typically of short duration (<6 months, range 4 days to 24 months), with few studies reporting longer term followup after the immediate intervention period.

The methodologic rigor of studies has increased substantially compared with those studies reported in our 2011 review of therapies for children with autism spectrum disorder (ASD).<sup>6</sup> However, while studies were generally well conducted, evidence remains insufficient for most interventions due to small sample sizes, lack of long term followup, and heterogeneous agents and populations.

Despite the number of new studies, we can make few conclusions beyond those reached in our 2011 review. Evidence supports the effectiveness of antipsychotics in improving challenging behaviors, but with significant harms. Methylphenidate also improves hyperactivity but with significant harms. Evidence is promising for the ADHD medication atomoxetine. More studies have addressed combination approaches, but data are inadequate to draw conclusions. Data were limited and inconsistent for other interventions.

### **Strength of Evidence**

#### **KQ1. Benefits and Harms of Medical Treatments**

**Antipsychotics.** Our confidence in the conclusion that risperidone and aripiprazole improve challenging behaviors in the short term (<6 months), with clinically significant harms, is high (high strength of evidence). Behaviors improved in the longer term ( $\geq 6$  months) with these agents compared with placebo, but our confidence in this conclusion is low (low strength of evidence) as only five studies had  $\geq 6$  months followup. In studies comparing risperidone and aripiprazole, BMI increased with both drugs over treatment durations of 6 months to more than 2 years, but group differences were not significant. We have low confidence that effects on BMI do not differ between agents given the few studies addressing this outcome (low strength of evidence). Other outcomes (e.g., challenging behaviors, attention) were not consistently addressed; thus we considered strength of evidence insufficient for all other intervention/outcome pairs. Table B outlines findings for all comparisons with greater than insufficient strength of evidence.

**Medications to treat ADHD.** Methylphenidate versus placebo improved hyperactivity and was associated with clinically significant harms (Table B). Our confidence in these conclusions is low as studies were small and short term (low strength of evidence). Data were inadequate to assess effects on social communication and oppositional behavior (insufficient strength of evidence). Findings for oppositional behavior were inconsistent in two studies; thus, we could not assess the strength of evidence (insufficient). We considered the evidence inadequate to comment on potential effects on social communication or oppositional behavior (insufficient strength of evidence).

We found positive effects of atomoxetine compared with placebo on hyperactivity in children with ASD and ADHD in the short term (<6 months), with effects maintained over the longer term (≥6 months) (Table B). Our confidence in this conclusion is low (low strength of evidence). Atomoxetine was associated with harms considered to be clinically moderate, and our confidence in this conclusion is low (low strength of evidence). Data were inadequate to assess effects on inattention as studies reported inconsistent findings (insufficient strength of evidence).

Data were inadequate in a small study of guanfacine to draw conclusions about effects on any outcomes (insufficient strength of evidence).

**Studies of combination medical and behavioral treatments.** Given that combination therapies were investigated in single studies, we could not make conclusions about their effects on any outcomes (insufficient strength of evidence).

**Nutritional supplements and dietary interventions.** Omega-3 fatty acid supplementation and placebo did not affect challenging behaviors. Our confidence in this conclusion is low (low strength of evidence for no effect) (Table B). We also have low confidence in the conclusion that omega-3 supplementation was associated with minimal harms (low strength of evidence).

Despite the number of RCTs with low or moderate risk of bias addressing other agents, evidence was inadequate to make conclusions about all clinical efficacy and harms outcomes because few, small, underpowered studies addressed each diet or supplement (insufficient strength of evidence). Data in two small studies of methyl-B12 were inadequate to draw conclusions (insufficient strength of evidence). While seven studies addressed variations of the gluten-free diet, studies addressed different outcomes and different approaches to restricted and control diets; thus, data were inadequate to make conclusions about the body of evidence (insufficient strength of evidence). Data were inadequate to allow conclusions about the relative effectiveness of other dietary interventions (e.g., camels' milk, challenge foods containing gluten) compared with placebo (insufficient strength of evidence).

**Risperidone adjuncts.** Data were inadequate to assess effects of risperidone plus adjunctive agents including amantadine, buspirone, celecoxib, memantine, riluzole, *Ginkgo biloba*, pioglitazone, or topiramate on any outcome assessed as no study addressed the same adjunctive agent (insufficient strength of evidence). While two RCTs addressed risperidone plus N-acetylcysteine, data are inadequate to comment on effects given the small number of participants and high attrition (insufficient SOE).

**Hyperbaric oxygen therapy.** Three RCTs of hyperbaric oxygen used different doses and reported inconsistent results. We considered SOE to be insufficient to assess effects.

**N-acetylcysteine.** N-acetylcysteine had no effect on social skills outcomes in two small RCTs; harms of this agent were not clinically significant. Our confidence in these conclusions is low (low strength of evidence) (Table B). Data were inadequate to assess effects on other outcomes given inconsistent findings in these two studies (insufficient strength of evidence).

**Tetrahydrobiopterin.** Tetrahydrobiopterin had no effect on symptom severity and was not associated with clinically significant harms. Our confidence in these conclusions is low (low strength of evidence) (Table B). Data were inadequate to assess effects on other outcomes (insufficient strength of evidence).

**Studies of other medical interventions.** Data were inadequate to make conclusions about the effects of amantadine, bumetanide, divalproex, oxytocin, mecamylamine, prednisolone, citalopram, melatonin, and neurostimulation vs. placebo as few studies addressed the same agents or outcomes (insufficient strength of evidence).

**Table B. Summary of evidence in studies addressing medical interventions for children with ASD**

Intervention and comparator	Number/Type of Studies (Total N Participants)	Key Outcome(s)	Strength of Evidence (SOE) Grade	Findings
<b>Antipsychotics</b>				
Risperidone vs. placebo	3 RCT (274)	Challenging behavior (<6 months)	High SOE	Significant improvement in treatment group vs. placebo in 3 RCTs with 6-8 week treatment phases; improvement maintained in 2 RCTs with 6 months of treatment
	3 RCT (118)	Challenging behavior (≥6 months)	Low SOE	Improvement maintained in 1 RCT with 6 months of treatment and in one open label extension with no comparison group with mean 21 months treatment duration; in another open label extension, more children relapsed with placebo vs. risperidone
	9 RCT (262) 1 Retrospective cohort (72)	Harms	High SOE for clinically significant harms associated with risperidone	Harms including weight gain, appetite changes, drowsiness, fatigue, extrapyramidal symptoms, drooling/hypersalivation, and gastrointestinal symptoms consistently reported
Aripiprazole vs. placebo	2 RCT (316)	Challenging behavior (<6 months)	High SOE	Significant improvements in 2 short-term RCTs in treatment groups
	2 RCT (415)	Challenging behavior (≥6 months)	Low SOE	In longer term followup, no differences in time to relapse of symptoms between aripiprazole and placebo groups in one 16 week RCT and continued improvements in ABC in one 52-week open label continuation with no control arm
	4 RCT (422) 1 Retrospective cohort (70)	Harms	High SOE for clinically significant harms associated with aripiprazole	Harms including weight gain, appetite changes, somnolence, extrapyramidal symptoms, drooling/hypersalivation, infection, and gastrointestinal symptoms consistently reported

Intervention and comparator	Number/Type of Studies (Total N Participants)	Key Outcome(s)	Strength of Evidence (SOE) Grade	Findings
Risperidone vs. aripirazole	1 RCT (37) 1 Retropective cohort (142)	BMI change	Low SOE for no difference in effects	BMI increased with both drugs over treatment durations of 6 months to more than 2 years, but group differences were not significant
<b>Medications to treat ADHD</b>				
MPH vs. placebo	2 RCT (90)	Hyperactivity	Low SOE	Significant improvement with MPH compared with placebo on parent and teacher-rated measures; differential effect of dose not clear (little effect on 1 study and linear effect in another); SOE is low given small sample size and lack of long-term followup
	2 RCT (90)	Oppositional behavior	Low SOE for no effect	Significant improvement with MPH on parent-rated measure at medium dose level only in 1 RCT; no differences on teacher-rated measures. No differences in teacher-, parent-, or clinician-rated measures in another RCT
	2 RCT (90)	Harms	Low SOE for association of MPH with clinically significant harms	Rates of children experiencing harms ranged from 0-75%; higher rates reported for repetitive behaviors or speech, loss of appetite, and irritability. Irritability responsible for withdrawals (n=6) in one RCT; SOE is low given small sample size
Atomoxetine vs. placebo	2 RCT (113)	Hyperactivity ( $\leq$ 3 months)	Low SOE for improvements in the short-term	Significant improvements in rating of hyperactivity in treatment group compared with placebo in both studies
	3 RCT (241)	Harms	Low SOE for clinically moderate harms associated with atomoxetine	No serious adverse events reported; most harms attenuated over open label extension phase
<b>Other agents</b>				
Omega-3 supplementation vs. placebo	3 RCT (119)	Challenging behaviors	Low SOE for no effect	No significant differences between groups in three small, short-term RCTs
		Harms	Low SOE for minimal harms	No clinically significant harms reported in any study
N-acetylcysteine vs. placebo	2 RCT (127)	Social skills	Low SOE for lack of effect	No significant effects in either small, short-term RCT
		Harms	Low SOE for minimal harms	No study reported harms considered clinically important
Tetra-hydrobiopterin vs. placebo	2 RCT (54)	Symptom severity	Low SOE for lack of effect	No significant effects in either small, short-term RCT
		Harms	Low SOE for minimal harms	No study reported harms considered clinically important

ADHD = attention deficit hyperactivity disorder; ASD = autism spectrum disorder; BMI = body mass index; MPH = methylphenidate; RCT = randomized controlled trial; SOE = strength of evidence

## Other Key Questions

Few studies reported modifying characteristics, and no characteristics were consistent modifiers. Few studies reported data to assess time to effect of interventions. Few studies had



longer-term followup and those few with 6 months or more of treatment or followup typically did not report functional outcomes; thus our understanding of whether effects at the end of treatment predict functional outcomes is limited. Four studies reported teacher ratings of outcome measures that provide some information to address effectiveness of treatments across environments or contexts, but the limited results preclude conclusions. Finally, we did not identify studies that provided data to address drivers of treatment outcomes.

## **Applicability**

Study participants were generally recruited from specialty clinical service programs and represent non–primary care populations. As such, families of these children may be seeking a higher level of care than those of the broader population of children with ASD based upon more severe or acute symptoms, including aggression or other challenging behaviors. Most studies of medical interventions targeted elementary school aged and older children with autism, with little data on the treatment of younger children. Most studies included majority male populations (consistent with the male prevalence of ASD).

Studies also included children with highly variable severity of challenging behaviors, ASD symptom severity, and cognitive impairment. Studies of pharmacological agents often sampled children with high levels of specific symptom patterns (e.g., children with severe challenging behavior at baseline where parents may be willing to pursue pharmacologic intervention and trial participation) who may not reflect the wider population of children with ASD in whom these challenges may not be present. Most of the studies reported including children with at least moderate level of severity of ASD. Studies of stimulants included children with cognitive impairment and with comorbidities including attention deficit hyperactivity disorder, oppositional defiant disorder, and obsessive compulsive disorder. Studies of other approaches had similarly heterogeneous populations. Dietary and nutritional studies included some younger children, with severity of autism not well described or the degree of intellectual functioning not well characterized in most studies. This heterogeneity in population characteristics may limit the generalizability of findings to children with differing levels of symptom expression or comorbidities but likely reflects the heterogeneity of the broader population of children with ASD.

Studies addressed a variety of agents and typically reported use of concurrent medications or other therapies. Most agents studied are accessible in the United States albeit with few receiving FDA approval for use. Comparators among nonplacebo controlled studies varied, and few studies assessed the effect of concomitant behavioral or other therapies, though many children with ASD receive multiple interventions. The treatments studied may not adequately reflect the broad range of treatment combinations used in the general population of children with ASD.

As noted, few studies evaluated longer term treatment ( $\geq 6$  months); short treatment and followup periods limit our ability to understand potential longer term outcomes such as academic achievement or longer term harms.

Overall, the heterogeneity of these studies parallels the heterogeneity of children with ASD, and some findings may be more applicable to children with specific levels of baseline severity or comorbidities. These limitations to generalizability likely reflect both the significant heterogeneity of ASD itself as well as its associated features, such as irritability. Thus, while there is a growing evidence base for treating certain symptoms in certain populations, these findings underscore the continued need for individualized treatment approaches that are informed by the emerging evidence base for benefits as well as harms of medical intervention,

with careful consideration of symptom presentation and functioning level relative to study populations and applicability of the known literature.

## **Limitations of the Comparative Effectiveness Review Process**

We included studies published in English only and did not include unpublished data. In our scan of a random sample of 150 non-English abstracts retrieved by our MEDLINE search, only two studies appeared to meet inclusion criteria; thus, given the high percentage of ineligible items in this scan (99%), we concluded that excluding non-English studies would not introduce significant bias into the review. We recognize that this preliminary scan did not address the entire corpus of ASD literature in other languages.

We also included only comparative studies of medical interventions with at least 10 children with ASD. To ensure comprehensive coverage of the literature, we included comparative studies with a smaller sample size that would have been excluded in our 2011 review (which required a sample size of 30) in the present report. We did not conduct a de novo search for such studies but re-examined the excluded studies from the prior review. This approach may have overlooked relevant studies.

Given heterogeneity in treatment regimens, outcomes addressed in each study, and patient populations, we were limited in our ability to meta-analyze findings or identify potential subgroups that may respond more favorably to specific treatments. Finally, we used a nonvalidated tool to assess risk of bias, though we note that the tool evaluates similar constructs to those assessed in tools such as that used by the Cochrane Collaboration, with the addition of ASD-specific domains.

## **Limitations of the Evidence Base**

As noted, studies in the review had small sample sizes and typically limited duration of intervention and followup after intervention, despite significant improvements in study design and execution over time. Populations across studies were heterogeneous in terms of challenging behaviors, ASD symptom severity, age, and comorbidities. Few studies addressed the same agent and outcomes, and few assessed potential factors that may modify effectiveness or drive effects of interventions. Many (n=63) studies also explicitly noted that concomitant interventions were held steady during the study treatment period; however, few studies reported specific analyses to control for or assess the effects of additional treatments.

Despite these limitations, investigators have made significant improvements in incorporating commonly used measures of symptom severity and behavior to facilitate comparisons across studies. Studies also typically described interventions fully, used standardized diagnostic processes and blinded assessors, and reported on the use or restriction of concomitant interventions.

## **Implications for Clinical and Policy Decisionmaking**

This review provides some evidence for decisionmaking about medical interventions for children with ASD. The clearest evidence favors the use of the antipsychotics risperidone and aripiprazole to address challenging behaviors in the short-term (<6 months); however, clinicians and caregivers must balance the significant harms of these agents. The significant side effect profiles make it clear that although these drugs are efficacious, caution is warranted regarding their use in patients without severe impairments or risk of injury. Few studies addressed longer

term effects of these agents; thus, our confidence in longer term ( $\geq 6$  months) effectiveness is low. Studies of adjuncts to risperidone typically reported positive effects on challenging behaviors, but few studies addressed the same agents, precluding our ability to draw conclusions about their effectiveness.

Some evidence supports the use of methylphenidate and atomoxetine for hyperactivity, but few comparative studies addressed each agent, so our confidence in effects is limited. Given that many children with ASD are currently treated with medical interventions, strikingly little evidence exists to support clear benefit for most medical interventions, especially in the realm of interventions such as restrictive diets and supplements. Studies of nutritional supplements or specialized diets were typically underpowered and provided little evidence of effects of these approaches. Several agents were addressed in single studies, which limits conclusions about their effects.

Decisional dilemmas remain regarding characteristics of the child, family, or intervention that may modify effectiveness or predict which children may be most likely to benefit from a given approach. Similarly, the literature base is currently insufficient to inform our understanding of the time to effect of interventions, longer term effectiveness of interventions, generalizability of effects outside the treatment context, effectiveness and applicability to broader ASD populations, and components that may drive effectiveness.

## **Research Gaps and Areas for Future Research**

Improving research in this area should include methodologic considerations of power and sample size and durability of effects. Sample size and participant followup were frequently insufficient to allow firm conclusions. Duration of treatment and followup were generally short ( $< 6$  months); those studies with longer duration of treatment were typically open label extensions of RCTs and lacked control arms. While duration was typically short, retaining participants in studies, especially in placebo arms, is difficult when parents or children perceive little improvement in symptoms. Longer duration of treatment, however, is also important to rule out meaningful improvements in placebo groups and help inform our understanding of the placebo effect.

Few studies provided data on long-term outcomes after cessation of treatment. Future studies should extend the followup period and assess the degree to which outcomes are durable in “real world” situations. The literature includes many single studies of various agents. Studies of adjuncts to risperidone, for example, examined different adjunct agents, with some positive effects on challenging behaviors reported with most. Understanding which agents should be examined further is lacking. Another critical area for further research is identifying which children are likely to benefit from particular interventions. To date, studies have provided limited characterization of the subpopulation of children who experience positive response to medical interventions and limited characterization of the extent or type of behavioral challenges children experience at baseline.

Children with ASD also typically receive multiple types of therapies, but few studies addressed combinations of medical and behavioral or other categories of interventions or a medical treatment compared with a nonmedical treatment. Few attempted to account for potential effects on ongoing interventions. This not only limited our ability to interpret the effects of medical treatments in isolation but represents a significant gap for families and providers in choosing additional treatments that may bolster (or impair) the effects of behavioral, medication, or other therapies. Few studies ( $n=10$ ) compared active treatments, and future

research to assess comparative effectiveness of antipsychotics, ADHD medications, and other medications is necessary.

In addition, much of the medical intervention literature relies on baseline and outcome measures that have specific limits in understanding individualized response. Future research attempting to elucidate potential biobehavioral markers of response may prove useful. Research in understanding outcomes of importance to patients and caregivers, such as quality of life, is also lacking.

Harms reporting varied across studies; some studies amply described how harms were tracked, while others listed harms with no indication of how they were assessed (e.g., parent recall, checklist, clinician assessment during followup). This lack of reporting makes comparing harms across studies difficult. For instance, while studies of atomoxetine generally reported fewer harms than did studies of methylphenidate in children with ADHD symptoms, exploring differences in safety profiles is an important area for additional research.

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## Conclusions

Risperidone and aripiprazole ameliorated challenging behaviors in the short term (<6 months), but had clinically significant side effects. Methylphenidate and atomoxetine were also associated with improvements in hyperactivity in small, short-term RCTs (with uncontrolled open label extensions). Atomoxetine plus parent training was not more effective for hyperactivity than atomoxetine alone. Omega-3 fatty acid supplementation was not associated with improvements in challenging behaviors, and N-acetylcysteine and tetrahydrobiopterin were not associated with improvements in social skills and symptom severity, respectively. Some positive effects were reported with other agents studied (risperidone adjuncts, melatonin), but few studies addressed the same agent or outcomes. Data on longer term ( $\geq 6$  months) results and harms of interventions are lacking. Similarly, more research is needed to understand characteristics of the child or treatment that modify outcomes and whether effectiveness of interventions generalizes across different settings such as the home or school. Current evidence also does not inform our understanding of components of interventions that may drive effects. Some therapies hold promise and warrant further study, and the conduct of studies has improved considerably over time (i.e., growing number of RCTs and use of standardized measures). However, additional studies with larger, well-characterized populations over longer time frames, and that utilize transparent and rigorous methods that permit comparison across studies, would further inform decisionmaking.

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# Introduction

## Background

Autism spectrum disorder (ASD) is a neurodevelopmental disorder broadly defined by impaired social communication as well as restricted or repetitive patterns of behavior and interest. As defined by the *Diagnostic and Statistical Manual of Mental Disorders*, Fifth edition (DSM-5), specific features of ASD include deficits in social and emotional reciprocity (e.g., atypical social approaches, conversational impairment, atypical sharing of interests, attention, and affect); deficits in nonverbal communication (e.g., poorly integrated verbal and nonverbal communication, atypical body-language and gesture use, deficits in use and understanding of nonverbal communication), and deficits in maintaining appropriate relationships (e.g., challenges with peer interest, vulnerabilities forming friendships, difficulties adjusting behavior to suit social contexts) as well as restricted and repetitive patterns of behavior such as stereotyped speech, motor movements, or use of objects; excessive adherence to routine or insistence on sameness; intense interest patterns; and atypical sensory interests or responses. Symptoms of the disorder impair and limit everyday functioning and are thought to be evident in early childhood; although they may not be fully evident until later ages. Although not core symptoms, many children with ASD may also have significant cognitive impairment and language impairments.

The prevalence of ASD in the United States is 14.7 cases per 1,000 children living in the communities surveyed, or 1 in 68, with rate estimates varying widely by region of the country, sex, and race/ethnicity.<sup>1</sup> Considerably more males (1 in 42) than females (1 in 189) are affected. For some individuals, symptoms of ASD may improve with intervention and maturation; however, core deficits typically translate into varying developmental presentations that persist throughout the lifespan.<sup>2</sup>

## Treatment of ASD

The manifestation and severity of symptoms of ASD differ widely, and treatments include a range of behavioral, psychosocial, educational, medical, and complementary approaches<sup>3-6</sup> that vary by a child's age and developmental status. The goals of treatment for ASD typically focus on improving core deficits in communication, social interactions, or restricted behaviors, as changing these fundamental deficits may help children develop greater functional skills and independence.<sup>7</sup> Treatment frequently is complicated by symptoms or comorbidities that may warrant targeted intervention (e.g., significant challenging behavior, attention and hyperactivity concerns, depression, anxiety). There is no cure for ASD and no global consensus on which intervention is most effective.<sup>8,9</sup> Individual goals for treatment vary for different children and may include combinations of behavioral therapies, educational therapies, medical and related therapies, approaches targeting sensory issues, and allied health therapies; parents may also pursue complementary and alternative medicine therapies.

The antipsychotics risperidone (Risperdal) and aripiprazole (Abilify) have been specifically approved by the U.S. Food and Drug Administration (FDA) for treatment of the comorbid symptoms of irritability and challenging behaviors in ASD. No medications have been approved specifically to treat core ASD symptoms such as communication impairments. Many medications are used off-label to manage behavioral symptoms such as anxiety and hyperactivity. In addition, other treatments such as nutritional supplements or devices such as

hyperbaric oxygen chambers have been used to treat symptoms of ASD, though neither supplements or hyperbaric oxygen have been approved by the FDA for ASD treatment.<sup>10</sup>

## **Scope and Key Questions**

### **Scope of Review**

This review updates findings reported in the 2011 Agency for Healthcare Research and Quality (AHRQ) review of Therapies for Children with ASD<sup>11</sup> with a focus on studies of medical interventions. We defined medical interventions broadly as interventions involving the administration of external substances to the body or use of external, nonbehavioral procedures to treat symptoms of ASD, which includes pharmacologic agents, diet therapies, vitamins and supplements, chelating agents, electroconvulsive therapy, transcranial magnetic stimulation and hyperbaric oxygen, among other modalities. We used this broad definition, developed with input from our clinical experts, in order to capture the landscape of medically-related interventions used to treat children with ASD.

We focused the review on children between 2 and 12 years of age. We chose to limit the age range to this span because a) diagnosis of ASD earlier than age 2 is less established and b) adolescents likely have substantially different challenges and would warrant different interventions than children in the preschool, elementary, and middle school age groups.

We integrate syntheses of comparative studies evaluating medical interventions addressed in our 2011 review of therapies for children with ASD<sup>11</sup> if they addressed an agent evaluated in a study identified for the current review. To ensure comprehensive coverage of the medical literature in the current update, we also included studies that had originally been excluded in the 2011 review because of sample size. We set a lower sample size inclusion criterion in the current update.

A companion review updating findings related to interventions targeting sensory challenges is available on the AHRQ Effective Health Care Web site.

### **Key Questions**

We developed Key Questions (KQs) in consultation with Key Informants and the Task Order Officer. KQs were posted for review to the AHRQ Effective Health Care Web site.

KQs were as follows:

**KQ1: Among children ages 2-12 with ASD, what is the comparative effectiveness (benefits and harms) of medical treatments?**

- a. What are the effects on core symptoms (e.g., deficits in social communication and interaction; restricted, repetitive patterns of behavior, interests, or activities including hyper- or hypo- reactivity to sensory input or unusual interest in sensory aspects of the environment) in the short term (<6 months)?
- b. What are the effects on commonly associated symptoms (e.g., motor, medical, mood/anxiety, irritability, and hyperactivity) in the short term (<6 months)?

- c. What are the longer term effects ( $\geq 6$  months) on core symptoms (e.g., social deficits, communication deficits, and repetitive behaviors)?
- d. What are the longer term effects ( $\geq 6$  months) on commonly associated symptoms (e.g., motor, medical, mood/anxiety, irritability, and hyperactivity)?

KQ2: Among children ages 2-12 with ASD, what are the modifiers of outcome for different medical treatments?

- a. Is the effectiveness of the therapies reviewed affected by the frequency, duration, intensity, or dose of the intervention?
- b. Is the effectiveness of the therapies reviewed affected by co-interventions or prior treatment, or the training and/or experience of the individual providing the therapy?
- c. What characteristics (e.g., age, symptom severity), if any, of the child modify the effectiveness of the therapies reviewed?
- d. What characteristics, if any, of the family modify the effectiveness of the therapies reviewed?

KQ3: What is the time to effect of medical interventions?

KQ4: What is the evidence that effects measured at the end of the treatment phase predict long-term functional outcomes of medical interventions?

KQ5: Is the effectiveness of medical interventions maintained across environments or contexts (e.g., people, places, materials)?

KQ6: What evidence supports specific components of treatment with medical interventions as driving outcomes, either within a single treatment or across treatments?

Table 1 outlines population, intervention, comparator, outcomes, timing, and setting (PICOTS) characteristics for each KQ.



**Table 1. PICOTS characteristics**

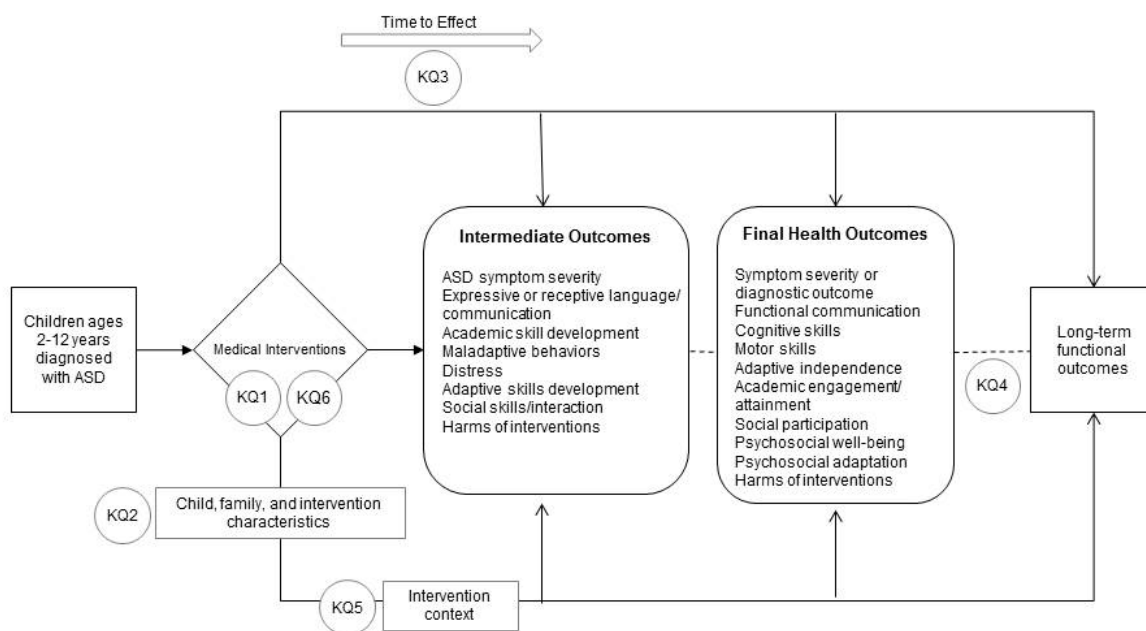
PICOTS	Criteria
<b>Population</b>	Children with ASD between the ages of 2 and 12 years (mean age plus standard deviation is $\leq$ 12 years and 11 months)
<b>Intervention(s)</b>	Medical interventions (pharmaceutical agents, supplements and diets, hyperbaric oxygen, etc.)
<b>Comparator</b>	<ul style="list-style-type: none"> <li>• Inactive control (e.g., no treatment, watchful waiting, waitlist control, placebo)</li> <li>• Alternate intervention</li> </ul>
<b>Outcomes</b>	<p><b><u>Intermediate outcomes</u></b></p> <ul style="list-style-type: none"> <li>• ASD symptom severity</li> <li>• Expressive or receptive language/communication</li> <li>• Academic skill development</li> <li>• Maladaptive behaviors</li> <li>• Distress</li> <li>• Adaptive skills development</li> <li>• Social skills/interaction</li> <li>• Harms of interventions</li> </ul> <p><b><u>Final health outcomes</u></b></p> <ul style="list-style-type: none"> <li>• Symptom severity or diagnostic outcome</li> <li>• Functional communication</li> <li>• Cognitive skills</li> <li>• Motor skills</li> <li>• Adaptive independence</li> <li>• Academic engagement/attainment (e.g., mainstream school placement or integration)</li> <li>• Social participation</li> <li>• Psychosocial well-being</li> <li>• Psychosocial adaptation</li> <li>• Harms of interventions</li> </ul>
<b>Timing</b>	Any (i.e., short and long term outcomes as reported in eligible study publications)
<b>Setting</b>	Any primary, specialty, community, or educational setting

ASD = autism spectrum disorder; PICOTS = population, intervention, comparator, outcome, timing, setting

## Analytic Framework

The analytic framework (Figure 1) illustrates the population, interventions, outcomes, and adverse effects that guided the literature search and synthesis.

**Figure 1. Analytic framework**



ASD=autism spectrum disorder; KQ=Key Question

## Organization of This Report

The Methods section describes the review processes including search strategy, inclusion and exclusion criteria, approach to review of abstracts and full publications, methods for extraction of data, and compiling evidence. We also describe our approach to grading the risk of bias of the literature and describing the strength of the body of evidence.

The Results section presents the findings of the literature search and the review of the evidence by KQ, synthesizing the findings across strategies. We present findings for each KQ organized by intervention and outcome area. We include summary tables in the Results section for those intervention areas for which we could assess the strength of evidence for effectiveness outcomes. All other summary tables are in Appendix F. Because few studies addressed sub-questions under KQ1 and 2, we present results in the aggregate under each of these KQ.

The Discussion section of the report discusses the results and expands on methodologic considerations relevant to each KQ. We also outline the current state of the literature and challenges for future research in the field. The report includes a number of appendixes to provide further detail on our methods and the studies assessed. The appendixes are as follows:

- Appendix A: Search Strategies
- Appendix B: Screening and Risk of Bias Assessment Forms
- Appendix C: Excluded Studies
- Appendix D: Risk of Bias Ratings
- Appendix E: Applicability Summary Tables
- Appendix F: Detailed Tables of Findings

## **Uses of This Evidence Report**

We anticipate that the report will be of value to clinicians who treat children with ASD, who can use the report to assess the evidence for different treatment strategies. In addition, this review will be of use to the National Institutes of Health, U.S. Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, and the Health Resources and Services Administration—all of which have offices or bureaus devoted to child health issues and who may use the report to compare treatments and determine priorities for funding. This report can bring practitioners up to date about the current state of evidence related to medical interventions, and it provides an assessment of the quality of studies that aim to determine the outcomes of medical options for the management of ASD. It will be of interest to families affected by ASD because of the recurring need for families and their health care providers to make the best possible decisions among numerous options. We also anticipate it will be of use to private sector organizations concerned with ASD; the report can inform such organizations' understanding of the effectiveness of treatments and the amount and quality of evidence available. Researchers can obtain a concise analysis of the current state of knowledge and future research needs related to medical interventions for ASD.

# Methods

In this chapter, we document the procedures that we used to produce a comparative effectiveness review update addressing medical interventions for children with autism spectrum disorder (ASD). These procedures follow the methods outlined in the Agency for Healthcare Research and Quality (AHRQ) Effective Health Care Program *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.<sup>12</sup>

## Topic Surveillance and Review Protocol

The topic for the original report (2011<sup>11</sup>) was nominated by Autism Speaks in a public process using the Effective Health Care Web site. AHRQ published an update addressing behavioral interventions in 2014.<sup>13</sup> We conducted a surveillance process to assess the need to update the report by contacting topic experts about the relevance of the Key Questions (KQs) and new evidence that may address them. All members of the research team were required to submit information about potential conflicts of interest before initiation of the work. No members of the review team had any conflicts.

In consultation with clinical experts and stakeholders, and based on our preliminary scan of the literature and surveillance findings, we focused the review update on medical approaches and approaches to address sensory challenges (reported in a separate update). These areas reflect both areas of clinical relevance and sufficient newly published literature for a review update. Based also on the surveillance process and discussions with stakeholders, we revised the Key Questions (KQs) addressed in the 2011 report<sup>11</sup> to reflect the focus on medical and sensory approaches specifically. We also eliminated a question on approaches for children at risk for ASD as such children are unlikely to be included in studies in the target areas for this review update.

After review from AHRQ, the questions and framework were posted online for public comment. No changes to the questions or framework were recommended. We identified technical experts on the topic to provide assistance during the project. The Technical Expert Panel (TEP), representing the fields of pediatrics and developmental pediatrics, psychiatry, family medicine, and occupational therapy and allied health, contributed to the AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential users of its products. Thus, the TEP was both an additional resource and a sounding board during the project. The TEP included seven members serving as technical or clinical experts. To ensure robust, scientifically relevant work, TEP members participated in conference calls to:

- Help to refine the analytic framework and KQ at the beginning of the project;
- Discuss inclusion/exclusion criteria; and
- Assist with determining key interventions and outcomes of interest.

The final protocol was posted to the AHRQ Effective Health Care Web site and registered in the PROSPERO international register of systematic reviews (ID#: CRD42016033941).

## Literature Search Strategy

### Search Strategy

To ensure comprehensive retrieval of relevant studies of medical therapies for children with ASD, we used four key databases: the MEDLINE<sup>®</sup> medical literature database via the PubMed<sup>®</sup> interface; EMBASE (Excerpta Medica Database), an international biomedical and

pharmacological literature database via the Ovid<sup>®</sup> interface; the Cumulative Index of Nursing and Allied Health Literature (CINAHL), and PsycINFO<sup>®</sup>. Search strategies for KQs applied a combination of controlled vocabulary (Medical Subject Headings [MeSH] and Emtree headings) and key words to focus specifically on medical interventions for ASD and harms of interventions (Appendix A). We restricted literature searches for KQs to studies published from 2010 to the present to reflect literature available since the publication of the 2011 review.<sup>11</sup> We last conducted searches for the review in September 2016.

## **Gray Literature**

We searched Web sites of organizations likely to conduct research, issue guidance, or generate policies for ASD (e.g., Autism Speaks, the American Academy of Child and Adolescent Psychiatry) to inform the review's background and discussion sections. We searched government and regulatory agency Web sites for contextual information on benefits and harms of ASD interventions. We searched ClinicalTrials.gov, the International Standard Randomized Controlled Trials Number (ISRCTN) registry, and other trial registries for information about relevant ongoing trials and to confirm that we had obtained available publications of results from completed trials.

## **Inclusion Criteria**

Table 2 outlines inclusion criteria. We required that eligible randomized controlled trials (RCTs) have a total minimum sample size of 10. We required a higher minimum sample size (n=20) for other comparative studies as they typically have fewer controls for bias than RCTs.

We included studies published in English only. In the opinion of our content experts, much of the relevant literature on ASD is published in English; however, we scanned a sample of 150 non-English abstracts to gauge the number of anticipated non-English studies that would meet inclusion criteria. Two non-English studies appeared to meet our criteria. Given this small proportion of potentially eligible studies, we feel that excluding these publications is unlikely to introduce significant bias.

Eligible studies also reported one or more outcomes of interest and included children at least 2 years of age and up to and including age 12. As noted, we focused the review on children in this age range given greater diagnostic stability and differences in behaviors and challenges across age ranges. Studies also included only children with a diagnosis of ASD (or data reported separately for children with ASD).

**Table 2. Inclusion criteria**

Category	Criteria
Study Population	Children ages 2-12 with ASD (mean age plus standard deviation is $\leq$ 12 years and 11 months)
Publication Languages	English only
Admissible Evidence (Study Design and Other Criteria)	<p>Admissible designs Randomized controlled trials, prospective and retrospective cohort studies with comparison groups, and nonrandomized controlled trials</p> <p>Other criteria Original research studies published from 2010—present and not addressed in prior reviews (except for those otherwise eligible studies with a sample size of &lt;30 that excluded them from the 2011 review)</p> <p>Studies must have relevant population and <math>\geq</math>20 participants with ASD (nonRCTs) or at least 10 total participants (RCTs)</p> <p>Studies must address one or more of the following for ASD:            -Outcomes of interest            -Treatment modality of interest            -Predictors or drivers of treatment outcomes (e.g., biomarkers, clinical changes)            -Maintenance of outcomes across environments or contexts            -Sufficiently detailed methods and results to enable data extraction            -Reporting of outcome data by target population or intervention</p>

ASD = autism spectrum disorder; RCT = randomized controlled trial

## Study Selection

Once we identified articles through the electronic database searches and hand-searching, we examined abstracts of articles to determine whether studies met our criteria. Two reviewers separately evaluated the abstracts of studies identified in our searches for KQs for inclusion or exclusion, using an Abstract Review Form (Appendix B). If one reviewer concluded that the article could be eligible for the review based on the abstract, we retained it. Following abstract review, two reviewers independently assessed the full text of each included study using a standardized form (Appendix B) that included questions stemming from our inclusion and exclusion criteria. A senior reviewer resolved disagreements between reviewers.

We conducted all abstract and full text reviews using the DistillerSR online screening application (Evidence Partners Incorporated, Ottawa, Ontario). Appendix C includes a list of excluded studies and the reasons for exclusion. Data extracted for each study are available via the Systematic Review Data Repository (<http://srdp.ahrq.gov/>).

## Data Extraction

The staff members and clinical experts (including two psychiatrists, two psychologists, and three epidemiologists/systematic reviewers) who conducted this review jointly developed the data extraction forms for the KQs. We designed forms to provide sufficient information to enable readers to understand the studies and to determine their quality; we gave particular emphasis to essential information related to the KQs. The team was trained to extract data by extracting several articles into the template and then reconvening as a group to discuss the utility of the template. We repeated this process through several iterations until we decided that the templates included the appropriate categories for gathering the information contained in the articles and for potential meta-analyses. Team data extractors shared the task of initially entering information into the evidence tables. A second team member also reviewed the articles and edited all initial

entries for accuracy, completeness, and consistency. A senior reviewer reconciled disagreements concerning the information reported.

The full research team met regularly during the article extraction period and discussed issues related to the data extraction process. In addition to outcomes related to the effectiveness of treatment (e.g., changes in ASD severity), we extracted all data available on harms. Harms encompass the full range of specific negative effects, including the narrower definition of adverse events.

## Data Synthesis

We summarized data for KQs qualitatively using summary tables. We integrate syntheses of comparative studies evaluating medical interventions addressed in our 2011 review of therapies for children with ASD<sup>11</sup> if they addressed an agent evaluated in a study identified for the current review.

We attempted to perform a quantitative meta-analysis for the effects of risperidone on outcomes related to challenging behaviors using a multivariate normal response to simultaneously model four outcome scales. However, only four studies satisfied the criteria for inclusion, which included reporting baseline and end-of-treatment (or change from baseline) means and standard deviations. This number of studies limited use of a random effects meta-analysis, which was warranted to account for the variation in outcomes. We fit a prototype model using a fixed effects meta-analysis, but the goodness-of-fit evaluation was very poor, so we elected not to continue the meta-analysis. We summarize prior meta-analyses and systematic reviews addressing many of the same agents in the Findings in Relation to What Is Already Known section of the report.

## Risk of Bias Assessment of Individual Studies

We evaluated the overall methodologic risk of bias of individual studies using the ASD-specific assessment approach we developed and used in our prior reviews of interventions for ASD and informed by the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.<sup>12</sup> We developed this tool (Appendix B) because standard risk of bias assessment tools (e.g., Cochrane risk of bias assessment) do not fully account for the complexity of interventions and populations represented in the ASD literature. Specifically, the tool includes questions to address diagnostic approaches and measures of treatment fidelity that may affect outcomes. The tool has not been formally validated.

Two senior investigators assessed each included study independently with disagreements resolved through discussion or by an independent senior investigator/methodologist. Appendix D includes ratings for each study.

## Determining Overall Risk of Bias Ratings

We used the thresholds we establish in prior reviews to assess overall high, medium or low risk of bias. We assessed the risk of bias based upon the study-defined primary outcome(s). We assessed each domain evaluated in the tool (i.e., study design, participant ascertainment/inclusion, intervention description, outcome measurement, statistical analysis). We considered the individual ratings to determine an overall quality assessment of low, moderate, or high risk of bias.

We required that studies receive positive scores questions related to randomization and diagnostic approach to be considered low risk of bias. We summed and weighted scores as described in Table 3 to determine overall study risk of bias. Studies could receive up to two points on the domains of study design, diagnostic approach, participant ascertainment, and intervention, and up to one point on the domains of outcome measurement and statistical analysis.

**Table 3. Quality scoring algorithm**

Definition and Scoring Algorithm	Rating
<ul style="list-style-type: none"> <li>• ≥8/10 points, including a ++ on study design and ++ on diagnostic approach</li> </ul>	Low risk of bias
<ul style="list-style-type: none"> <li>• ≥6/10 points, including at least a + on intervention</li> </ul>	Moderate risk of bias
<ul style="list-style-type: none"> <li>• ≤5/10 points</li> </ul>	High risk of bias

## Strength of the Body of Evidence

The assessment of the literature is done by considering both the observed effectiveness of interventions and the confidence that we have in the stability of those effects in the face of future research. The degree of confidence that the observed effect of an intervention is unlikely to change is presented as strength of evidence, and it can be regarded as insufficient, low, moderate, or high. Strength of evidence describes the adequacy of the current research, both in terms of quantity and quality, as well as the degree to which the entire body of current research provides a consistent and precise estimate of effect. Interventions that have demonstrated benefit in a small number of studies but have not yet been replicated using the most rigorous study designs will therefore have insufficient or low strength of evidence to describe the body of research. Future research may find that the intervention is either effective or ineffective. Strength of the evidence is assessed for a limited set of critical outcomes, typically those related to effectiveness of an intervention.

Methods for applying strength of evidence assessments are established in the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*<sup>12</sup> and are based on consideration of five domains (Table 4): study limitations, consistency in direction of the effect, directness in measuring intended outcomes, precision of effect, and reporting bias. Strength of evidence is assessed separately for major intervention-outcome pairs and incorporates data from the entire body of reviewed evidence on behavioral interventions (i.e., comparative studies—both RCTs and prospective and retrospective cohort studies—reported in the 2011 review<sup>11</sup> and studies reported in the current review). We required at least one low risk of bias study for moderate strength of evidence and two low risk studies for high strength of evidence. In addition, to be considered “moderate” or higher, intervention-outcome pairs needed a positive response on two out of the three domains other than study limitations.

Once we had established the maximum strength of evidence possible based upon these criteria, we assessed the number of studies and range of study designs for a given intervention-outcome pair, and downgraded the rating when the cumulative evidence was not sufficient to justify the higher rating. The possible grades were:

- High: High confidence that the evidence reflects the true effect. Further research is unlikely to change estimates.
- Moderate: Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.



- Low: Low confidence that the evidence reflects the true effect. Further research is likely to change confidence in the estimate of effect and is also likely to change the estimate.
- Insufficient: Evidence is either unavailable or does not permit a conclusion.

**Table 4. Domains used to assess strength of evidence<sup>a</sup>**

Domain	Explanation
Study Limitations	Degree to which included studies for a given outcome have a high likelihood of adequate protection against bias (i.e., good internal validity), assessed through study design and study conduct.
Consistency	Degree to which included studies find either the same direction or similar magnitude of effect. Assessed through two main elements: <ul style="list-style-type: none"> <li>• Direction of effect: Effect sizes have the same sign (that is, are on the same side of no effect or a minimally important difference).</li> <li>• Magnitude of effect: The range of effect sizes is similar.</li> </ul>
Directness	Extent to which evidence links interventions directly to a health outcome of specific importance for the review, and for comparative studies, whether the comparisons are based on head-to-head studies. Evidence may be indirect in several situations such as: <ul style="list-style-type: none"> <li>• Outcome being graded is considered intermediate in a review that is focused on clinical health outcomes (such as morbidity, mortality).</li> <li>• Data do not come from head-to-head comparisons but rather from two or more bodies of evidence to compare.</li> <li>• Data are available only for proxy respondents instead of directly from patients for situations in which patients are capable of self-reporting and self-report is more reliable.</li> </ul>
Precision	Degree of certainty surrounding an effect estimate with respect to a given outcome, based on the sufficiency of sample size and number of events. A body of evidence will generally be imprecise if the optimal information size (OIS) is not met. OIS refers to the minimum number of patients (and events when assessing dichotomous outcomes) needed for an evidence base to be considered adequately powered.
Reporting bias	Degree of selective publishing or reporting of research findings based on the favorability of direction or magnitude of effect.

<sup>a</sup> Excerpted from Berkman et al. 2013<sup>14</sup>

## Applicability

We assessed the applicability of findings reported in the included literature addressing our KQs to the general population of children with ASD by determining the population, intervention, comparator, and setting in each study and developing an overview of these elements for each intervention category. We anticipated that areas in which applicability would be especially important to describe would include ASD severity, comorbidities, age at treatment, and intervention characteristics such provider, dosing/intensity, and setting. Applicability tables for each KQ are in Appendix E.

## Peer Review and Public Commentary

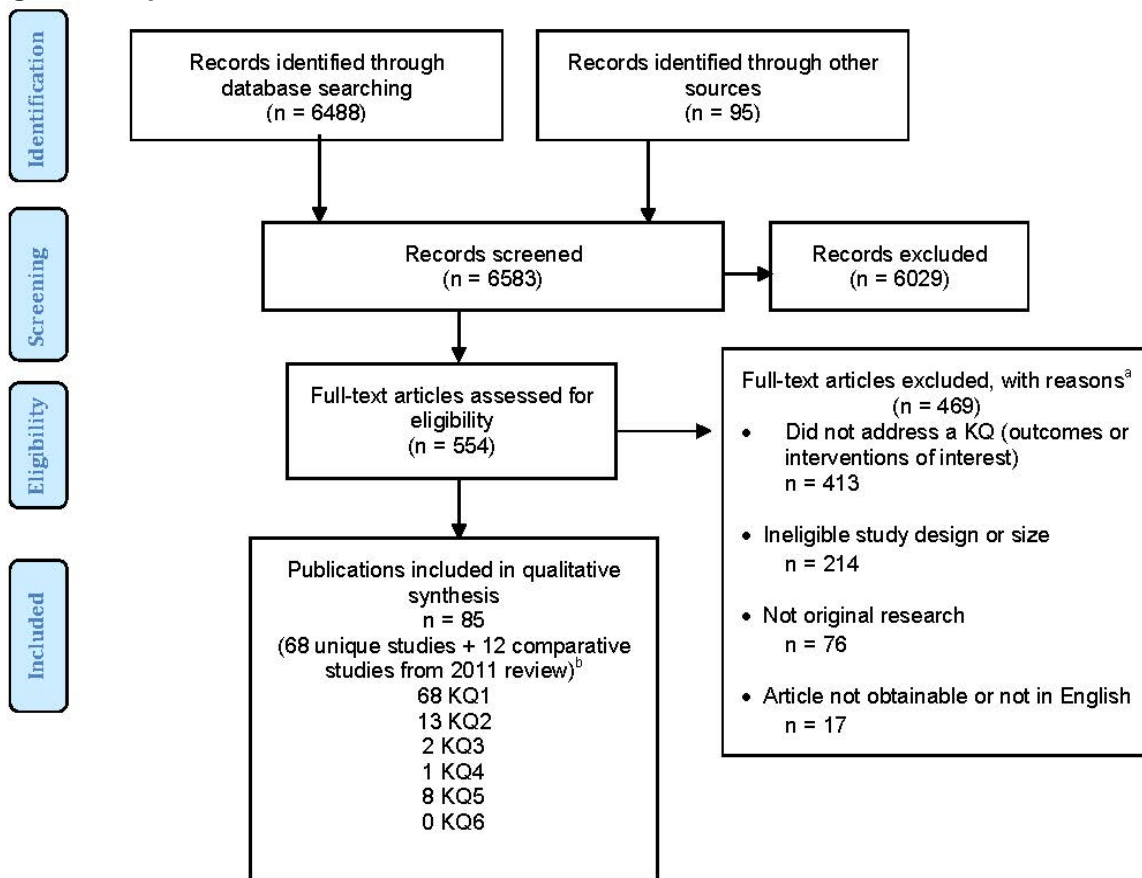
Researchers and clinicians with expertise in treating children with ASD and individuals representing stakeholder and user communities provided external peer review of this report. The draft report was posted on the AHRQ Web site for 4 weeks to elicit public comment. We addressed all reviewer comments, revised the text as appropriate, and documented changes and revisions to the report in a disposition of comments report that will be made available 3 months after AHRQ posts the final review on the AHRQ Web site.

# Results

## Results of Literature Searches for Key Questions

We identified 6583 nonduplicative titles or abstracts with potential relevance, with 554 proceeding to full text review (Figure 2). We excluded 469 studies at full text review. We included 68 unique studies (85 publications) in the review. In addition to these 68 studies included since the completion of our original review of therapies for children with autism spectrum disorder (ASD) in 2011,<sup>11</sup> we include 12 comparative studies addressed in the 2011 review that also addressed an agent used in the current review. Four studies (reported in multiple publications) included in the 2011 review now include followup analyses published since the completion of that report.<sup>15-39</sup> We outline findings from all 76 studies below.

**Figure 2. Disposition of studies identified for this review**



Numbers next to each Key Question indicate number of unique studies addressing the question. Studies could address more than one Key Question.

<sup>a</sup>Numbers do not tally as studies could be excluded for multiple reasons.

<sup>b</sup>We also include analysis of 12 comparative studies reported in our 2011 review of therapies for children with ASD, four of which include new sub-analyses or longer term analyses published since the completion of the 2011 review; thus, we describe a total of 76 studies. Abbreviations: KQ = key question; n = number.

## Description of Included Studies

The 76 studies included in the review comprised 72 randomized controlled trials (RCTs) reported in multiple publications,<sup>15-119</sup> two nonrandomized trials,<sup>120, 121</sup> and two retrospective

cohort studies.<sup>122, 123</sup> Among the 65 studies clearly reporting a funding source, 12 were industry-sponsored,<sup>15-21, 40-44, 48, 51-53, 67, 75, 101, 108, 112, 113, 115</sup> and the remainder were funded by government health agencies, foundations, or universities.

We considered 39 studies to have low risk of bias,<sup>15-39, 41-46, 48-55, 57, 58, 60, 67, 73-76, 78, 81, 83, 89-100, 102, 108, 110, 111, 114</sup> 29 to have moderate,<sup>40, 47, 59, 63, 66, 68-72, 77, 79, 80, 82, 84-87, 101, 103, 106, 107, 109, 112, 113, 115-118, 121, 122, 124</sup> and eight to have high risk.<sup>56, 61, 62, 64, 65, 88, 104, 105, 120, 123</sup> Despite the high number of

low and moderate risk of bias studies, few studies addressed the same interventions or outcomes, and most studies included few participants, evaluated only in the short term (<6 months); thus, evidence for many agents remains insufficient. Table 5 outlines key study characteristics. Because few studies addressed sub-questions under Key Questions (KQ) 1 and 2, we present results in the aggregate under each of these KQ.

**Table 5. Overview of studies**

Characteristic	RCTs (n=72)	Nonrandomized Trials (n=2)	Retrospective Cohort Studies (n=2)	Total Literature
<b>Intervention category</b>				
Antipsychotics	11	0	1	12
Medications used to treat ADHD	5	0	0	5
Combined medical and behavioral approaches	3	2	0	5
Nutrition and diet	19	0	0	19
Risperidone adjuncts	14	0	0	14
Hyperbaric oxygen therapy	3	0	0	3
N-acetylcysteine	2	0	0	2
Tetrahydrobiopterin	2	0	0	2
Other medical approaches <sup>a</sup>	13	0	1	14
<b>Treatment duration</b>				
<1-4 weeks	7	1	0	8
5-8 weeks	15	0	0	15
9-12 weeks	28	1	0	29
13-20 weeks	5	0	0	5
21-36 weeks	13	0	1	14
>52 weeks	4	0	1	5
<b>Region of study conduct</b>				
Africa	2	0	0	2
Asia	23	2	0	25
Australia	3	0	0	3
Europe	11	0	0	11
North America	33	0	2	35
<b>Risk of bias</b>				
Low	39	0	0	39
Moderate	27	1	1	29
High	6	1	1	8
<b>Total N participants</b>	<b>3902</b>	<b>102</b>	<b>186</b>	<b>4190</b>

<sup>a</sup>Includes two of donepezil and one each of neurostimulation, amantadine, divalproex, stem cell transplantation, melatonin, bumetanide, oxytocin, mecamylamine, prednisolone, and citalopram. ADHD = attention deficit hyperactivity disorder; N = number; RCT = randomized controlled trial

Table 6 outlines key outcomes addressed by studies evaluating each intervention class. Challenging behaviors and symptom severity were frequently targeted. All studies reported harms.

**Table 6. Key outcomes targeted in studies of medical interventions**

Intervention Category/ Outcome	Challenging Behavior	ASD Symptom Severity	Repetitive Behavior	Attention/ ADHD Symptoms	Adaptive Behavior	Communication	Medical Symptoms (e.g., Sleep, GI)	Neurocognitive Skills	Repetitive Behavior	Social Skills	Harms
Antipsychotics <sup>15-21, 28-39, 47-52, 101, 102, 109, 112, 113, 122</sup>	X	X	X	X	X				X		X
ADHD medications <sup>24-27, 40-46</sup>	X	X	X	X	X	X		X	X		X
Combination medical and behavioral treatments <sup>54, 55, 57, 120, 121</sup>	X	X		X				X			X
Omega-3 fatty acids <sup>80-82, 84</sup>	X	X			X	X				X	X
Specialized diets <sup>58-65, 104-107</sup>	X	X		X		X	X	X			X
Nutritional supplements <sup>83, 85-88, 117</sup>	X	X		X		X		X			X
Risperidone adjuncts <sup>47, 89-100, 118, 124</sup>	X	X									X
Hyperbaric oxygen <sup>66, 67, 114</sup>	X	X			X	X		X		X	X
N-acetylcysteine <sup>78, 79</sup>	X	X	X			X			X	X	X
Tetrahydrobiopterin <sup>53, 103</sup>	X	X		X	X	X				X	X
Other medical treatments <sup>22, 23, 56, 68-75, 77, 101, 108, 115, 116, 123</sup>	X	X	X	X	X	X	X	X	X	X	X

ADHD = attention deficit hyperactivity disorder; ASD = autism spectrum disorder

## Gray Literature

Our searches of ClinicalTrials.gov and other trial registers did not yield additional eligible studies for the review. We did not receive information in response to requests for scientific information from manufacturers or device makers. We used information from organization web sites searched to provide additional context for the discussion section of the report.

# KQ1. Benefits and Harms of Medical Treatments

## Studies of Antipsychotics

### Key Points

- Five RCTs addressing risperidone reported significant improvements in measures of irritability and other challenging behaviors in the treatment group compared with placebo in the short-term ( $\leq 6$  months), with continued positive effects over a mean 21-month treatment period in an uncontrolled extension study. Side effects including somnolence and weight gain were clinically significant.
- Two RCTs of aripiprazole reported statistically significant improvements in irritability and challenging behavior in the treatment groups compared with placebo over 8 weeks of treatment and maintenance of improvements in a 52-week uncontrolled extension. Harms were also clinically significant. Another RCT reported no differences in time to relapse (return of significant negative symptoms) between children taking aripiprazole versus placebo; quality of life measures also did not differ between groups.
- Three small studies comparing risperidone with aripiprazole reported no significant differences in effects on challenging behaviors or general improvement; one study noted no significant differences in weight gain associated with each agent.
- One small RCT reported greater improvements in challenging behavior with risperidone vs. haloperidol, and one comparing risperidone and memantine and reported no group differences on any outcomes.
- Risperidone and aripiprazole improved challenging behaviors in the short-term ( $< 6$  months), with clinically significant harms. Our confidence in these conclusions is high (high strength of evidence). Behaviors improved in the longer term ( $\geq 6$  months) with these agents compared with placebo, but our confidence in this conclusion is low (low strength of evidence) as few studies had longer-term followup.
- In studies comparing risperidone and aripiprazole, BMI increased with both drugs over treatment durations of 6 months to more than 2 years, but group differences were not significant. We have low confidence in this conclusion given the few studies addressing this outcome (low strength of evidence).
- Other outcomes (e.g., challenging behaviors, attention) were not consistently addressed; thus we considered strength of evidence insufficient for all other intervention/outcome pairs.

### Overview of the Literature

We identified 11 unique RCTs (reported in multiple publications and including comparative studies identified for the current review and those reported in our 2011 review<sup>11</sup>) addressing antipsychotics<sup>15-21, 28-39, 47-52, 101, 102, 109, 111-113</sup> and one retrospective cohort that reported harms data only.<sup>122</sup> Seven studies had low risk of bias,<sup>15-21, 28-39, 48-52, 102, 112, 113</sup> and five had moderate risk.<sup>47, 101, 109, 112, 113, 122</sup> Studies included a total of 1055 children ranging in age from 2 to 20 years and were conducted in the United States (n=5), Iran (n=2), and one each in Canada, Turkey, Italy, the Netherlands, and India.

Two RCTs addressed aripiprazole compared with placebo;<sup>15-21, 48</sup> five addressed risperidone compared with placebo;<sup>28-39, 51, 52, 102, 109, 111-113</sup> and two compared risperidone and aripiprazole.<sup>49, 50</sup> A retrospective cohort compared these agents and reported differences in weight gain.<sup>122</sup> One

RCT compared risperidone and haloperidol,<sup>101</sup> while another compared risperidone and memantine.<sup>47</sup>

Five of these eight RCTs were also included in our 2011 review,<sup>15-21, 28-39, 52, 109, 111-113, 125</sup> and investigators of four of these studies have published additional analyses of participants included in the original trials. These studies included two “families” of papers that report post-hoc and additional or combined analyses of participants in the initial trials. The first family of studies, conducted by Research Units on Pediatric Psychopharmacology (RUPP) Autism Network investigators, assessed risperidone and included an initial 8-week trial comparing risperidone and placebo in 101 children;<sup>34</sup> one paper reporting potential moderators of effect in the 8-week trial;<sup>29</sup> one paper reporting parent concerns assessed during the initial 8-week trial;<sup>35</sup> one paper reporting social interaction measures in these participants<sup>39</sup> and including data from a study (included in our 2011 review) that compared risperidone alone with risperidone plus parent training;<sup>126</sup>; one reporting measures of repetitive behavior<sup>38</sup> and also including data from the risperidone plus parent training study<sup>126</sup> and one paper that reported cognitive changes in a subset of children in the original 8-week trial.<sup>30</sup> This family also includes another paper that assessed longer term (16 weeks) effects in children who responded to risperidone in the original 8-week trial plus children who originally received placebo and were considered placebo nonresponders but had subsequent positive response to risperidone (total n=63);<sup>36</sup> 32 of these children went on to enroll in an RCT comparing either continued risperidone or risperidone with gradual placebo replacement.<sup>31</sup> The investigators followed up these reports with a paper reporting additional social interaction and stereotypy analyses of the 101 original participants in the 8-week trial and the 63 participants in the extension trial,<sup>32</sup> analyses of weight changes in the 63 children in the extension trial,<sup>33</sup> and analysis of adaptive behavior measures in 48 of these 63 children for whom such data were available.<sup>37</sup> Finally, the family includes a paper reporting longer term effects (mean 21 months) in 84 of the original 101 trial participants (38 of whom participated in the extension trial); among these 84 individuals, 53 continued to receive risperidone in the month before followup.<sup>28</sup> Another paper reports changes in prolactin levels in these children after 8 weeks, 6 months, and roughly 22 months of risperidone treatment.<sup>111</sup>

The second family of papers assessed aripiprazole and includes one 8-week trial comparing fixed doses of aripiprazole with placebo;<sup>20</sup> another 8-week trial comparing titrated doses of aripiprazole with placebo;<sup>21</sup> one paper reporting safety data in these two original trials;<sup>19</sup> another reporting health-related quality of life measures assessed in the two original trials;<sup>17</sup> and another outlining Aberrant Behavior Checklist (ABC) data in the two trials.<sup>16</sup> The family also includes an open label extension that combined children from the original RCTs (both treatment and placebo groups) and added children who had not participated in the prior studies (de novo subjects) and in which all 330 participants received 52 weeks of aripiprazole.<sup>15</sup> Finally, this family includes a paper reporting adverse events/safety data for children in the 52-week open label extension.<sup>18</sup>

Across studies, treatment duration ranged from 8 weeks to over 2 years, with followup immediately post-treatment in all studies.

## Detailed Analysis

The literature on antipsychotic effects in children with ASD reports a variety of outcomes but converges on the ABC, a rating scale completed by caregivers of individuals with ASD. Studies also typically assessed potential side effects or harms, including assessment of weight gain, somnolence, and gastrointestinal symptoms and used the Clinical Global Impression (CGI) rating scale. Studies of antipsychotics addressed either risperidone or aripiprazole and reported

significant improvements in measures of challenging behavior in the short term (<6 months) in children receiving the medications compared with those receiving placebo. Harms of these agents, including extrapyramidal symptoms and weight gain, were also significant. Studies reporting longer term followup (up to 21 months for risperidone) reported continued effectiveness in most children but did not include control groups. We report brief summaries of outcomes reported in each study below and end of treatment outcomes on the ABC and CGI in Tables 7-10. Appendix F includes detailed summary tables outlining other outcomes.

## Studies of Risperidone

The four RCTs comparing risperidone and placebo included one study (reported in multiple publications) conducted by RUPP investigators (low risk of bias).<sup>28-39, 112, 113</sup> In the initial 8-week trial including 101 children,<sup>34</sup> baseline ratings of irritability were similar across risperidone and placebo arms. The risperidone arm had significantly greater decreases (improvement) in ABC-Irritability scores compared with the placebo arm (improvements of 15.1 vs. 3.6 points,  $p<0.001$ ). Clinician ratings of outcomes considered by parents to be chief concerns paralleled these findings of significant improvement in challenging behavior in the risperidone group.<sup>35</sup> In other sub-analyses of participants in the original 8-week trial, ABC-Social Withdrawal scores were significantly improved in the treatment group compared with placebo (mean difference of 3.82,  $p=0.05$ , effect size: 0.42) as were scores on the Children's Yale-Brown Obsessive Compulsive Scale (CYBOCS) ( $p=0.005$ , effect size: 0.74), but scores on cognitive measures in a subset of 38 participants who were able to complete the assessments typically did not differ between groups, though no decline in cognitive skills was associated with treatment.<sup>30, 38, 39</sup>

In another series of followup papers from this original RCT, investigators randomized responders to risperidone from the original trial and children who originally received placebo and were considered placebo nonresponders but had subsequent positive response to risperidone to either risperidone or risperidone with gradual placebo replacement for 16 weeks.<sup>31, 36</sup> More children in the gradual replacement arm ( $n=10$ , 62.5%) compared with risperidone ( $n=2$ , 12.5%,  $p=0.01$ ) experienced relapse (25% increase in ABC-Irritability score and CGI-Improvement rating of much or very much worse compared with baseline). In followup analyses of these participants plus children from the initial 101 in the 8-week trial, children receiving risperidone for up to 16 weeks had significant improvements in parent-rated measures of affect, repetitive and restricted behaviors, and sensory responses compared with children receiving placebo, but measures of social relatedness or language did not differ between groups.<sup>32</sup> In a report of 48 children participating in the 16-week extension and receiving risperidone, scores on Vineland Adaptive Behavior Scales (VABS) measures of communication and daily living skills improved significantly over the treatment period; however, this analysis lacked a control arm.<sup>37</sup>

In an extension of these analyses, investigators followed 84 of the initial 101 children in the 8-week trial (38 also participated in the extension trials).<sup>28</sup> These 84 children received risperidone for some portion of the mean 21-month uncontrolled followup; children could have received another antipsychotic or other medication, but 96 percent received risperidone over the followup period, and 68 percent were taking an antipsychotic in the month prior to followup. CGI-Severity scores improved significantly from baseline, regardless of treatment in the original trial (effect size: -0.75) with risperidone. ABC-Irritability similarly improved significantly from baseline (effect size -1.01) as did the ABC-Social Withdrawal (effect size: -0.85), ABC-Stereotypy (effect size: -0.82), ABC-Hyperactivity (effect size: -1.07), and ABC-Inappropriate Speech (-0.41) scales. Scores on the CYBOCS also improved significantly from baseline (effect

size: -0.79), while scores on the VABS typically improved, but not significantly. IQ did not change significantly with risperidone.

Finally, in post-hoc analyses reporting data from the original RUPP trial<sup>34</sup> and an RUPP trial of risperidone compared with risperidone plus parent training<sup>126</sup> (reported in detail in our 2011 review), effect sizes on the ABC-Social withdrawal subscale were 0.65 in the risperidone only group and 0.65 in the combination group;<sup>39</sup> scores were significantly better than those of the placebo arm in the original 8-week trial or risperidone vs. placebo.<sup>34</sup> In another subanalysis,<sup>38</sup> effect sizes on the CYBOCS were 0.88 in the risperidone only group and 0.86 in the combination group, both significantly improved compared with the placebo arm in the original RUPP risperidone trial.

In another RCT (low risk of bias) comparing a low dose risperidone group, a high dose risperidone group, and a placebo group (total n=96), baseline scores for ABC-Irritability and the CGI scales were similar across all groups.<sup>51, 52</sup> The high dose risperidone arm had the greatest improvement in ABC-Irritability scores, followed by the low-dose group and placebo. The difference between high dose risperidone and placebo alone was statistically significant ( $p < 0.001$ ), but differences between low dose and placebo were not. The study reported similar improvements in CGI, with the greatest decrease in CGI scores for high dose risperidone and statistically significant differences between only the high dose group and placebo ( $p < 0.001$ ). In a 6-month open label extension of risperidone including 79 (56 completers) of the 96 children originally enrolled in the RCT, children received either fixed dose or flexibly dose risperidone with a median dose of 0.875mg/day in the open-label phase. All groups improved from baseline on the ABC-Irritability scale, with no significant differences between groups. Other measures taken at the end of the study included ABC-Hyperactivity, ABC-Stereotypic Behavior, ABC-Inappropriate Speech, ABC-Social Withdrawal, CYBOCS, CGI-Severity and CGI-Improvement, all of which showed improvement from baseline with no significant group differences.

One moderate risk of bias RCT reported in the 2011 review reported statistically significant improvements on the ABC-Irritability, Stereotypy, and Hyperactivity subscales in children receiving risperidone compared with the placebo group.<sup>112, 113</sup> The final RCT (moderate risk of bias) assessed outcomes after 6 months of risperidone treatment using a variety of general rating scales but provided quantitative data on only some of these scales.<sup>109</sup> The primary outcome measures were parent ratings on the Childhood Autism Rating Scale (CARS) and clinician ratings on the Children's Global Assessment Scale (CGAS). The study only reported CARS median ratings for those participants with at least a 20 percent response; more children receiving risperidone achieved this goal compared with placebo (12 vs. 0,  $p < 0.001$ ). Average ratings on the CGAS were similar in the risperidone (29.8) and placebo (32.7) arms, with more improvement in the risperidone vs. placebo arms ( $p = 0.04$ ). Parent-rated scores did not differ between groups.

In one discontinuation study, investigators randomized children who had responded to risperidone in an initial 24-week trial to discontinuation (taper for three weeks and 5 weeks off of risperidone) or continuation for eight weeks.<sup>102</sup> For the primary outcome measure of relapse, 8 of 12 patients relapsed in the placebo group and 3 of 12 patients relapsed in the risperidone group ( $p = 0.49$ ). ABC-Irritability scores increased by 60 percent in the placebo group 14 percent in the risperidone group ( $p = 0.43$ ). Differences in other ABC scales (Social Withdrawal, Stereotypy, Hyperactivity and Inappropriate Speech) were not statistically significant. Table 7 outlines key outcomes.



**Table 7. Key outcomes in studies comparing risperidone and placebo**

<p>Author, Year, Study Design Groups (Dose), N Enrollment / N Final</p> <p>Treatment Duration/Follow-Up Time Point Post-Treatment</p> <p>Risk Of Bias</p>	<p>Baseline Scores, Mean ± SD</p>	<p>Post-Treatment Scores, Mean ± SD</p>
<p>Scahill 2015<sup>34</sup> RCT</p> <p>G1: Risperidone (up to 2.5 mg/kg), 49/49 G2: Placebo (NA), 52/52</p> <p>8 weeks/EOT</p> <p>Moderate ROB</p>	<p>ABC-Irritability G1: 26.2 ± 7.9 G2: 25.5 ± 6.6</p> <p>ABC-Lethargy/Social Withdrawal G1: 16.4 ± 8.2 G2: 16.1 ± 8.7</p> <p>ABC-Stereotypic Behavior G1: 10.6 ± 4.9 G2: 9 ± 4.4</p> <p>ABC-Hyperactivity G1: 31.8 ± 9.6 G2: 32.3 ± 8.5</p> <p>ABC-Inappropriate Speech G1: 4.8 ± 4.1 G2: 6.5 ± 3.6</p> <p>CGI-S – Moderate G1: 9 (18) G2: 9 (18)</p> <p>CGI-S – Marked G1: 27 (55) G2: 28 (57)</p> <p>CGI-S – Severe G1: 12 (24) G2: 12 (24)</p> <p>CGI-S – Extreme G1: 1 (2) G2: 0 (0)</p>	<p>ABC-Irritability G1: 11.3 ± 7.4 G2: 21.9 ± 9.5 G1 vs. G2: p&lt;0.001; ES=1.2</p> <p>ABC-Lethargy/Social Withdrawal G1: 8.9 ± 6.4 G2: 12 ± 8.3 G1 vs. G2: p=0.03, ES=0.4</p> <p>ABC-Stereotypic Behavior G1: 5.8 ± 4.6 G2: 7.3 ± 4.8 G1 vs. G2: p&lt;0.001 ES=0.8</p> <p>ABC-Hyperactivity G1: 17 ± 9.7 G2: 27.6 ± 10.6 G1 vs. G2: p&lt;0.001</p> <p>ABC-Inappropriate Speech G1: 3 ± 3.1 G2: 5.9 ± 3.8 G1 vs. G2: p=0.03, ES=0.3</p> <p>CGI-I – Much Improved or very much improved + 25% reduction on ABI-I G1: 34 (69) G2: 6 (12)</p>
<p>Scahill 2015<sup>36</sup> RCT</p> <p>G1: Risperidone (2.5 mg/day), 63/63 G2: Placebo-Substitution (NA), NA</p> <p>4 weeks during open label extension/EOT</p> <p>Moderate ROB</p>	<p><b>End of initial 8 wks of treatment exposure</b></p> <p>CGI-I – Very much improved G1: 19 (30.2) G2: ND</p> <p>CGI-I – Much Improved G1: 42 (66.7) G2: ND</p> <p>CGI-I Minimally Improved G1: 0 (0) G2: ND</p> <p>CGI-I – No Change G1: 2 (3.2) G2: ND</p>	<p>ABC-Irritability G1: 11.7 ± 8 G2: ND</p> <p>ABC-Social Withdrawal/Lethargy G1: 6.8 ± 5.9 G2: ND</p> <p>ABC-Stereotypy G1: 5.8 ± 4.7 G2: ND</p> <p>ABC-Hyperactivity G1: 15.8 ± 10.2 G2: ND</p> <p>ABC-Inappropriate Speech G1: 3.4 ± 3.2</p>

<p><b>Author, Year, Study Design Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow-Up Time Point Post-Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Baseline Scores, Mean ± SD</b></p>	<p><b>Post-Treatment Scores, Mean ± SD</b></p>
	<p>CGI-I – Worse G1: 0 (0) G2: ND</p> <p>CGI-I – Much Worse G1: 0 (0) G2: ND</p> <p>ABC-Irritability G1: 9.5 ± 6.8 G2: ND</p> <p>ABC-Social Withdrawal/Lethargy G1: 7.3 ± 5.4 G2: ND</p> <p>ABC-Stereotypy G1: 4.9 ± 4.3 G2: ND</p> <p>ABC-Hyperactivity G1: 15.1 ± 10 G2: ND</p> <p>ABC-Inappropriate Speech G1: 3.4 ± 3.6 G2: ND</p>	<p>G2: ND</p>
<p>Scahill 2015<sup>28</sup> RCT</p> <p>G1: Risperidone (2.5 mg/day), 57/55 G2: Placebo (NA), 27/26</p> <p>Mean 21 months/2 Years post- treatment</p> <p>Moderate ROB</p>	<p>ABC-Irritability G1: 27.22 ± 7.28 G2: 23.44 ± 7.24</p> <p>ABC-Social Withdrawal G1: 16.05 ± 8.55 G2: 18.52 ± 9.72</p> <p>ABC-Stereotypic Behavior G1: 10.5 ± 4.43 G2: 8.84 ± 5.22</p> <p>ABC-Hyperactivity/Noncompliance G1: 34.3 ± 7.95 G2: 28.58 ± 10.4</p> <p>ABC-Inappropriate Speech G1: 5.71 ± 3.93 G2: 5.59 ± 4.03</p> <p>CGI-Severity G1: 5.09 0.7 G2: 5.23 0.65</p>	<p><b>2 years post-treatment</b></p> <p>ABC-Irritability G1: 14.82 ± 8.4 G2: 17.78 ± 10.82 G1 vs. G2: p=0.0147</p> <p>ABC-Social Withdrawal G1: 8.43 ± 6.77 G2: 13.33 ± 8.73 G1 vs. G2: p=0.0130</p> <p>ABC-Stereotypic Behavior G1: 6.02 ± 4.4 G2: 6.76 ± 5.37 G1 vs. G2: p=0.0866</p> <p>ABC-Hyperactivity/Noncompliance G1: 17.68 ± 10.16 G2: 23.38 ± 12.06 G1 vs. G2: p=0.0020</p> <p>ABC-Inappropriate Speech G1: 3.86 ± 3.01 G2: 5.15 ± 4.24 G1 vs. G2: p=0.0433</p>

<p><b>Author, Year, Study Design Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow-Up Time Point Post-Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Baseline Scores, Mean ± SD</b></p>	<p><b>Post-Treatment Scores, Mean ± SD</b></p>
		<p>CGI-Severity G1: 4.4 ± 0.89 G2: 4.65 ± 1.09 G1 vs. G2: p=0.3004</p>
<p>Kent 2013<sup>51, 52</sup> RCT</p> <p>G1: Risperidone (0.125-0.175 mg/day; low dose), 30/25 G2: Risperidone (1.25-1.75 mg/day; high dose), 31/25 G3: Placebo (NA), 35/27</p> <p>6 weeks/EOT</p> <p>Low ROB</p>	<p>ABC-Irritability G1: 27.1 ± 6.26 G2: 28.0 ± 7.81 G3: 28.9 ± 6.10</p> <p>CGI – Severity G1: 5.1 ± 0.92 G2: 5.0 ± 0.78 G3: 4.9 ± 0.67</p> <p>ABC-Irritability G1: 13.4 ± 3.99 G2: 14.4 ± 4.64 G3: 13.7 ± 2.66</p> <p>ABC-Hyperactivity G1: 30.1 ± 11.46 G2: 33.8 ± 9.75 G3: 31.4 ± 8.60</p> <p>ABC-Stereotypic Behavior G1: 9.3 ± 5.17 G2: 11.5 ± 5.06 G3: 10.5 ± 5.26</p> <p>ABC-Inappropriate Speech G1: 6.6 ± 3.49 G2: 7.5 ± 2.78 G3: 5.9 ± 3.42</p> <p>ABC-Social Withdrawal G1: 18.2 ± 9.71 G2: 21.4 ± 9.09 G3: 18.1 ± 10.16</p> <p>CGI-Severity G1: 5.1 ± 0.93 G2: 5 ± 0.75 G3: 4.9 ± 0.67</p>	<p>Mean change in: ABC-Irritability G1: -7.4 ± 8.12 G2: -12.4 ± 6.52 G3: -3.5 ± 10.67 G1 vs. G3: p=ns G2 vs. G3: p&lt;0.001</p> <p>CGI – Severity G1: -0.4 ± 0.73 G2: -1.0 ± 0.78 G3: -0.3 ± 0.79 G1 vs. G3: p=ns G2 vs. G3: p&lt;0.001</p> <p><b>Mean change score</b> ABC-Irritability G1: -13.2 ± 9.29 G2: -13 ± 10.55 G3: -11.8 ± 7.68</p> <p>ABC-Hyperactivity G1: -10.5 ± 12.42 G2: -12.3 ± 11.78 G3: -11.7 ± 8.54</p> <p>ABC-Stereotypic Behavior G1: -4.2 ± 6.51 G2: -4.6 ± 5.14 G3: -2.8 ± 4.12</p> <p>ABC-Inappropriate Speech G1: -1.8 ± 3.93 G2: -2.1 ± 3.07 G3: -1.5 ± 2.69</p> <p>ABC-Social Withdrawal G1: -8.3 ± 9.03 G2: -10.4 ± 8.57 G3: -6.9 ± 8.08</p> <p>CGI-Severity G1: -1 ± 1.02 G2: -1.3 ± 1.17 G3: -0.9 ± 0.88</p> <p>CGI-Much or Very Much Improved G1: 14 (58) G2: 15 (60) G3: 20 (69) G1 vs. G2 vs. G3: p=ns</p>

<p><b>Author, Year, Study Design Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow-Up Time Point Post-Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Baseline Scores, Mean ± SD</b></p>	<p><b>Post-Treatment Scores, Mean ± SD</b></p>
<p>Troost 2005<sup>102</sup> RCT</p> <p>G1: Risperidone (0.5-3.5 mg/day), 12/12 G2: Placebo (ND), 12/12</p> <p>8 weeks/EOT</p> <p>Low ROB</p>	<p>ABC-Irritability G1: 11.1 ± 8.1 G2: 12.7 ± 7.7</p> <p>ABC-Social Withdrawal/Lethargy G1: 5 ± 6 G2: 6.7 ± 6.9</p> <p>ABC-Stereotypic Behavior G1: 2.3 ± 3.2 G2: 4.7 ± 4.3</p> <p>ABC-Hyperactivity G1: 16.8 ± 11.5 G2: 15.8 ± 9.4</p> <p>ABC-Inappropriate Speech G1: 3.2 ± 3.2 G2: 2.3 ± 1.9</p>	<p>ABC-Irritability G1: 12.6 ± 9.8 G2: 20.3 ± 10.2 G1 vs G2, p=0.043</p> <p>ABC-Social Withdrawal/Lethargy G1: 2.8 ± 3.1 G2: 4.8 ± 3.5 G1 vs G2, p=ns</p> <p>ABC-Stereotypic Behavior G1: 3.3 ± 3.5 G2: 3.4 ± 4.6 G1 vs G2, p=0.305</p> <p>ABC-Hyperactivity G1: 18 ± 11.8 G2: 20.8 ± 12.1 G1 vs G2, p=0.118</p> <p>ABC-Inappropriate Speech G1: 3 ± 2.8 G2: 3 ± 2.3 G1 vs G2: p=0.303</p> <p>CGI-Minimally Improved G1: 5 (42) G2: 3 (25)</p> <p>CGI-Much Improvement G1: 3 (25) G2: 6 (50)</p> <p>CGI-Very Much Improved G1: 4 (33) G2: 3 (25)</p>
<p>Shea 2004<sup>112, 113</sup> RCT</p> <p>G1: Risperidone (0.02 mg/kg/day), 39/39 G2: Placebo (NA), 38/38</p> <p>8 weeks/EOT</p> <p>Moderate ROB</p>	<p>ABC-Irritability G1: 18.9 ± 8.8 G2: 21.2 ± 9.7</p> <p>ABC-Hyperactivity G1: 13.7 ± 7 G2: 14.3 ± 8.2</p> <p>ABC-Social Withdrawal/Lethargy G1: 27.3 ± 9.7 G2: 30.9 ± 8.8</p> <p>ABC-Stereotypy G1: 4.6 ± 3.4 G2: 4.8 ± 3.7</p> <p>ABC-Inappropriate Speech G1: 7.9 ± 5 G2: 8.1 ± 5.6</p>	<p>Mean Change Scores</p> <p>ABC-Irritability G1: -12.1 ± 5.8 G2: -6.5 ± 8.4 G1 vs. G2: p≤0.001</p> <p>ABC-Hyperactivity G1: -8.6 ± 5.9 G2: -5.7 ± 6.9 G1 vs. G2: p≤0.01</p> <p>ABC-Social Withdrawal/Lethargy G1: -14.9 ± 6.7 G2: -7.4 ± 9.7 G1 vs. G2: p≤0.001</p> <p>ABC-Stereotypy G1: -2.6 ± 2.6 G2: -1.6 ± 3</p>

Author, Year, Study Design Groups (Dose), N Enrollment / N Final	Baseline Scores, Mean ± SD	Post-Treatment Scores, Mean ± SD
Treatment Duration/Follow-Up Time Point Post-Treatment  Risk Of Bias		G1 vs. G2: p≤0.05  ABC-Inappropriate Speech G1: -4.3 ± 3.8 G2: -2.4 ± 4 G1 vs. G2: p≤0.05

ABC = Aberrant Behavior Checklist; CGI-I = Clinical Global Impression Scale Improvement, EOT = end of treatment; ES = effect size; G = group; kg = kilograms; mg = milligrams; mL = milliliters; NA = not applicable; ND = no data; RCT = randomized controlled trial; ROB = risk of bias; SD = standard deviation

## Studies of Aripiprazole

Two 8-week RCTs (low risk of bias) of aripiprazole compared with placebo were reported in our 2011 review.<sup>20, 21</sup> In these two studies, baseline ratings of irritability were similar across aripiprazole and placebo arms (Table 8). Decreases in ABC-Irritability were significantly greater for the aripiprazole arms in both studies, with improvements of 12.4 to 14.4, in comparison with the placebo arms, with improvements of 5.0 to 8.4. The trial with differing set doses of aripiprazole demonstrated increasing response with increasing dose.<sup>20</sup> Overall, the results of the trial that used titration following clinical judgment were more pronounced.<sup>21</sup> Decreases (improvements) in ABC-Hyperactivity and Stereotypy subscales were significantly greater in children receiving aripiprazole compared with placebo arms. Scores in the ABC-Inappropriate Speech subscale were also significantly improved in the treatment group vs. placebo in the flexibly dosed study but not in the fixed dose RCT. Both studies also used the CYBOCS scale to assess repetitive behavior, finding no baseline differences between the groups but a greater decrease in the aripiprazole compared with placebo arms (2.4 to 3.8 vs. 0.8 to 1.7). A number of other outcomes were measured in these two studies, but none outside of challenging behavior and repetitive behavior yielded statistically significant findings once corrected for multiple comparisons.

Post-hoc analyses of these RCTs analyzed changes in ABC scores<sup>16</sup> and quality of life measures.<sup>17</sup> The first post-hoc analysis<sup>16</sup> analyzed the following changes in ABC subscales. Scores on the ABC-Irritability, Stereotypy, Hyperactivity, and Inappropriate Speech subscales were significantly improved in the aripiprazole arms compared with placebo (all p values <0.05), typically with greater decreases in the flexibly dosed group compared with the fixed dose group. Scores on the Social Withdrawal subscale did not differ significantly between treatment and placebo groups. Compared with placebo, the pooled aripiprazole groups had greater improvements in total health-related quality of life scores and emotional, social, and cognitive functioning scores measured using the Pediatric Quality of Life Inventory (all p values < 0.05).<sup>17</sup> Children who received aripiprazole were also more likely to have clinically meaningful improvement on all these scales compared with those receiving placebo (odds ratios ranging from 1.2 to 2.2, p values <0.05).

Investigators extended these 8-week studies with an uncontrolled, 52-week open label analysis including 70 children who had received placebo in the original RCTs, 174 who had received aripiprazole, and 86 “de novo” subjects.<sup>15</sup> Primary outcomes included the ABC-Irritability and CGI-Severity scales. ABC-Irritability mean scores at baseline were higher for the

de novo ( $23.2 \pm 8.9$ ) and prior placebo ( $21.5 \pm 9.8$ ) groups compared with the prior aripiprazole group ( $15.0 \pm 9.2$ ). Mean change from baseline in the de novo group was  $-8.0 \pm 10.1$  and in the prior placebo group was  $-6.1 \pm 11.9$ . Improvements in scores in the de novo and prior aripiprazole groups occurred in first 8 weeks of the open label phase. The CGI decreased in the same manner, with greater reductions (improvements) in the de novo and prior placebo groups than in the prior aripiprazole group, in which improvements reported in the prior RCTs were maintained. Scores in the ABC-Hyperactivity subscale and CYBOCS followed similar patterns.

An additional low risk of bias RCT randomized 85 children who had shown a stable improvement ( $\geq 25\%$  decrease in ABC-Irritability scores for 12 weeks) in an initial 13-26 week open label phase to continued, flexibly dosed aripiprazole or placebo until relapse (defined as  $\geq 25\%$  increase in ABC-Irritability score, CGI ratings of worse or much worse, loss-to-followup plus elevated scores, elevated scores plus initiation of other medication to treat symptoms, or discontinuation due to worsening symptoms) or 16 weeks.<sup>48</sup> The difference between the two groups in time to relapse was not statistically significant (35% in the aripiprazole arm at 16 weeks vs. 52% in placebo, hazard ratio=0.57, 95% confidence interval [CI]: 0.28 to 1.12, number needed to treat=6). Mean change in the ABC-Irritability and Social Withdrawal scores or CGI-Improvement score from baseline to week 16 did not differ between groups ( $p \geq 0.05$ ), but children in the placebo group had greater increases (i.e., worsening behavior) on the ABC-Hyperactivity and Inappropriate Speech subscales than did children in the treatment group ( $p$  values  $< 0.05$ ); pediatric quality of life measures also did not differ between groups.

**Table 8. Key outcomes in studies comparing aripiprazole and placebo**

<p>Author, Year, Study Design Groups (Dose), N Enrollment / N Final</p> <p>Treatment Duration/Follow-Up Time Point Post-Treatment</p> <p>Risk Of Bias</p>	<p>Baseline Scores, Mean ±SD</p>	<p>Post-Treatment Scores, Mean ± SD</p>
<p>Marcus 2011<sup>20</sup> RCT</p> <p>G1: Aripiprazole (5 mg/kg), 53/44 G2: Aripiprazole (10 mg/kg), 59/49 G3: Aripiprazole (15 mg/kg), 54/47 G4: Placebo (NA), 52/38</p> <p>8 weeks/EOT</p> <p>Moderate ROB</p>	<p>ABC-Irritability G1: 28.6 ± 7.6 G2: 28.2 ± 7.4 G3: 28.9 ± 6.4 G4: 28 ± 6.9</p> <p>ABC-Hyperactivity/Noncompliance G1: 33.1 ± 1.4 G2: 33.7 ± 1.3 G3: 32.2 ± 1.4 G4: 31 ± 1.4</p> <p>ABC-Stereotypic Behavior G1: 11.4 ± 0.8 G2: 11.6 ± 0.8 G3: 11.6 ± 0.8 G4: 10.7 ± 0.8</p> <p>ABC-Social Withdrawal/Lethargy G1: 17.7 ± 1.4 G2: 16.8 ± 1.3 G3: 18.9 ± 1.4 G4: 18 ± 1.5</p> <p>ABC-Inappropriate Speech G1: 5.8 ± 0.6 G2: 6.8 ± 0.5 G3: 6.3 ± 0.5 G4: 5.9 ± 0.6</p> <p>CGI-S G1: 5 ± 0.1 G2: 4.9 ± 0.1 G3: 5.1 ± 0.1 G4: 4.7 ± 0.1</p>	<p><b>Change scores</b></p> <p>ABC-Irritability G1: -12.4 G2: -13.2 G3: -14.4 G4: -8.4 G1 vs. G4: p=0.032 G2 vs. G4: p=0.008 G3 vs. G4: p=0.001</p> <p>ABC-Hyperactivity/Noncompliance G1: -14 ± 1.6 G2: -13.3 ± 1.5 G3: -16.3 ± 1.6 G4: -7.7 ± 1.7 G1 vs. G4: p≤0.005 G2 vs. G4: p≤0.05 G3 vs. G4: p≤0.001</p> <p>ABC-Stereotypic Behavior G1: -4.5 ± 0.68 G2: -4.2 ± 0.63 G3: -4.5 ± 0.66 G4: -1.8 ± 0.69 G1 vs. G4: p≤0.005 G2 vs. G4: p≤0.05 G3 vs. G4: p≤0.005</p> <p>ABC-Social Withdrawal/Lethargy G1: -5.8 ± 1.2 G2: -4.9 ± 1.1 G3: -7.9 ± 1.1 G4: -5.2 ± 1.2</p> <p>ABC-Inappropriate Speech G1: -2 ± 0.5 G2: -1.8 ± 0.4 G3: -2.3 ± 0.4 G4: -1.1 ± 0.5</p> <p>CGI-S G1: -0.9 ± 0.2 G2: -1 ± 0.1 G3: -1.1 ± 0.2 G4: -0.6 ± 0.2</p>
<p>Marcus 2011<sup>21</sup> RCT</p> <p>G1: Aripiprazole (2-15 mg/kg), 47/39 G2: Placebo (NA), 51/36</p> <p>8 weeks/EOT</p>	<p>ABC-Irritability G1: 29.6 ± 6.4 G2: 30.2 ± 6.5</p> <p>ABC-Hyperactivity/Noncompliance G1: 34.1 G2: 34.7</p>	<p><b>Change Scores</b></p> <p>ABC-Irritability G1: -12.9 G2: -5 G1 vs. G2: p&lt;0.001</p> <p>ABC-</p>

<p><b>Author, Year, Study Design Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow-Up Time Point Post-Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Baseline Scores, Mean <math>\pm</math>SD</b></p>	<p><b>Post-Treatment Scores, Mean <math>\pm</math> SD</b></p>
<p>Moderate ROB</p>	<p>ABC-Stereotypic Behavior G1: 11.9 G2: 10.7</p> <p>ABC-Inappropriate Speech G1: 7 G2: 7</p>	<p>Hyperactivity/Noncompliance G1: -12.7 G2: -2.8 G1 vs. G2: <math>p &lt; 0.001</math></p> <p>ABC-Stereotypic Behavior G1: -4.8 G2: -2 G1 vs. G2: <math>p &lt; 0.001</math></p> <p>ABC-Inappropriate Speech G1: -2.5 G2: -0.4 G1 vs. G2: <math>p &lt; 0.001</math></p> <p>CGI-Severity G1: -1.2 G2: -0.4</p> <p>CGI-I – Very much improved or much improved G1: 31 (67) G2: 8 (16)</p> <p>CGI-I – Minimally improved G1: 7 (15) G2: 10 (20)</p> <p>CGI-I – No change G1: 6 (13) G2: 22 (45)</p> <p>CGI-I – Minimally worse G1: 2 (4) G2: 5 (10)</p> <p>CGI-I – Much or very much worse G1: 0 (0) G2: 4 (8)</p>
<p>Marcus 2011<sup>15</sup> RCT</p> <p>G1: De Novo Subjects (2-15 mg/kg), 84/55 G2: Prior Placebo (2-15 mg/kg), 69/37 G3: Prior Aripiprazole (2-15 mg/kg), 169/107</p> <p>52 weeks</p> <p>Moderate ROB</p>	<p>CGI-Severity G1: <math>4.8 \pm 1</math> G2: <math>4.2 \pm 1</math> G3: <math>3.9 \pm 1.1</math></p> <p>ABC-Irritability G1: <math>23.2 \pm 8.9</math> G2: <math>21.5 \pm 9.8</math> G3: <math>15 \pm 9.2</math></p> <p>ABC-Lethargy/Social Withdrawal G1: <math>14.6 \pm 8.6</math> G2: <math>11.3 \pm 9.2</math> G3: <math>10.4 \pm 8.9</math></p>	<p>CGI-Severity G1: <math>-1 \pm 0.8</math> G2: <math>-0.6 \pm 1.2</math> G3: <math>-0.1 \pm 1</math></p> <p>ABC-Irritability G1: <math>-8 \pm 10.1</math> G2: <math>-6.1 \pm 1.9</math> G3: <math>0.7 \pm 10.2</math></p> <p>ABC-Lethargy/Social Withdrawal G1: <math>-6.4 \pm 7.9</math> G2: <math>-4.1 \pm 7.2</math> G3: <math>-2.3 \pm 6.4</math></p>



<p><b>Author, Year, Study Design Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow-Up Time Point Post-Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Baseline Scores, Mean <math>\pm</math>SD</b></p>	<p><b>Post-Treatment Scores, Mean <math>\pm</math> SD</b></p>
	<p>ABC-Stereotypic Behavior G1: 8.1 <math>\pm</math> 5.2 G2: 9.1 <math>\pm</math> 5.6 G3: 6.4 <math>\pm</math> 5.5</p> <p>ABC-Hyperactivity G1: 28.4 <math>\pm</math> 10.9 G2: 25.8 <math>\pm</math> 13.2 G3: 18.4 <math>\pm</math> 12</p> <p>ABC-Inappropriate Speech G1: 5.8 <math>\pm</math> 3.2 G2: 5.7 <math>\pm</math> 4.2 G3: 4.2 <math>\pm</math> 3.6</p>	<p>ABC-Stereotypic Behavior G1: -2.7 <math>\pm</math> 3.1 G2: -1.9 <math>\pm</math> 4.1 G3: -0.5 <math>\pm</math> 4.4</p> <p>ABC-Hyperactivity G1: -12.3 <math>\pm</math> 8.5 G2: -9.1 <math>\pm</math> 11.5 G3: 0.6 <math>\pm</math> 10.3</p> <p>ABC-Inappropriate Speech G1: -2 <math>\pm</math> 2.5 G2: -1.8 <math>\pm</math> 3 G3: -0.3 <math>\pm</math> 2.4</p>
<p>Marcus 2011<sup>16</sup> RCT</p> <p>G1: Aripiprazole (2-15 mg/kg; flexibly dosed study), 46/46 G2: Aripiprazole (5 mg/kg), 52/52 G3: Aripiprazole (10 mg/kg), 59/59 G4: Aripiprazole (15 mg/kg), 53/53 G5: Placebo (flexibly dosed study) 49/49 G6: Placebo (fixed-dose study) 49/49</p> <p>8 weeks/EOT</p> <p>Moderate ROB</p>	<p>ABC-Irritability G1: 29.6 <math>\pm</math> 1 G2: 28.3 <math>\pm</math> 1 G3: 27.6 <math>\pm</math> 0.9 G4: 28.3 <math>\pm</math> 1 G5: 30.8 <math>\pm</math> 1 G6: 26.9 <math>\pm</math> 1</p> <p>ABC-Social Withdrawal/Lethargy G1: 19.9 <math>\pm</math> 1.6 G2: 17.7 <math>\pm</math> 1.4 G3: 16.8 <math>\pm</math> 1.3 G4: 18.9 <math>\pm</math> 1.4 G5: 18.1 <math>\pm</math> 1.6 G6: 18 <math>\pm</math> 1.5</p> <p>ABC-Stereotypic Behavior G1: 11.9 <math>\pm</math> 0.9 G2: 11.4 <math>\pm</math> 0.8 G3: 11.6 <math>\pm</math> 0.8 G4: 10.7 <math>\pm</math> 0.9 G5: 10.7 <math>\pm</math> 0.8 G6: 10.7 <math>\pm</math> 0.8</p> <p>ABC-Hyperactivity G1: 34.1 <math>\pm</math> 1.4 G2: 33.1 <math>\pm</math> 1.4 G3: 33.7 <math>\pm</math> 1.3 G4: 32.2 <math>\pm</math> 1.4 G5: 34.7 <math>\pm</math> 1.4 G6: 31.1 <math>\pm</math> 1.4</p> <p>ABC-Inappropriate Speech G1: 7 <math>\pm</math> 0.6 G2: 5.8 <math>\pm</math> 0.6 G3: 6.8 <math>\pm</math> 0.5 G4: 6.3 <math>\pm</math> 0.5 G5: 7 <math>\pm</math> 0.6 G6: 5.9 <math>\pm</math> 0.6</p>	<p><b>Change scores</b></p> <p>ABC-Irritability G1: -12.9 <math>\pm</math> 1.4 G2: -12.4 <math>\pm</math> 1.4 G3: -13.2 <math>\pm</math> 1.3 G4: -14.4 <math>\pm</math> 1 G5: -5 <math>\pm</math> 1.4 G6: -8.4 <math>\pm</math> 1.4 G1 vs. G6, p&lt;0.05 G2 vs. G6, p&lt;0.05 G3 vs. G6, p&lt;0.05 G4 vs. G6, p&lt;0.05</p> <p>ABC-Social Withdrawal/Lethargy G1: -7.9 <math>\pm</math> 1.2 G2: -5.8 <math>\pm</math> 1.2 G3: -4.9 <math>\pm</math> 1.1 G4: -7.9 <math>\pm</math> 1.1 G5: -6.2 <math>\pm</math> 1.1 G6: -5.2 <math>\pm</math> 1.2 G5 vs. G6, p=ns</p> <p>ABC-Stereotypic Behavior G1: -4.8 <math>\pm</math> 0.6 G2: -4.5 <math>\pm</math> 0.7 G3: -4.2 <math>\pm</math> 0.6 G4: -4.5 <math>\pm</math> 0.7 G5: -2 <math>\pm</math> 0.6 G6: -1.8 <math>\pm</math> 0.7 G1 vs. G6, p&lt;0.05 G2 vs. G6, p&lt;0.05 G3 vs. G6, p&lt;0.05 G4 vs. G6, p&lt;0.05</p> <p>ABC-Hyperactivity G1: 12.7 <math>\pm</math> 1.5 G2: -14 <math>\pm</math> 1.6 G3: -13.3 <math>\pm</math> 1.5 G4: -16.3 <math>\pm</math> 1.6</p>

<b>Author, Year, Study Design Groups (Dose), N Enrollment / N Final</b>  <b>Treatment Duration/Follow-Up Time Point Post-Treatment</b>  <b>Risk Of Bias</b>	<b>Baseline Scores, Mean ±SD</b>	<b>Post-Treatment Scores, Mean ± SD</b>
		G5: -2.8 ± 1.5 G6: -7.7 ± 1.7 G1 vs. G6, p<0.05 G2 vs. G6, p<0.05 G3 vs. G6, p<0.05 G4 vs. G6, p<0.05  ABC-Inappropriate Speech G1: -2.5 ± 0.4 G2: -2 ± 0.5 G3: -1.8 ± 0.4 G4: -2.3 ± 0.4 G5: -0.4 ± 0.4 G6: -1.1 ± 5 G4 vs. G6: p<0.05
Findling 2014 <sup>48</sup> RCT  G1: Aripiprazole (2-15 mg/day), 41/22 G2: Placebo (NA), 44/19  16 weeks/EOT  Low ROB	ABC-I – adjusted mean score NR  CGI - improvement scale NR	<b>Change scores</b> ABC- I G1: 5.2 G2: 9.6 G1 vs. G2: p=ns  ABC- Hyperactivity G1: 5.0 G2: 10.3 G1 vs. G2: p=0.041  ABC- Stereotypy G1: 0.8 G2: 2.8 G1 vs. G2: p=0.018  ABC- Inappropriate speech G1: 0.6 G2: 2.1 G1 vs. G2: p=0.013  ABC- Social withdrawal G1: 0 G2: 1.5 G1 vs. G2: p=ns  CGI- I G1: 4.2 G2: 4.8 G1 vs. G2: p=ns

ABC = Aberrant Behavior Checklist; CGI-I = Clinical Global Impression Scale Improvement, EOT = end of treatment; G = group; kg = kilograms; mg = milligrams; NR = not reported; NS = not significant; RCT = randomized controlled trial; ROB = risk of bias; SD = standard deviation

## Studies Comparing Risperidone and Aripiprazole

Three small studies comparing these agents reported no significant group differences in measures of challenging behavior or general improvement (Table 9). In one 24-week RCT (low

risk of bias) comparing two groups of patients with ASD and attention deficit hyperactivity disorder (ADHD), both groups improved on measures of symptom severity including the ADHD Rating Scale and CGI (all p=NS) Of note, improvement with aripiprazole was evident in the first 12 weeks of treatment without additional improvements at 24 weeks, while scores on measures in children taking risperidone improved at 12 weeks and continued to improve over the 24 week period.<sup>50</sup> Another 8-week RCT (low risk of bias) reported improvements in ABC-Irritability, Hyperactivity, Lethargy, Stereotypy, and Inappropriate speech scores in both risperidone and aripiprazole arms.<sup>49</sup> Most patients were much or minimally improved on the CGI-Improvement scale, but differences between the groups on all of these scales were not statistically significant. Another retrospective cohort study (moderate risk of bias), which primarily reports weight change (see Harms section below), noted no significant group differences in mean CGI-Improvement scores (risperidone=3.2±1.2, aripiprazole=2.9±1.2, p=0.32) after treatment with risperidone (mean treatment duration=2.37±2.55 years) or aripiprazole (mean treatment duration=1.47±1.21 years).<sup>122</sup> The study did not report CGI scores at baseline so the magnitude of change cannot be assessed.

**Table 9. Key outcomes in studies comparing risperidone and aripiprazole**

Author, Year, Study Design Groups (Dose), N Enrollment / N Final  Treatment Duration/Follow-Up Time Point Post-Treatment  Risk Of Bias	Baseline Scores, Mean ±SD	Post-Treatment Scores, Mean ± SD
Lamberti 2016 <sup>50</sup> RCT  G1: Aripiprazole (up to 15 mg/day), 22/19 G2: Risperidone (up to 3 mg/day), 22/18  24 weeks/EOT  Low ROB	CGI – Severity G1: 5.4 ± 0.5 G2: 5.5 ± 0.6  CGAS – Total Score G1: 38 ± 8.3 G2: 31.42 ± 12.4  ADHD Rating Scale – Total Score G1: 39.4 ± 2.8 G2: 37.4 ± 3.9  CPRS – Hyperactivity G1: 5.7 ± 0.7 G2: 5.4 ± 0.7  CPRS – Inattention G1: 5.4 ± 0.8 G2: 4.9 ± 0.9	CGI – Severity G1: 5.4 ± 0.5 G2: 5.5 ± 0.6  CGAS – Total Score G1: 38 ± 8.3 G2: 31.42 ± 12.4  ADHD Rating Scale – Total Score G1: 39.4 ± 2.8 G2: 37.4 ± 3.9  CPRS – Hyperactivity G1: 5.7 ± 0.7 G2: 5.4 ± 0.7  CPRS – Inattention G1: 5.4 ± 0.8 G2: 4.9 ± 0.9
Ghanizadeh 2014 <sup>49</sup> RCT  G1: Aripiprazole (1.25-10 mg/day), 29/29 G2: Risperidone (0.25-3 mg/day), 30/30  2 months/EOT  Low ROB	ABC-Irritability G1: 26.2 ± 4.1 G2: 21.5 ± 7.4  ABC-Hyperactivity G1: 37.1 ± 7 G2: 36 ± 6.2  ABC-Lethargy G1: 27.5 ± 8.4 G2: 25.3 ± 8.9  ABC-Stereotypy	<b>EOT</b> ABC-Irritability G1: 14.6 ± 5.5 G2: 12.5 ± 5.4 G1 vs. G2: p=ns  ABC-Hyperactivity G1: 21.1 ± 9 G2: 19.1 ± 6.1 G1 vs. G2: p=ns  ABC-Lethargy G1: 17.3 ± 7.4

<p>Author, Year, Study Design Groups (Dose), N Enrollment / N Final</p> <p>Treatment Duration/Follow-Up Time Point Post-Treatment</p> <p>Risk Of Bias</p>	<p>Baseline Scores, Mean <math>\pm</math>SD</p>	<p>Post-Treatment Scores, Mean <math>\pm</math> SD</p>
	<p>G1: 13.6 <math>\pm</math> 5.7 G2: 13.2 <math>\pm</math> 4.2</p> <p>ABC-Speech G1: 8.6 <math>\pm</math> 3.1 G2: 8.9 <math>\pm</math> 3.6</p>	<p>G2: 16.1 <math>\pm</math> 6.9 G1 vs. G2: p=ns</p> <p>ABC-Stereotypy G1: 8.2 <math>\pm</math> 5 G2: 7.4 <math>\pm</math> 3.9 G1 vs. G2: p=ns</p> <p>ABC-Speech G1: 4.9 <math>\pm</math> 2.3 G2: 5.7 <math>\pm</math> 3.1 G1 vs. G2: p=ns</p> <p>CGI-Improvement, n Much improved G1: 9 G2: 5 Minimally improved G1: 7 G2: 12</p> <p>No change G1: 5 G2: 8</p> <p>Minimally worse G1: 3 G2: 2 G1 vs. G2: p=ns</p>

ABC = Aberrant Behavior Checklist; CGI = Clinical Global Impression Scale; EOT = end of treatment; ES = effect size; G = group; mg = milligrams; N = number; NS = not significant; RCT = randomized controlled trial; ROB = risk of bias; SD = standard deviation

## Studies Comparing Risperidone and Other Agents

**Haloperidol.** In one small RCT (moderate risk of bias) comparing risperidone with haloperidol, both groups improved from baseline on the Ritvo-Freeman scale, ABC, and Turgay DSM-IV Pervasive Development Disorder scale, with significantly greater improvements in the risperidone group on the ABC and Turgay scales (p values <0.01).<sup>101</sup> Appendix F outlines key data from this study.

**Memantine.** In one small RCT (moderate risk of bias) comparing risperidone with memantine, children in both groups improved significantly from baseline on all ABC subscales except stereotypy and on most CARS subscales (no improvements in either group in fear/nervousness, nonverbal communication, and intellectual response. Improvements in memantine arm on taste, smell, touch response and imitation), but differences between groups were not significant.<sup>47</sup> CGI ratings were not significantly different between groups. Appendix F outlines key data from this study.

## Harms of Antipsychotics

**Risperidone.** Table 10 outlines harms reported in study arms addressing risperidone. Among clinically important harms, appetite increase occurred in over 70 percent of children and extrapyramidal symptoms in 36 percent. Gastrointestinal symptoms (including constipation, diarrhea, and abdominal pain) occurred in nearly all children in the 8 week RCT, and more than 25 percent across phases experienced anxiety and hypersalivation. Across studies, six children withdrew due to adverse events.

Some studies reported comparative analyses of harms data: In the RUPP extension study urinary problems occurred in 19.6 percent of patients who took risperidone, and 0% of patients that did not ( $p=0.01$ ). Excessive appetite occurred in 42.1 percent of patients who took risperidone and 20 percent of those who did not ( $p=ns$ ). In another RCT comparing risperidone doses and placebo, the incidence of treatment-emergent adverse events was higher in the high dose group compared with the low dose group and placebo.<sup>125, 127</sup> In combining high and low dose groups, the most common events included increased appetite (26%), sedation (15%), somnolence (11%) and weight increase (11%). Sedation, somnolence and increased appetite occurred with twice the frequency in the high dose group than in the low dose group.

In an analysis of prolactin changes in children participating in the RUPP trial, serum prolactin increased significantly from baseline in children taking risperidone at 8 weeks and 6 months, though concentrations were lower at 6 months than at weeks.<sup>111</sup> Levels were higher in treated children compared with those in the placebo group. In the 20 treated children with measurements at 8 weeks, 6 months, and ~22 months, levels were significantly elevated at each time point compared with baseline, but levels at 22 months were significantly lower than those at 6 months ( $p=0.016$ ). While these elevations represented 2 to 4 fold increases in prolactin, no children reported clinical complaints such as galactorrhea, gynecomastia, or menstrual changes. Another study reported no significant differences in weight change between risperidone and placebo groups (increase of 17% in the risperidone group and 9.3% in placebo).<sup>109</sup>

One analysis of side effects in a discontinuation study<sup>102</sup> reported adverse events that occurred in at least 10 percent of patients taking risperidone, including increased appetite (mild-49%, moderate 8%), anxiety (mild 31%, moderate 7%), fatigue (mild 32%, moderate 3%), increased thirst (26%), enuresis (19%), insomnia, (17%), headache (13%), rhinitis (11%), stomachache (10%), nausea (10%) and drooling (10%). The authors did not report differences in groups during the discontinuation period.

**Table 10. Harms/adverse events reported by study phase in RUPP risperidone studies**

Treatment Duration Adverse Event	Risperidone: 8 weeks <sup>34</sup> (n=49) N (%)	Risperidone: 6 months <sup>36</sup> (n=95) N (%)	Risperidone: 21.4 months (mean) <sup>28</sup> (n=84) N (%)	Placebo: 8 weeks <sup>34</sup> (n=51) N (%)
Accidental injury	NR	2 (3.2)	NR	NR
Agitation/nervousness/ restlessness	3 (6)	1 (1.6)	NR	3 (6)
Anxiety	12 (24)	3 (4.8)	7 (12.3)	10 (20)
Appetite change	NR	NR	4 (7.1)	
Appetite increase	36 (73)	5 (7.9)	24 (42.1)	15 (29)
Appetite decrease	3 (6)	NR	NR	5 (10)
Depression/sadness	NR	1 (1.6)	NR	NR
Dizziness	8 (16)	NR	NR	2 (4)
Drooling/increased saliva	13 (27)	2 (3.2)	10 (17.5)	3 (6)
Dry mouth	9 (18)	NR	6 (10.6)	5 (10)
EPS/impaired movement	18 (36)	3 (4.8)	NR	5 (10)
Gastrointestinal symptoms	48 (98)	7 (11.1)	25 (44.2)	43 (86)
Headache	9 (18)	2 (3.2)	NR	6 (12)
Heart rate changes	6 (12)	NR	NR	1 (2)
Infection/fever/cold/ congestion symptoms	35 (71)	18 (28.6)	7 (12.5)	23 (45)
Insomnia	7 (14)	3 (4.8)	NR	15 (29)
Skin changes	11 (22)	3 (4.8)	3 (5.4)	7 (14)
Sleep changes	11 (22)	NR	6 (10.5)	9 (18)
Fatigue	23 (47)	1 (1.1)	NR	6 (12)
Drowsiness	16 (32.6)	2 (4.1)	13 (15.5)	NR
Thirst	6 (12)	NR	NR	5 (10)
Urinary changes	15 (31)	3 (4.8)	11 (19.6)	15 (29)

EPS = Extrapyramidal Symptoms; N = number; NR = Not Reported; RUPP = Research Units on Pediatric Psychopharmacology

Harms reported in other risperidone studies were similar (Table 11).

**Table 11. Harms/adverse effects in other studies of risperidone**

Harm/Adverse Event <sup>a</sup>	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
<b>Risperidone, 1-1.17mg/day</b>		
Appetite increase <sup>49, 112, 113</sup>	2 (21/70)	22.5%-40%
Insomnia <sup>112, 113</sup>	1 (6/40)	15%
Challenging behavior <sup>112, 113</sup>	1 (5/40)	12.5%
Headache <sup>112, 113</sup>	1 (5/40)	12.5%
Somnolence <sup>49, 109, 112, 113</sup>	3 (46/89)	10%-72.5%
Drooling/increased saliva <sup>49, 112, 113</sup>	2 (16/70)	10%-40%
Infection/fever/cold/congestion symptoms <sup>112, 113</sup>	1 (44/40)	10%-37.5%
Appetite decrease <sup>49, 112, 113</sup>	2 (8/70)	10%-13.3%
Gastrointestinal symptoms <sup>49, 112, 113</sup>	2 (25/70)	3.3%-20%
EPS/impaired movement <sup>49, 109, 112, 113</sup>	3 (24/89)	3.3%-16%
Heart rate changes <sup>49, 112, 113</sup>	2 (6/70)	3.3%-12.5%
Agitation/nervousness/restlessness <sup>49</sup>	1 (3/30)	10%
Dizziness <sup>49</sup>	1 (3/30)	10%
Weight gain <sup>112, 113</sup>	1 (4/40)	10%
Urinary changes <sup>49</sup>	1 (2/30)	6.7%
<b>Risperidone, 1.25-1.75mg/day</b>		
Somnolence <sup>51, 52</sup>	1 (20/31)	64.5%
Infection/fever/cold/congestion symptoms <sup>51, 52</sup>	1 (7/25)	28%
EPS/impaired movement <sup>51, 52</sup>	1 (7/31)	22.6%
Gastrointestinal symptoms <sup>51, 52</sup>	1 (4/25)	16%

Harm/Adverse Event <sup>a</sup>	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Pain <sup>51, 52</sup>	1 (2/25)	8%
<b>Risperidone, 0.125-0.175mg/day</b>		
Infection/fever/cold/congestion symptoms <sup>51, 52</sup>	1 (8/24)	33.3%
Gastrointestinal symptoms <sup>51, 52</sup>	1 (4/24)	16.7%
Somnolence <sup>51, 52</sup>	1 (3/30)	10%
Appetite increase <sup>51, 52</sup>	1 (2/24)	8%
EPS/impaired movement <sup>51, 52</sup>	1 (2/24)	8%
Insomnia <sup>51, 52</sup>	1 (2/24)	8%
<b>Risperidone (0.01 – 0.08 mg/kg/day)</b>		
Gastrointestinal symptoms <sup>101</sup>	1 (3/13)	23.1%
Urinary changes <sup>101</sup>	1 (3/13)	23.1%
Infection/fever/cold/congestion symptoms <sup>101</sup>	1 (7/13)	53.8%
<b>Risperidone (0.5 – 3.5 mg/kg/day)</b>		
Appetite increase (mild) <sup>102</sup>	1 (13/26)	49%
Appetite increase (moderate) <sup>102</sup>	1 (3/12)	8%
Anxiety (mild) <sup>102</sup>	1 (8/12)	7%-1%
Anxiety (moderate) <sup>102</sup>	1 (1/12)	7%
Fatigue (mild) <sup>102</sup>	1 (8/12)	32%
Fatigue (moderate) <sup>102</sup>	1 (1/12)	3%
Thirst <sup>102</sup>	1 (7/12)	26%
Urinary changes <sup>102</sup>	1 (5/12)	19%
Insomnia <sup>102</sup>	1 (4/12)	17%
Headache <sup>102</sup>	1 (3/12)	13%
Infection/fever/cold/congestion symptoms <sup>102</sup>	1 (3/12)	11%
Gastrointestinal symptoms <sup>102</sup>	1 (6/12)	10%
Drooling/increased saliva <sup>102</sup>	1 (3/12)	10%
<b>Risperidone (up to 3 mg/kg/day)</b>		
Appetite increase <sup>47, 50</sup>	2 (19/34)	50%-53%
Abnormal behavior <sup>47</sup>	1 (3/15)	20%
Agitation/nervousness/restlessness <sup>50</sup>	1 (1/19)	4%
Anxiety <sup>50</sup>	1 (1/19)	4%
Drooling/increased saliva <sup>47, 50</sup>	2 (3/34)	6.7%-9%
Dry mouth <sup>50</sup>	1 (3/19)	13%
Enuresis <sup>47, 50</sup>	2 (6/34)	13.3%-18%
EPS/impaired movement <sup>50</sup>	1 (1/19)	4%
Fatigue <sup>47</sup>	1 (1/15)	6.7%
Gastrointestinal symptoms <sup>50</sup>	1 (1/19)	4%
Infection/fever/cold/congestion symptoms <sup>47</sup>	1 (5/15)	6.7%-26.7%
Somnolence <sup>47, 50</sup>	2 (11/34)	27%-33.3%
Weight gain <sup>50</sup>	1 (8/19)	42%
<b>Placebo</b>		
Agitation/nervousness/restlessness <sup>51, 52</sup>	1 (2/30)	7%
Appetite increase <sup>51, 52, 112, 113</sup>	2 (11/69)	15.9%
Challenging behavior <sup>51, 52</sup>	1 (3/35)	9%
EPS/impaired movement <sup>51, 52, 112, 113</sup>	2 (4/58)	6.9%
Gastrointestinal <sup>48, 51, 52, 112, 113</sup>	3 (20/117)	17.1%
Headache <sup>51, 52, 112, 113</sup>	2 (9/74)	12.2%
Infection/fever/cold/congestion symptoms <sup>48, 51, 52, 112, 113</sup>	3 (35/112)	31.3%
Insomnia <sup>51, 52, 112, 113</sup>	2 (9/74)	12.2%
Somnolence <sup>51, 52, 112, 113</sup>	2 (15/74)	20.3%
Urinary changes <sup>51, 52</sup>	1 (2/30)	7%

<sup>a</sup>Harms reported by more than one participant; EPS = Extrapyramidal Symptoms; kg = kilograms; mg = milligrams; N = number

**Aripiprazole.** Table 12 outlines harms reported in study arms addressing aripiprazole. Harms reported across studies included weight gain, appetite changes, lethargy, and extrapyramidal

symptoms. Across studies 34 children withdrew due to adverse events. Some studies reported comparative analyses of harms data: in an analysis of harms reported in two 8-week trials<sup>20, 21</sup> of aripiprazole vs. placebo, the percentage of patients who discontinued due to at least adverse event with aripiprazole was 10.4 percent compared with 6.9 percent in the placebo groups.<sup>19</sup> The most common adverse events reported in the aripiprazole groups compared with placebo were: sedation (10.4% vs. 4.0%), fatigue (16.5% vs. 2.0%), vomiting (13.7% vs 6.9%), increased appetite (12.7% vs. 6.9%), somnolence (10.4% vs. 4.0%), and tremor (9.9% vs. 0.0%). Younger children (6-12 years) had a higher group rate of salivary hypersecretion in the aripiprazole group (6.6% vs 0% in the placebo group), but older children (13-17 years) did not. The majority of adverse events had a peak incidence of onset at week 1 or 2, except for nasopharyngitis and tremor, which had a peak incidence at week 3, extrapyramidal disorder and aggression at week 4, drooling at week 5, diarrhea at weeks 2 and 5, enuresis and upper respiratory tract infection at week 6 and cough at week 7. Investigators rated most adverse events as mild or moderate. Most of the adverse events rated as severe were in the younger (6-12 years) subgroup, with one event of severe fatigue in the 13-17 age group. Fatigue was the only adverse event that showed a statistically significant dose-response relationship, with 3.8 percent reporting fatigue at 5mg/d, 22 percent at 10mg/d and 18.5 percent at 15mg/d. The adjusted mean change (last observation carried forward) in body weight was higher in the aripiprazole group (1.6 kg) than the placebo group (0.4 kg) ( $p < 0.001$ ). The median change in BMI (0.7 vs. 0.2 kg/m<sup>2</sup>) was also higher in the aripiprazole group than the placebo group. Extrapyramidal-related adverse events were also more frequent in the aripiprazole group (20.8% vs. 9.9%). The most common extrapyramidal-related adverse events were tremor (9.9% vs 0% in placebo) and extrapyramidal disorder (6.1% vs 0% in placebo).

In the 52-week open label extension of these trials, 286 of 330 patients (86.7%) reported adverse events.<sup>18</sup> Discontinuations were significant in the three groups: 36 percent of de novo patients discontinued, 47.1 percent of prior placebo patients discontinued, and 38.5 percent of prior aripiprazole patients discontinued. Common reasons for discontinuation were adverse events, withdrawal of consent, lost to follow up and lack of efficacy. The most common adverse events reported from the three groups combined were weight increased (23%), vomiting (18.8%), nasopharyngitis (13.3%), increased appetite (13.0%), pyrexia (11.8%), upper respiratory tract infection (11.5%), insomnia (10.0%), headache (9.7%), cough (9.4%), diarrhea (9.1%), aggression (8.8%), sedation (8.2%) and fatigue (7.0%). Drooling, agitation, epistaxis, ear infection, nasal congestion, sinusitis, and constipation were also reported in >5% of patients.

In another RCT, 56.4 percent of children in the aripiprazole group reported a treatment-emergent adverse event compared with 32.6 percent of the placebo group. Adverse events reported by at least 5 percent of participants and at least twice the rate of placebo included upper respiratory tract infections (10.3% for aripiprazole vs. 2.3% for placebo), constipation (5.1% for aripiprazole vs. 0% for placebo), and movement disorder (5.1% for aripiprazole vs. 0% for placebo,  $p = \text{NR}$ ). Weight change was 0.15 standard deviations greater in the aripiprazole group compared with placebo (mean gain of 2.2kg vs. 0.6kg,  $p = 0.001$ ). Fasting metabolic measurements were not different between groups, but the mean change in prolactin showed a difference of -4.8 (95% CI: -6.8 to -2.9; -0.2ng/ml for aripiprazole and 4.6ng/ml for placebo).<sup>48</sup>



**Table 12. Harms/adverse events reported by study phase in aripiprazole “family” studies**

Treatment Duration	Aripiprazole: Fixed Dose+Flexible Dose, 8 weeks <sup>19</sup> (n=212 <sup>a</sup> ) N (%)	Aripiprazole: 52 week open label extension <sup>18</sup> (n=330) N (%)	Placebo: 8 weeks <sup>19</sup> (n=101) N (%)
Agitation/nervousness/restlessness	NR	21 (6.4)	NR
Anxiety	NR	13 (3.9)	NR
Appetite increase	27 (12.7)	43 (13.0)	7 (6.9)
Appetite decrease	14 (6.6)	15 (4.5)	2 (2.0)
Challenging behavior	6 (2.8)	44 (13.3)	7 (6.9)
Drooling/increased saliva	31 (14.7)	22 (6.7)	1 (1.0)
Epistaxis	NR	21 (6.4)	NR
EPS/impaired movement	34 (16.0)	16 (4.8)	0
Gastrointestinal symptoms	56 (26.4)	132 (40.0)	20 (19.8)
Headache	16 (7.5)	32 (9.7)	10 (9.9)
Infection/fever/cold/congestion symptoms	56 (26.4)	220 (70.8)	16 (16.0)
Insomnia	11 (5.2)	33 (10.0)	11 (10.9)
Lethargy	10 (4.7)	10 (3.0)	0
Menstrual	NR	1 (2.3)	NR
Skin changes	NR	15 (4.5)	NR
Somnolence	101 (47.7)	63 (19.1)	10 (10.0)
Urinary changes	7 (3.3)	15 (4.5)	5 (5.0)
Weight gain	NR	76 (23.0)	NR

<sup>a</sup>Study reported only events occurring in at least 5% of participants. EPS = extrapyramidal symptoms; N = number; NR = not reported

Harms reported in other studies of aripiprazole were similar (Table 13).

**Table 13. Harms/adverse effects in other studies of aripiprazole**

Harm/Adverse Event <sup>a</sup>	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Appetite decrease <sup>49</sup>	1 (6/29)	20.7%
EPS/impaired movement <sup>48, 49</sup>	2 (14/68)	20.6%
Weight gain <sup>50</sup>	1 (4/18)	18%
Skin changes <sup>49</sup>	1 (4/29)	13.8%
Infection/fever/cold/congestion symptoms <sup>48</sup>	1 (4/39)	10.3%
Enuresis <sup>50</sup>	1 (2/18)	9%
Somnolence <sup>49, 50</sup>	2 (15/47)	18%-37.9%
Appetite increase <sup>49, 50</sup>	2 (15/47)	22%-34.5%
Drooling/increased saliva <sup>49, 50</sup>	2 (10/47)	4%-31%
Gastrointestinal symptoms <sup>48-50</sup>	3 (16/86)	9%-20.6%
Agitation/nervousness/restlessness <sup>49, 50</sup>	2 (4/47)	4%-10.3%
Dry mouth <sup>49, 50</sup>	2 (4/47)	6.9%-9%
Heart rate changes <sup>49</sup>	1 (2/29)	6.9%
Anxiety <sup>50</sup>	1 (1/18)	4%
Dizziness <sup>50</sup>	1 (1/18)	4%
Insomnia <sup>50</sup>	1 (1/18)	4%

<sup>a</sup>Harms reported by more than one participant. EPS = extrapyramidal symptoms; N = number

**Risperidone Versus Aripiprazole.** In one RCT the three most common side effects in both groups were increased appetite, weight gain and drowsiness.<sup>50</sup> Differences in changes in height, weight gain, BMI and blood glucose between the two groups were not statistically significant, while prolactin increased in the risperidone arm compared with aripiprazole (mean increase from 167.5± 80 to 464± 190 in the risperidone group, mean decrease from 158.2± 70.2 to 127.5± 75.1 in the aripiprazole group, p<0.001). One retrospective cohort study compared these agents in 142 children, all of whom were relatively overweight at baseline (BMI Z scores of 0.67±1.44 in children receiving risperidone and 0.64±1.94 in those receiving aripiprazole, p=ns).<sup>122</sup> Children taking aripiprazole were older than those taking risperidone at baseline (9.74±3.46 years vs. 8.41±3.59, p=0.03), and children taking risperidone had a longer mean treatment duration (2.37±2.55 vs. 1.47±1.21 years, p=0.01). Other demographic characteristics and use of concomitant medications did not differ significantly between groups. Both groups gained weight over time (significant increases in BMI and BMI Z-scores in each group), with no significant group differences in BMI change per year of treatment (2.36±3.80 in risperidone group vs. 2.05±5.02 for aripiprazole, p=0.68) or BMI Z-score change per year of treatment (0.53±1.21 for risperidone vs. 0.56±2.21 for aripiprazole, p=0.91). Investigators note that the study was underpowered to detect differences in Z-scores. In another RCT, four children withdrew from the study because of adverse events.<sup>49</sup>

**Risperidone Versus Haloperidol.** Alanine amino transferase (ALT) was increased in the haloperidol group and decreased in the risperidone group (p=0.04) and prolactin increased more in the risperidone group vs. the haloperidol group (p=0.01). Both groups experienced weight gain (risperidone increase from 33.3kg ± 9.1 to 37.6 ± 9.8, haloperidol 42.1± 17.9 to 46.7 ± 18, p=NS), constipation, enuresis, and upper respiratory tract infections.

# Studies of Medications Used To Treat ADHD

## Key Points

- Both RCTs addressing methylphenidate reported significant improvements in hyperactivity in children treated with medium to high doses compared with placebo. One RCT also noted significant treatment effects on inattention. Harms were frequent and included challenging behavior, anxiety, and appetite changes.
- Methylphenidate improved hyperactivity vs. placebo and was associated with clinically significant harms. Our confidence in these conclusions is low as studies were small and short term (low strength of evidence). Data were inadequate to assess effects on social communication and oppositional behavior (insufficient strength of evidence).
- Studies of atomoxetine compared with placebo reported promising findings related to improvements in hyperactivity in children with ASD and ADHD with clinically moderate adverse effects.
- We found positive effects of atomoxetine compared with placebo on hyperactivity in children with ASD and ADHD and moderate harms. Our confidence in these conclusions is low (low strength of evidence). Data were inadequate to assess effects on inattention as studies reported inconsistent findings (insufficient strength of evidence).
- One RCT of guanfacine reported significant improvements in hyperactivity in treated participants compared with the placebo group and no significant group differences in measures of cognitive skills. Harms included drowsiness and fatigue.
- Data were inadequate to assess effects of guanfacine given the small sample size and short-term assessment in one RCT (insufficient strength of evidence).

## Overview of the Literature

We identified five RCTs (reported in multiple publications) addressing medications for ADHD.<sup>24-27, 40-46</sup> Two RCTs addressed methylphenidate<sup>24-27, 45</sup> One study, conducted by the RUPP network, was included in our 2011 review.<sup>24-27</sup> Two RCTs assessed atomoxetine.<sup>40-44</sup> We describe effectiveness outcomes reported in another RCT comparing atomoxetine with and without parent training and placebo with and without parent training<sup>54, 55</sup> in the section on Studies Addressing Combined Medical and Behavioral Treatments but report harms data from this study with other atomoxetine studies. Finally, one RCT evaluated guanfacine,<sup>46</sup>

Studies included a total of 265 children between the ages of 5 and 17. Four RCTs had low risk of bias,<sup>24-27, 41-45</sup> and one had moderate.<sup>40</sup> Studies were conducted in the United States<sup>24-27, 40, 45, 46</sup> Treatment duration ranged from 4 to 28 weeks, with one trial including a 4-week randomized phase and an 8-week open label continuation phase<sup>24-27</sup> and another including 8 weeks of treatment followed by a 20-week open label phase.<sup>41-44</sup>

## Detailed Analysis

Studies of methylphenidate, atomoxetine, and guanfacine reported improvements in hyperactivity and other challenging behaviors with treatment compared with placebo (Table 14). Side effects were associated with all agents, including aggressive behavior and appetite changes (methylphenidate); irritability and gastrointestinal symptoms (atomoxetine); and gastrointestinal symptoms and somnolence (guanfacine).

**Methylphenidate.** The RUPP Autism Network’s double-blind cross-over trial of methylphenidate compared a one-day placebo followed by two days at each of three (low, medium, high) test doses of methylphenidate;<sup>25-27</sup> doses ranged from 7.5 mg/day to 50.0 mg/day. Children tolerating methylphenidate (n=66) moved on to a 4-week, double-blind crossover phase. Children with a positive response in the double blind phase (n=34) completed an 8-week open-label continuation phase at their best dose. The primary outcome measure was hyperactivity as assessed by the ABC teacher-rated hyperactivity subscale; secondary measures included the ABC parent-rated hyperactivity subscale. Blinded clinicians also assessed participants using the Clinical Global Impression (CGI)-Irritability scale; investigators combined this subscale and the ABC parent and teacher rated hyperactivity subscales to assess response (Table 14).

In the double-blind crossover phase, all methylphenidate doses demonstrated effects that were statistically superior to placebo, and effect sizes favored the medium dose for parent ratings and high dose for teacher ratings. Parent-rated lethargy/ social withdrawal significantly worsened during the high dose of methylphenidate compared with placebo. Parent-rated stereotypy and inappropriate speech scores improved significantly at the medium dose of methylphenidate compared with placebo. Hyperactivity/impulsivity also improved more with the medium and high methylphenidate doses than at the low dose. Significantly more joint attention behaviors occurred in the intervention group both at the best methylphenidate dose and at the low dose compared with placebo. Self-regulation, as assessed in a “competing demands” task, improved in low dose as well as in medium dose methylphenidate compared with placebo, and neutral affect significantly increased at the medium and high dose, which could be either beneficial, in the case of children with a labile mood, or damaging, in the case of children with flattened affect due to a medication side effect.<sup>25-27</sup>

In another 4-week RCT comparing extended release methylphenidate and placebo in children with ASD and significant ADHD symptoms with higher IQs (mean=85±16.8), children in the treatment group received extended release methylphenidate (low, medium, or high doses) in the morning and immediate release methylphenidate in the afternoon.<sup>45</sup> Parent-rated measures of attention, ASD symptoms, hyperactivity and impulsivity improved significantly more at higher doses compared with lower doses and with placebo, and teachers reported significant improvements in hyperactivity, inattention and impulsivity at higher doses compared with lower doses and with placebo. Teachers (but not parents) also reported significant improvements in oppositional behavior with high dose methylphenidate compared with placebo. Neither teachers nor parents reported significant group differences in measures of emotional lability or social communication. Clinician-rated severity was significantly improved at all methylphenidate doses compared with placebo.

**Atomoxetine.** Two RCTs of atomoxetine reported significant treatment-related improvements compared with placebo that were maintained over 20 weeks of open label, uncontrolled treatment in one study; inattention was significantly improved in one study, and side effects were generally moderate (Table 16). In one low risk of bias RCT (reported in multiple publications), the initial study phase included participants with ASD and ADHD and compared atomoxetine with placebo.<sup>41-44</sup> After 8 weeks of treatment, the atomoxetine group improved significantly more on the clinician-rated ADHD Rating Scale total score and on the inattention and hyperactivity/impulsivity subscales (p values ≤ 0.003). Nine of 48 treatment group participants and 4/49 placebo group were considered very much or much improved in the CGI-ADHD-I

( $p=ns$ ). Scores on only the hyperactivity subscale of the Conners Teacher Rating Scale were significantly different between groups (difference in least square means: -2.0 [95% CI: -3.7 to -0.3],  $p=0.02$ ). Children in the atomoxetine arm also had greater improvements on the ABC Hyperactivity, Inappropriate Speech, and Stereotypic Behavior (but not other subscales) than did children receiving placebo ( $p$  values  $<0.05$ , effect sizes of 0.4 to 0.6). Scores on the Children's Social Behavior Questionnaire did not differ between groups. Response inhibition (as measured using a go-no go task) improved significantly in the atomoxetine group versus placebo but distractibility did not.<sup>41</sup>

In a 20-week open label extension including 88 children from the 8-week study (42 from the treatment group and 46 from placebo), overall scores on the ADHD Rating Scale improved from the 8-week baseline to the 28 week followup ( $p=0.015$ ); changes on the inattention subscale were not significant.

An earlier 6-week crossover RCT (moderate risk of bias) including children with ASD and ADHD reported significant improvements in hyperactivity associated with atomoxetine compared with placebo (effect size=0.90,  $p=0.04$ ), but changes in inattention measures were not significantly different between groups.<sup>40</sup> Investigators considered seven children (43%) to be responders to atomoxetine (25% improvement in ABC-Hyperactivity scale and CGI rating of very much improved or improved). Table 14 outlines outcomes.

**Guanfacine.** One RCT evaluating extended release guanfacine included mostly males with ASD and hyperactivity, impulsiveness, and distractibility and reported significant improvements in hyperactivity (effect size=1.67,  $p<0.001$ ) in the treated group compared with placebo.<sup>46</sup> Cognitive tests of working memory did not differ between groups (Table 14).

**Table 14. Key outcomes in studies of ADHD medications**

<p><b>Author, Year, Study Design</b></p> <p><b>Groups (dose), N enrollment / N Final</b></p> <p><b>Treatment Duration</b></p> <p><b>Risk of Bias</b></p>	<p><b>Baseline Scores, Mean ±SD</b></p>	<p><b>Post-Treatment Scores, Mean ± SD</b></p>
<p><b>Methylphenidate</b></p>		
<p>McCracken 2014<sup>24-27</sup> RCT (crossover)</p> <p>Total N=66 G1: MPH - low dose (0.125 mg/kg), 66/45 G2: Methylphenidate - medium dose (0.250 mg/kg), 66/52 G3: MPH - high dose 0.500 mg/kg (), 66/33 G4: MPH - optimal dose (NR), 66/58 G5: Placebo (NA), 66/46</p> <p>13 weeks/EOT</p> <p>Low ROB</p>	<p>Overall ratings: CGI severity sub-scale rating, n (%): Moderately ill: 20 (30.3) Markedly ill: 35 (52.0) Severely ill: 11 (16.7)</p> <p>ABC score, parent-rated, mean ± SD (range):† Irritability: 16.9 ± 10.1 (0-41) Lethargy/social withdrawal: 12.1 ± 8.9 (0-33) Stereotypy: 7.6 ± 5.9 (0-21) Hyperactivity: 33.2 ± 8.7 (2-47) Inappropriate speech: 6.0 ± 4.1 (0-12)</p> <p>ABC score, teacher-rated, mean ± SD (range):† Irritability: 16.1 ± 9.4 (0-43) Lethargy/social withdrawal: 15.5 ± 10.9 (0-42) Stereotypy: 7.6 ± 5.1 (0-19) Hyperactivity: 30.9 ± 7.9 (16-45) Inappropriate speech: 5.8 ± 3.6 (0-12)</p>	<p>ABC-hyperactivity subscale score, mean ± SD: Parent-rated: G1: 23.0 ± 11.29 G2: 20.6 ± 10.27 G3: 22.1 ± 9.67 G4: 17.2 ± 9.87 G5: 26.0 ± 9.90 G1 vs. G5: p = 0.03 (ES = 0.29) G2 vs. G5: p &lt; 0.001 (ES = 0.54) G3 vs. G5: p = 0.003 (ES = 0.40) G4 vs. G5: p &lt; 0.001 (ES = 0.89) Teacher-rated: G1: 22.9 ± 12.84 G2: 23.6 ± 12.53 G3: 20.3 ± 11.94 G4: 20.1 ± 12.40 G5: 26.0 ± 11.66 G1 vs. G5: p = 0.03 (ES = 0.25) G2 vs. G5: p = 0.008 (ES = 0.20) G3 vs. G5: p = 0.002 (ES = 0.48) G4 vs. G5: p &lt; 0.001 (ES = 0.48)</p>
<p>Pearson 2013<sup>45</sup> RCT (crossover)</p> <p>G1: MPH - low dose (0.125 mg/kg), 24/24 G2: MPH - medium dose (0.250 mg/kg), 24/24 G3: MPH - high dose (0.500 mg/kg), 24/24 G4: Placebo, 24/24</p> <p>4 weeks/EOT</p> <p>Low ROB</p>	<p>ABC NR</p>	<p><b>EOT</b></p> <p>Parent Ratings ABC-Irritability G1: 10 ± 9.2 G2: 8.2 ± 8.1 G3: 7.2 ± 6.9 G4: 12.6 ± 10.4</p> <p>ABC-Social Withdrawal/Lethargy G1: 7.3 ± 5.6 G2: 8.1 ± 5.9 G3: 8.5 ± 6.6 G4: 9.3 ± 8.1</p> <p>ABC-Stereotypy G1: 4.3 ± 4.5 G2: 4 ± 3.8 G3: 3.5 ± 3.8 G4: 4.9 ± 5.4</p>

<p><b>Author, Year, Study Design</b></p> <p><b>Groups (dose), N enrollment / N Final</b></p> <p><b>Treatment Duration</b></p> <p><b>Risk of Bias</b></p>	<p><b>Baseline Scores, Mean ±SD</b></p>	<p><b>Post-Treatment Scores, Mean ± SD</b></p>
		<p>ABC-Hyperactivity G1: 18.1 ± 10.5 G2: 14.5 ± 7.7 G3: 14.5 ± 9.2 G4: 24.1 ± 13</p> <p>ABC-Inappropriate Speech G1: 4.3 ± 3.2 G2: 4 ± 3.1 G3: 3.9 ± 3.1 G4: 5.2 ± 3.1</p> <p>CGI-Severity (clinician 1) G1: 4 ± 0.81 G2: 3.8 ± 0.82 G3: 3.8 ± 0.74 G4: 4.8 ± 0.61</p> <p>CGI-Improvement (clinician 1) G1: 2.8 ± 1.3 G2: 2.4 ± 1.3 G3: 2.1 ± 1.2 G4: 4 ± 0.81</p> <p>CGI-Severity (clinician 2) G1: 4 ± 0.72 G2: 4 ± 0.62 G3: 3.9 ± 0.74 G4: 4.7 ± 0.76</p> <p>CGI-Improvement (clinician 2) G1: 2.8 ± 1.4 G2: 2.6 ± 1.3 G3: 2 ± 1 G4: 4.1 ± 0.95</p>
<b>Atomoxetine</b>		
<p>Van der Meer 2013<sup>41-44</sup> RCT</p> <p>G1: Atomoxetine (1.2mg/kg/day), 48/43 G2: Placebo (NA), 49/46</p> <p>8 weeks/EOT</p> <p>Low ROB</p>	<p>ADHD Rating Scale – Total Score G1: 40.7 ± 7.5 G2: 38.6 ± 8.4</p> <p>ADHD Rating Scale – Inattention G1: 20.7 ± 3.9 G2: 20.6 ± 4.6</p> <p>ADHD Rating Scale – Hyperactivity/impulsivity G1: 20.0 ± 5.3 G2: 17.9 ± 6.1</p> <p>CTRS-R:S – Oppositional G1: 4.1 ± 3.5 G2: 3.6 ± 3.5</p>	<p><b>EOT (8 wks)</b></p> <p>ADHD Rating Scale – Total Score G1: 31.2 (29.2-33.9) G2: 38.3 (36.0-40.5) G1 vs. G2: p&lt;0.001</p> <p>ADHD Rating Scale – Inattention G1: 17.0 (15.7-18.4) G2: 19.9 (18.7-21.1) G1 vs. G2: p=0.002</p> <p>ADHD Rating Scale – Hyperactivity/impulsivity G1: 14.2 (12.8-15.7) G2: 18.4 (17.0-19.7) G1 vs. G2: p=0.001</p> <p>CTRS-R:S – Oppositional</p>

<b>Author, Year, Study Design</b>  <b>Groups (dose), N enrollment / N Final</b>  <b>Treatment Duration</b>  <b>Risk of Bias</b>	<b>Baseline Scores, Mean ±SD</b>	<b>Post-Treatment Scores, Mean ± SD</b>
	<p>CTRS-R:S – Hyperactivity G1: 8.8 ± 5.5 G2: 8.2 ± 5.1</p> <p>CTRS-R:S – Cognitive/Attention G1: 6.8 ± 4.5 G2: 4.8 ± 3.7</p> <p>CTRS-R:S – ADHD G1: 18.5 ± 9.3 G2: 18.1 ± 7.5</p> <p>Go/No-Go Task – Proportion false alarms G1: 0.07 ± 0.1 G2: 0.06 ± 0.08</p> <p>Missed Go Signals – Proportion misses G1: 0.02 ± 0.06 G2: 0.02 ± 0.05</p> <p>Response Time G1: 532.7 ± 144.9 G2: 485 ± 120.7</p> <p>Response Time Variability G1: 125.1 ± 64 G2: 120 ± 77.2</p> <p>ABC – Irritability G1: 17.3 ± 9.1 G2: 16.2 ± 9.5</p> <p>ABC – Lethargy/Social Withdrawal G1: 12.5 ± 8.4 G2: 12.5 ± 8</p> <p>ABC – Stereotypic Behavior G1: 6.5 ± 5.1 G2: 4.1 ± 4.5</p> <p>ABC – Hyperactivity G1: 28.4 ± 9.3 G2: 25.4 ± 11.5</p> <p>ABC – Inappropriate Speech G1: 4.7 ± 3.2 G2: 4.6 ± 3.4</p> <p>CSBQ – Total Score G1: 53.6 ± 14.8 G2: 53.1 ± 15.7</p>	<p>G1: 3.2 (2.3 - 4) G2: 3.7 (2.9 – 4.6) G1 vs. G2: p=0.37</p> <p>CTRS-R:S – Hyperactivity G1: 6.8 (5.5 - 8) G2: 8.8 (7.6 - 10) G1 vs. G2: p=0.024</p> <p>CTRS-R:S – Cognitive/Attention G1: 5.1 (4.4 – 5.8) G2: 5.8 (5.1 – 6.5) G1 vs. G2: p=0.18</p> <p>CTRS-R:S – ADHD G1: 15.1 (13 – 17.2) G2: 17.8 (15.7 – 19.8) G1 vs. G2: p=0.077</p> <p>ABC – Irritability G1: 14.6 G2: 15.6 G1 vs. G2: p=0.452, d=0.2</p> <p>ABC – Lethargy/Social Withdrawal G1: 11.4 G2: 11.7 G1 vs. G2: p=0.850, d=0.0</p> <p>ABC – Stereotypic Behavior G1: 3.0 G2: 4.6 G1 vs. G2: p=0.014, d=0.5</p> <p>ABC – Hyperactivity G1: 21.2 G2: 25.6 G1 vs. G2: p=0.010, d=0.6</p> <p>ABC – Inappropriate Speech G1: 3.7 G2: 4.5 G1 vs. G2: p=0.045, d=0.4</p> <p>CSBQ – Total Score G1: 46.2 G2: 50.1 G1 vs. G2: p=0.069, d=0.4</p> <p>CGI – Very Much Improved G1: 0 (0) G2: 1 (2.2)</p> <p>CGI – Much Improved G1: 9 (20.9)</p>



<p><b>Author, Year, Study Design</b></p> <p><b>Groups (dose), N enrollment / N Final</b></p> <p><b>Treatment Duration</b></p> <p><b>Risk of Bias</b></p>	<p><b>Baseline Scores, Mean ±SD</b></p>	<p><b>Post-Treatment Scores, Mean ± SD</b></p>
		<p>G2: 3 (6.5) G1 vs. G2: p=ns</p> <p>CGI – Minimally Improved G1: 12 (27.9) G2: 6 (13)</p> <p>CGI – No Change G1: 16 (37.2) G2: 30 (65.2)</p> <p>CGI – Minimally Worse G1: 4 (9.3) G2: 3 (6.5)</p> <p>CGI – Much Worse G1: 2 (4.7) G2: 3 (6.5)</p> <p>CGI – Very Much Worse G1: 0 (0) G2: 0 (0)</p>
<p>Arnold 2006<sup>40</sup> RCT</p> <p>G1: Atomoxetine (up to 1.4mg/kg/day), 16/16 G2: Placebo (1.2 mg/kg/day), 16/16</p> <p>6 weeks/EOT (crossover)</p> <p>Moderate ROB</p>	<p>ABC – Hyperactivity G1: 24.69 ± 13.08 G2: 22.5 ± 12.87</p> <p>ABC – Irritability G1: 16 ± 9.28 G2: 14.13 ± 9.89</p> <p>ABC-Lethargy/social withdrawal G1: 8.69 ± 9.24 G2: 6.62 ± 8.36</p> <p>ABC – Stereotypic behavior G1: 7.37 ± 6.20 G2: 6.19 ± 5.86</p> <p>ABC – Inappropriate speech G1: 5.75 ± 3.38 G2: 5.43 ± 3.16</p> <p>CGI-Severity G1 + G2: 4.69 ± 0.60</p> <p>Repetitive behavior scales – Total score G1: 53.12 ± 22.2 G2: 49.06 ± 21.54</p>	<p><b>Week 6</b></p> <p>ABC – Hyperactivity G1: 19.31 ± 13.42 G2: 22.37 ± 12.89 G1 vs. G2: p=0.04; ES=0.9</p> <p>ABC – Irritability G1: 13.06 ± 9.28 G2: 14.13 ± 9.89 G1 vs. G2: p=ns; ES=0.61</p> <p>ABC-Lethargy/social withdrawal G1: 6.50 ± 8 G2: 7.43 ± 9.64 G1 vs. G2: p=0.01; ES=1.18</p> <p>ABC – Stereotypic behavior G1: 4.69 ± 5.84 G2: 6.63 ± 5.8 G1 vs. G2: p=ns; ES=0.87</p> <p>ABC – Inappropriate speech G1: 4.87 ± 2.85 G2: 5.43 ± 3.16 G1 vs. G2: p=ns; ES=0.52</p> <p>CGI-Improvement (1 or 2) G1: 9 (56) G2: 4 (25)</p> <p>Repetitive behavior scales – Total score G1: 43.5 ± 23.94</p>

Author, Year, Study Design Groups (dose), N enrollment / N Final Treatment Duration Risk of Bias	Baseline Scores, Mean ±SD	Post-Treatment Scores, Mean ± SD
		G2: 45 ± 5.99 G1 vs. G2: p=ns; ES=0.09
<b>Guanfacine</b>		
Scahill 2015 <sup>46</sup> RCT G1: Extended-Release Guanfacine (1-3 mg/day), 30/26 G2: Placebo (NA), 32/28 8 weeks/EOT Low ROB	ABC-Irritability G1: 20.30 ± 9.4 G2: 18.06 ± 9.77 ABC-Social withdrawal G1: 13.60 ± 9.43 G2: 12.06 ± 9.29 ABC-Stereotypy G1: 8.53 ± 5.69 G2: 9.31 ± 5.56 ABC-Hyperactivity G1: 34.40 ± 5.35 G2: 34.25 ± 6.97 ABC-Inappropriate speech G1: 6.33 ± 3.53 G2: 6.84 ± 3.38	ABC-Irritability G1: 13.5 G2: 16.1 G1 vs. G2: p=ns ABC-Social withdrawal G1: 9.8 G2: 8.6 G1 vs. G2: p=ns ABC-Stereotypy G1: 3.6 G2: 5.9 G1 vs. G2: p=0.02 ABC-Hyperactivity G1: 19.3 G2: 29.7 G1 vs. G2: p<0.001 ABC-Inappropriate speech G1: 4.2 G2: 5.99 G1 vs. G2: p=0.004

ABC = Aberrant Behavior Checklist; ADHD = attention deficit hyperactivity disorder; CGI = Clinical Global Impressions Scale; CSBQ = Children's Social Behavior Questionnaire; CTRS = Connor's Teacher Rating Scales; EOT = end of treatment; ES = effect size; G = groups; kg = Kilograms; mg = milligrams; NA = not applicable; NS = not significant; RCT = randomized controlled trial; ROB = risk of bias; SD = standard deviation

## Harms of ADHD Medications

**Methylphenidate.** Methylphenidate was associated with changes in appetite and challenging and repetitive behavior at all doses (rates ranging from 5% to 50%) and with anxiety and insomnia (at lower doses). Five (out of 24) children discontinued an afternoon dose of medication because of irritability in one study,<sup>45</sup> and 13 of 72 discontinued a second RCT due to irritability (n=6) or other adverse effects.<sup>24-27</sup> Table 15 outlines harms.

**Table 15. Harms/adverse effects in studies of methylphenidate**

Harm/Adverse Event <sup>a</sup>	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
<b>Methylphenidate (0.125-0.21 mg/kg/day)</b>		
Repetitive language <sup>45</sup>	1 (13/24)	54.2%
EPS/impaired movement <sup>24-27, 45</sup>	2 (6/90)	4.6%-8%
Appetite decrease <sup>24-27, 45</sup>	2 (10/90)	4.6%-29%
Anxiety <sup>24-27, 45</sup>	2 (7/90)	4.6%-17%
Gastrointestinal symptoms <sup>24-27, 45</sup>	2 (6/90)	4%-7.6%
Heart rate changes <sup>24-27, 45</sup>	2 (3/90)	4%-4.6%
Headache <sup>24-27, 45</sup>	2 (4/90)	3.0%-8%
Withdrawal <sup>24-27</sup>	1 (2/66)	3.0%
Repetitive behavior <sup>24-27, 45</sup>	2 (20/90)	3%-46%
Challenging behavior <sup>24-27, 45</sup>	2 (18/90)	15.2%-33%
Insomnia <sup>24-27, 45</sup>	2 (14/90)	10.6%-50%
Depression/sadness <sup>24-27, 45</sup>	2 (3/90)	1.5%-8%
Somnolence <sup>24-27, 45</sup>	2 (2/90)	1.5%-4%
<b>Methylphenidate (0.24-0.35 mg/kg/day)</b>		
Repetitive language <sup>45</sup>	1 (12/24)	50%
Hair/skin pulling <sup>45</sup>	1 (3/24)	12.5%
Dry mouth <sup>45</sup>	1 (2/24)	8%
Staring <sup>45</sup>	1 (2/24)	8%
Withdrawal <sup>24-27</sup>	1 (4/66)	6.1%
Self-injury behavior <sup>24-27</sup>	1 (3/66)	4.6%
Somnolence <sup>24-27, 45</sup>	2 (5/90)	4%-6.1%
EPS/impaired movement <sup>24-27, 45</sup>	2 (3/90)	1.5%-8%
Challenging behavior <sup>24-27, 45</sup>	2 (25/90)	25.7%-33%
Gastrointestinal symptoms <sup>24-27, 45</sup>	2 (9/90)	7.6%-17%
Depression/sadness <sup>24-27, 45</sup>	2 (7/90)	4.6%-17%
Appetite decrease <sup>24-27, 45</sup>	2 (25/90)	24.2%-38%
Headache <sup>24-27, 45</sup>	2 (5/90)	1.5%-17%
Anxiety <sup>24-27, 45</sup>	2 (7/90)	1.5%-25%
Insomnia <sup>24-27, 45</sup>	2 (14/90)	18.2%-50%
Repetitive behavior <sup>24-27, 45</sup>	2 (16/90)	6%-50%
<b>Methylphenidate (0.27-0.50 mg/kg/day)</b>		
Repetitive language <sup>45</sup>	1 (9/24)	37.5%
Appetite decrease <sup>24-27, 45</sup>	2 (21/74)	24%-38%
Insomnia <sup>24-27, 45</sup>	2 (21/74)	24%-38%
Challenging behavior <sup>24-27, 45</sup>	2 (17/74)	20%-29%
Gastrointestinal symptoms <sup>24-27, 45</sup>	2 (10/74)	12%-12.2%
Hair/skin pulling <sup>45</sup>	1 (2/24)	8.3%
Anxiety <sup>24-27, 45</sup>	2 (6/74)	8%
Self-injury behavior <sup>24-27</sup>	1 (3/50)	6.0%
Repetitive behavior <sup>24-27, 45</sup>	2 (12/74)	6%-37%
Depression/sadness <sup>24-27, 45</sup>	2 (5/74)	4%-8%
Headache <sup>24-27, 45</sup>	2 (4/74)	4%-6%
Withdrawal <sup>24-27</sup>	1 (2/50)	4%
EPS/impaired movement <sup>24-27, 45</sup>	2 (3/74)	2%-8%
Somnolence <sup>24-27, 45</sup>	2 (2/74)	1.5%-8%

<sup>a</sup>Harms reported by more than one participant. EPS = extrapyramidal symptoms; N = number

**Atomoxetine.** During the 8-week treatment versus placebo phase in one RCT, 81.3 percent of children receiving atomoxetine compared with 65.3 percent of placebo participants reported at least one adverse event (p=ns) in one study; one child in the atomoxetine group discontinued due to fatigue.<sup>41-44</sup> Significantly more treatment than placebo participants reported nausea (14 vs. 4), decreased appetite (13 vs. 3), fatigue (11 vs. 3), and early morning awakening (5 vs. 0, all p values <0.05). In the open-label extension phase, 11 of 88 participants withdrew from the study due to adverse effects. Adverse effects occurring in more than 10 percent of participants in the first 8 weeks of treatment included upper abdominal pain (12.5%), decreased appetite (18.2%), fatigue (18.2%), headache (20.5%), and nausea (13.6%). Most harms attenuated over time: during the open label phase, only headache continued to occur in more than 10 percent of participants (14.8%).

In another RCT, more children in the atomoxetine group had gastrointestinal symptoms, fatigue, and racing heart rate (p values <0.05) than did children in the placebo group.<sup>40</sup> Four children receiving placebo had severe adverse events including restlessness, mood swings, decreased appetite; among those receiving atomoxetine severe events included rage requiring hospitalization in one child (leading to study withdrawal) and tiredness in another.

In an RCT comparing atomoxetine plus parent training with atomoxetine alone, placebo, and placebo plus parent training (see effectiveness outcomes reported in the section on Combination Medical and Behavioral Treatment), abdominal pain and decreased appetite occurred more frequently in the atomoxetine groups than in placebo groups (p values ≤0.07) as did greater issues with sleep onset (p=NS). One child in the atomoxetine group who received levetiracetam for seizures was hospitalized for a seizure, but investigators did not consider the event related to atomoxetine. Fifteen participants withdrew from the study due to adverse events, five of whom were receiving atomoxetine (8% of children receiving active medication). Table 16 outlines harms.

**Table 16. Harms/adverse effects in studies of atomoxetine**

Harm/Adverse Event <sup>a</sup>	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
<b>Atomoxetine</b>		
Somnolence <sup>40</sup>	1 (12/16)	75%
Skin changes <sup>40</sup>	1 (8/16)	67%
EPS/impaired movement <sup>40</sup>	1 (7/16)	43.8%
Constipation <sup>54, 55</sup>	1 (20/64)	31%
Abdominal pain <sup>54, 55</sup>	1 (19/64)	30%
Vomiting <sup>54, 55</sup>	1 (19/64)	28%
Dry mouth <sup>40</sup>	1 (4/16)	25%
Headache <sup>40</sup>	1 (4/16)	25%
Heart rate changes <sup>40</sup>	1 (4/16)	25%
Gastrointestinal symptoms <sup>40-44</sup>	2 (59/64)	25%-64.6%
Appetite decrease <sup>40-44, 54, 55</sup>	3 (54/128)	27.1%-75%
Insomnia <sup>40, 54, 55</sup>	2 (26/80)	22%-75%
Agitation/nervousness/restlessness <sup>40, 54, 55</sup>	2 (43/80)	42%-100%
Challenging behavior <sup>41-44, 54, 55</sup>	3 (64/128)	4.2%-88%
Diarrhea <sup>54, 55</sup>	1 (11/64)	17%
Dizziness <sup>40-44</sup>	1 (3/48)	6.3%
<b>Placebo</b>		
Gastrointestinal symptoms <sup>40</sup>	1 (14/16)	87.5%
Agitation/nervousness/restlessness <sup>40, 54, 55</sup>	2 (26/80)	16%-100

EPS/impaired movement <sup>40-44</sup>	2 (11/65)	8.2%-31%
Challenging behavior <sup>40-44, 54, 55</sup>	3 (35/129)	6.1%-81%
Appetite decrease <sup>40-44, 54, 55</sup>	3 (18/129)	6.1%-52%
Insomnia <sup>40, 54, 55</sup>	2 (11/80)	6%-44%
Abdominal pain <sup>54, 55</sup>	1 (4/64)	6%
Vomiting <sup>54, 55</sup>	1 (3/64)	5%
Constipation <sup>54, 55</sup>	1 (3/64)	5%
Headache <sup>40</sup>	1 (7/16)	44%
Somnolence <sup>40</sup>	1 (7/16)	44%
Skin changes <sup>40</sup>	1 (6/16)	38%
Diarrhea <sup>54, 55</sup>	1 (2/64)	3%
Dry mouth <sup>40</sup>	1 (4/16)	25%

Note: The Handen study<sup>54, 55</sup> collapsed harms of atomoxetine and atomoxetine plus parent training under atomoxetine and harms in the placebo and placebo plus parent training groups under placebo.

<sup>a</sup>Harms reported by more than one participant. EPS = extrapyramidal symptoms; n = number

**Guanfacine.** Guanfacine was fairly well tolerated: four children withdrew from the trial (2 for adverse events and 2 for lack of efficacy), and one child had severe aggressive behavior that resulted in patient psychiatric hospitalization. Other side effects included fatigue, decreased appetite, drowsiness, dry mouth, emotional lability, and anxiety. Heart rate and blood pressure decreased in treated patients with attenuation over time. Table 17 outlines harms.

**Table 17. Harms/adverse effects in studies of guanfacine**

Harm/Adverse Event <sup>a</sup>	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
<b>Guanfacine-extended release (1-3 mg/day)</b>		
Gastrointestinal symptoms <sup>46</sup>	1 (24/30)	80%
Somnolence <sup>46</sup>	1 (19/30)	63.3%
Challenging behavior <sup>46</sup>	1 (18/30)	60%
Appetite Decrease <sup>46</sup>	1 (13/30)	43.3%
Dry mouth <sup>46</sup>	1 (12/30)	40%
Anxiety <sup>46</sup>	1 (9/30)	30%
Energy level changes <sup>46</sup>	1 (9/30)	30%
Headache <sup>46</sup>	1 (9/30)	30%
Insomnia <sup>46</sup>	1 (9/30)	30%
Repetitive behaviors or language <sup>46</sup>	1 (6/30)	20%
Infection/fever/cold/congestion symptoms <sup>46</sup>	1 (5/30)	16.7%
Depression/sadness <sup>46</sup>	1 (4/30)	13.3%
EPS/impaired movement <sup>46</sup>	1 (4/30)	13.3%
Dizziness <sup>46</sup>	1 (3/30)	10%
Self-injury behavior <sup>46</sup>	1 (3/30)	10%
Silliness <sup>46</sup>	1 (3/30)	10%
Sleep changes <sup>46</sup>	1 (3/30)	10%
Appetite Increase <sup>46</sup>	1 (2/30)	6.7%
Eye/vision changes <sup>46</sup>	1 (2/30)	6.7%
Nightmares <sup>46</sup>	1 (2/30)	6.7%
Skin changes <sup>46</sup>	1 (2/30)	6.7%
Urinary changes <sup>46</sup>	1 (2/30)	6.7%
<b>Placebo</b>		
Repetitive language <sup>45</sup>	1 (12/24)	50%
Infection/fever/cold/congestion symptoms <sup>46</sup>	1 (7/32)	21.9%
Energy level changes <sup>46</sup>	1 (6/32)	18.8%
Staring <sup>45</sup>	1 (4/24)	17%
Silliness <sup>46</sup>	1 (5/32)	15.6%
Headache <sup>45, 46</sup>	2 (7/56)	12.5%
Skin changes <sup>46</sup>	1 (4/32)	12.5%
Somnolence <sup>45, 46</sup>	1 (7/56)	12.5%
Appetite Increase <sup>46</sup>	1 (2/32)	6.3%
Dizziness <sup>46</sup>	1 (2/32)	6.3%
Sleep changes <sup>46</sup>	1 (2/32)	6.3%
Urinary changes <sup>46</sup>	1 (2/32)	6.3%
Self-injury behavior <sup>24-27</sup>	1 (2/66)	3%
Appetite decrease <sup>24-27, 45, 46</sup>	3 (5/122)	3.0%-6.3%
Hair/skin pulling <sup>45, 46</sup>	2 (6/56)	4%-9.4%
Depression <sup>45, 46</sup>	2 (7/56)	3.1%-13%
EPS/impaired movement <sup>24-27, 45, 46</sup>	3 (4/122)	1.5%-13%
Anxiety <sup>24-27, 45, 46</sup>	3 (7/122)	3.0%-17.0%
Insomnia <sup>24-27, 45, 46</sup>	3 (10/122)	1.5%-21%
Gastrointestinal <sup>24-27, 45, 46</sup>	3 (18/122)	7.6%-34.4%
Repetitive behavior <sup>24-27, 45, 46</sup>	3 (25/122)	3%-50%
Challenging behavior <sup>24-27, 45, 46</sup>	3 (30/122)	3.0%-53.1%

<sup>a</sup>Harms reported by more than one participant. EPS = extrapyramidal symptoms; mg = milligrams; n = number

## Studies of Combined Medical and Behavioral Treatments

### Key Points

- Atomoxetine plus parent training or atomoxetine alone were both associated with improvements in ADHD, inattention, hyperactivity, noncompliance, and overall symptom severity compared with placebo, with improvements maintained over 24 weeks for most treatment responders. Differences between atomoxetine groups were not statistically significant for any outcome.
- Melatonin and melatonin plus cognitive behavioral therapy (CBT) both improved sleep-related outcomes.
- Folic acid plus Treatment and Education of Autistic and Related Communication Handicapped Children (TEACCH) treatment and folic acid alone both improved behaviors, with no statistically significant group differences.
- Bumetanide plus applied behavior analysis improved symptom severity and behavior more than applied behavior analysis alone.
- Stem cell transplantation plus rehabilitation therapy improved symptom severity, lethargy, and stereotypy more than umbilical cord blood cell transplant plus rehabilitation therapy or rehabilitation therapy alone.
- Given that combination therapies were investigated in single studies, we could not make conclusions about their effects on any outcomes (insufficient strength of evidence).

### Overview of the Literature

Three RCTs<sup>54-57</sup> and two nonrandomized trials<sup>120, 121</sup> evaluated different medical treatments in combination with behavioral compared with another treatment or placebo. Studies had low,<sup>54, 55, 57</sup> moderate,<sup>121</sup> and high risk of bias<sup>56, 120</sup> and included a total of 419 children (median=66/study) ranging in age from 3 to 14 years. One RCT comparing risperidone plus parent training with risperidone alone was included in our 2011 review but not in the present medical treatment update as it evaluates the effect of parent training;<sup>126</sup> however, it is one of the few studies to compare a combination medical and behavioral treatment.

### Detailed Analysis

**Atomoxetine.** A 10-week trial with a 24-week extension randomized children with ASD and ADHD symptoms to one of 4 arms: atomoxetine, atomoxetine plus parent training, placebo, or placebo plus parent training.<sup>54, 55</sup> Families assigned to parent training received nine 60-90 minute training sessions addressing preventing behavior problems and behavioral reinforcement. After 10 weeks of treatment over 45 percent of children in each of the atomoxetine groups met the definition of response (>30% decrease [improvement] on measures of ADHD and symptom severity) compared with 29 percent in the placebo plus parent training group and 19 percent in the placebo group ( $p=0.015$  for atomoxetine vs. placebo). More children in the atomoxetine groups improved on measures of noncompliance but differences compared with the placebo group were not statistically significant. Parent ratings of inattention, hyperactivity, and ADHD were significantly improved in active treatment groups compared with placebo alone ( $p$  values  $\leq 0.05$ ); teacher ratings improved in all groups from baseline to followup but group differences were not significant. Both parents and teachers rated children in the atomoxetine groups as significantly improved compared with the placebo group on noncompliance (Home Situations

Questionnaire) (p values  $\leq 0.05$ ). Parents also rated children in the placebo plus parent training group as significantly improved on the ABC-Hyperactivity and Inappropriate Speech scales compared with placebo alone (p values  $\leq 0.05$ ). Differences between the atomoxetine plus parent training and atomoxetine alone groups were not statistically significant for any outcomes.

After 10 weeks of treatment, 117 of the 128 children in the 10-week trial entered a 24-week extension. Atomoxetine responders and nonresponders who originally been assigned to a placebo group continued or began atomoxetine and maintained parent training if originally assigned to it in the 10-week trial. At followup, analyses of the effects of parent training vs. no parent training showed no significant group differences on measures of symptom severity, ADHD, inattention, hyperactivity, and parent-rated irritability and hyperactivity, though improvements were typically greater with parent training. Twenty-six of 40 children (60%) who were responders to atomoxetine maintained response; 37 percent of placebo nonresponders had favorable ADHD outcomes and 34 percent had favorable noncompliance outcomes. Harms reported in this study are described in Table 16.

**Melatonin.** One 12-week RCT with low risk of bias compared cognitive behavioral therapy (CBT) alone, melatonin alone, CBT plus melatonin, and placebo in 160 children.<sup>57</sup> CBT consisted of four 50-minute sessions focused on recognizing dysfunctional attitudes about sleep, parent-management of children's sleep, and replacing poor sleep habits with appropriate behavior. All active treatment groups improved in most measures of sleep quality compared with the control group (p<0.01). In general, the combination group improved more than the others, followed by melatonin, and CBT. Scores for children who received melatonin alone improved on bedtime resistance, sleep onset delay, sleep duration, and night waking compared with the CBT group (p<0.001). Effect sizes ranged from medium to high. Sleep onset latency (time to fall asleep) and sleep efficiency (ratio of total sleep time to total time in bed) were reduced by 50 percent (sleep latency) or 85 percent (efficiency) in 85 and 63 percent of children in the combination group and 39 and 46 percent of children in the melatonin group, respectively. In the CBT arm, 10 percent of children met each criterion, and no children in the control arm achieved these percentages of reduced latency or improved efficiency.

**Folic Acid.** One 12-week nonrandomized trial (moderate risk of bias) compared folic acid supplementation plus the TEACCH program to the TEACCH program alone and reported no statistically significant differences between groups on measures of challenging behavior, symptom severity, and teacher-rated communication, though both groups typically improved from baseline.<sup>121</sup>

**Bumetanide.** In a high risk of bias, 12-week RCT comparing bumetanide plus daily applied behavior analysis and applied behavior analysis alone, children in the combination arm had significantly improved ABC, CARS, and CGI scores (p values <0.05).<sup>56</sup>

**Stem Cell Transplantation.** In one 24-week nonrandomized trial (high risk of bias) including 37 children received either rehabilitation therapy plus umbilical cord blood cell transplant, rehabilitation therapy plus stem cell transplant (4 intravenous or intrathecal transplants at 5-7 day intervals), or rehabilitation therapy alone.<sup>120</sup> All children also received sensory integration and behavioral treatment. Symptom severity improved over time in all groups, with significantly greater improvements in the stem cell group compared with each of the other arms (p<0.05). CGI



and total ABC scores also improved more in the stem cell group compared with the other groups. Lethargy/social withdrawal and stereotypy scales improved significantly more in the stem cell group compared with the other arms ( $p < 0.05$ ), but scores on the other individual ABC scales did not differ significantly.

## Studies of Nutritional Supplements or Specialized Diets

### Key Points

- Four RCTs compared omega-3 fatty acid supplementation and placebo and three addressing the outcome reported no significant effects on challenging behaviors. Our confidence in this conclusion is low (low strength of evidence for no effect). We also have low confidence in the conclusion that omega-3 supplementation was associated with minimal harms (low strength of evidence).
- Despite the number of RCTs with low or moderate risk of bias addressing other agents, evidence was inadequate to make conclusions about all clinical efficacy and harms outcomes because few, small, underpowered studies addressed each diet or supplement (insufficient strength of evidence).
- While seven studies addressed variations of the gluten-free casein-free (GFCF) diet, studies addressed different outcomes and different approaches to restricted and control diets; thus, data were inadequate to make conclusions about the body of evidence (insufficient strength of evidence).
- Data were inadequate to allow conclusions about the relative effectiveness of the other dietary interventions (e.g., camels' milk, gluten- or casein-containing challenge foods) compared with placebo (insufficient strength of evidence).

### Overview of the Literature

We identified 19 RCTs (three reported in multiple publications)<sup>58-65, 80-88, 104-107, 117, 128</sup> that evaluated the use of supplements or dietary manipulation to treat ASD symptoms. Two of these studies<sup>117, 128</sup> were included in our 2011 review. Studies addressed nutritional supplements including omega-3 long-chain free fatty acid (FFA) supplementation,<sup>80-82, 84</sup> methyl-B12 supplement,<sup>83, 87</sup> digestive enzymes,<sup>85, 117</sup> and L-carnitine.<sup>86, 88</sup> Dietary interventions addressed in studies included GFCF diets,<sup>58, 62-65, 104-107</sup> gluten/casein challenge foods,<sup>59, 60</sup> and camels' milk.<sup>61</sup>

Studies were conducted in the United States,<sup>58, 60, 63, 80-83, 87, 88, 106, 107, 128</sup> Australia,<sup>117</sup> Belgium,<sup>59</sup> Denmark,<sup>64, 65</sup> Egypt,<sup>85, 86</sup> Iran,<sup>62</sup> Holland,<sup>84</sup> Norway,<sup>104, 105</sup> and Saudi Arabia.<sup>61</sup> Study treatment durations ranged from 7 days to 2 years, and sample sizes ranged from 12 to 92 (total  $N=732$ ). Followup occurred immediately post-treatment in all studies. Four RCTs had low risk of bias,<sup>58, 60, 81, 83</sup> 10 had moderate,<sup>59, 63, 80, 82, 84-87, 106, 107, 117, 128</sup> and five had high risk.<sup>61, 62, 64, 65, 88, 104, 105</sup>

### Detailed Analysis

Despite the number of RCTs with low or moderate risk of bias addressing supplements or diets, evidence is insufficient to determine their effects on any outcome in the short- or long-term. Most studies were small (median 30 total participants), short-term (ranging from 1 week to 7 months, with 24 months of treatment in one study). We provide brief summaries of reported outcomes by agent below. Appendix F includes summary tables with detailed findings.

## Studies of Nutritional Supplements

### Free Fatty Acid (Omega-3) Supplementation

Little evidence supports the effectiveness of FFA supplementation to improve core or associated ASD symptoms (Table 18). Three RCTs of omega-3 FFA versus placebo (low<sup>81</sup> and moderate<sup>80, 84</sup> risk of bias) reported no significant group differences on most measures of challenging behavior, communication, language, and adaptive behavior including the ABC, CGI, Peabody Picture Vocabulary Test, Pervasive Development Disorder Behavioral Inventory (PDD-BI), VABS, Behavior Assessment System for Children (BASC), and Social Responsiveness Scale.<sup>80, 81, 84</sup> One study reported significantly improved scores in the placebo group compared with the omega-3 group on the BASC externalizing problems scale after 6 months of treatment,<sup>84</sup> and another reported significant improvement in parent ratings of stereotypy and lethargy in children receiving omega-3 supplements compared with those receiving placebo, but teacher ratings were not significantly different.<sup>80</sup>

Another moderate risk of bias RCT of dietary docosahexanoic acid (DHA) supplementation versus placebo reported improvement in parent-rated social skills on the BASC in children receiving placebo vs. those receiving DHA, while teachers rated communication as more improved in the treatment group compared with placebo.<sup>82</sup> Scores on other measures including the CGI, ABC, and Child Development Inventory did not differ significantly between groups.

**Table 18. Key outcomes in studies of omega-3 fatty acids**

Author, Year, Study Design Groups (dose), N Enrollment / N Final Treatment Duration/Follow-up Timepoint Post-Treatment Risk of Bias	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
Mankad 2015 <sup>84</sup> RCT  G1: Omega-3 fatty acid (3.5 mL/day), 19/18 G2: Placebo, 19/19  6 months/EOT  Moderate RoB	Baseline scores NR	Change from Baseline PDDBI – Autism Composite G1: -4.5 G2: -6.4 G1 vs G2: p=ns  BASC – Externalizing G1: 3.2 G2: -3.0 G1 vs G2: p=0.02  CGI G1: NR G2: NR G1 vs G2:p=ns  VABS G1: 2.8 G2: -0.2 G1 vs G2: p=ns  Preschool Language Scale (PLS4) G1: 0.7 G2: -0.6 G1 vs G2: p=ns
Voigt 2014 <sup>82</sup> RCT  G1: Docosahexaenoic acid (DHA)	CGI-I Parent NR	CGI-I Parent <b>3 months</b> G1: 4/21 (19)

<p>(500 mg/day), 24/19 G2: Placebo, 24/15</p> <p>6 months/EOT</p> <p>Moderate ROB</p>	<p>BASC – Parent G1: 26.5 ± 7.1 G2: 30.3 ± 9.1</p> <p>BASC – Teacher G1: 32.2 ± 7.6 G2: 38.5 ± 4.3</p>	<p>G2: 5/16 (31) G1 vs G2: p=ns</p> <p><b>6 months</b> G1: 5/18 (28) G2: 2/13 (15) G1 vs G2: p=ns</p> <p>CGI-I Investigator <b>3 months</b> G1: 1/17 (6)) G2: 0/13 (0) G1 vs G2: p=ns</p> <p><b>6 months</b> G1: 0/18 (0) G2: 1/14 (7) G1 vs G2: p=ns</p> <p><b>EOT</b> BASC – Parent G1: 26.3 ± 6.8 G2: 33.3 ± 9.7 G1 vs G2: p=0.04</p> <p>BASC – Teacher G1: 33.6 ± 9.3 G2: 34.0 ± 5.6 G1 vs G2: p=0.02</p>
<p>Bent 2011<sup>81</sup> RCT</p> <p>G1: Omega-3 fatty acid (1.3 g/day), 14/13 G2: Placebo, 13/12</p> <p>12 weeks/EOT</p> <p>Low RoB</p>	<p>ABC –Hyperactivity G1: 16.8 ± 13 G2: 20.3 ± 8</p> <p>PPVT G1: 72.2 ± 28 G2: 85.8 ± 12</p> <p>EVT G1: 70.8 ± 33 G2: 86.4 ± 14</p> <p>SRS G1: 76.9 ± 11 G2: 79.0 ±</p> <p>BASC-Externalizing G1: 53.8 ± 13 G2: 66.3 ± 25</p> <p>BASC- Internalizing G1: 43.3 ± 10 G2: 50.1 ± 9</p> <p>BASC-Behavioral G1: 60.9 ± 14 G2: 65.4 ± 3</p> <p>BASC-Adaptive skill G1: 29.8 ± 9 G2: 31.9 ± 9</p> <p>BASC-Hyperactivity G1: 61.8 ± 17</p>	<p>Mean change score ABC – Hyperactivity G1: 2.7 ± 4.8 G2: 0.3 ± 7.2 G1 vs G2: p=ns</p> <p>PPVT G1: 2.7 ± 11.6 G2: 1.9 ± 12.4 G1 vs G2: p=ns</p> <p>EVT G1: 2.2 ± 7.6 G2: 5.8 ± 5.7 G1 vs G2: p=ns</p> <p>SRS G1: -0.9 ± .5 G2: 1.7 ± 7.2 G1 vs G2: p=ns</p> <p>BASC-Externalizing G1: 0.1 ± 6.7 G2: 6.6 ± 30.4 G1 vs G2: p=ns</p> <p>BASC-Internalizing G1: 0.3 ± 6.6 G2: -2.9 ± 7.6 G1 vs G2: p=ns</p> <p>BASC-Behavioral G1: -1.1 ± 6.1 G2: -2.0 ± 4.9</p>

	G2: 64.6 ± 7	G1 vs G2: p=ns  BASC-Adaptive skill G1: 1.8 ± 6.8 G2: 0.8 ± 7.1 G1 vs G2: p=ns  BASC-Hyperactivity G1: 2.1 ± 6.3 G2: 1.2 ± 5.8 G1 vs G2: p=ns
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ABC = Aberrant Behavior Checklist; BASC = Behavior Assessment System for Children; CGI = Clinical Global Impression; EOT = end of treatment; EVT = Expressive Vocabulary Test; PPVT = Peabody Picture Vocabulary Test; ROB = risk of bias; SRS = Social Responsiveness Scale

## Digestive Enzyme Supplementation

Evidence is insufficient to determine if short-term digestive enzyme supplements affect ASD core or associated symptoms. Two RCTs with moderate risk of bias addressed digestive enzyme supplements compared with placebo: one evaluated a proteolytic enzyme supplement (Peptizyde)<sup>117</sup> and the other a digestive enzyme supplement (Neo-Digestin).<sup>85</sup> The Peptizyde RCT reported no significant differences in measures of behavior, sleep quality, or gastrointestinal symptoms, and no significant differences in adverse effects.<sup>117</sup> In a 3-month trial of Neo-Digestin versus placebo, CARS scores improved significantly in the treatment group compared with placebo.<sup>85</sup>

## Other Supplements

Two RCTs with low<sup>83</sup> and moderate<sup>87</sup> risk of bias addressed methyl B12 supplementation. CGI scores improved significantly in the methyl B12 group in one RCT (effect size=0.84, p=0.005), but studies reported few other significant group differences in measures of behavior or communication.<sup>87</sup> In two RCTs addressing L-carnitine (moderate<sup>86</sup> and high<sup>88</sup> risk of bias), ASD severity scores improved significantly in the L-Carnitine group compared with placebo in one, but scores on other behavioral measures or measures of adverse effects did not differ between groups.<sup>88</sup> In the second RCT, symptom severity did not differ between groups after 6 months of treatment.<sup>86</sup>

## Studies of Dietary Manipulation

### Gluten-Free Casein-Free Diets (GFCF)

Data to assess effects of GFCF diets are limited as dietary approaches and outcome measures varied among studies as did control diets and monitoring of adherence to GFCF diets. Four RCTs (in multiple publications) compared GFCF diets to either an unaltered diet,<sup>64, 65, 104-107</sup> or a low sugar diet (Total N across studies=82).<sup>63</sup> One 12-week RCT (moderate risk of bias) reported no significant differences between groups on measures of development or behavior (Mullen Scales of Early Learning, Child Behavior Checklist), though the control group improved significantly from baseline on visual reception, withdrawal, aggression, and attention subscales (p values <0.05) Another 12-week crossover RCT (moderate risk of bias) similarly reported no significant differences between groups on measures of symptom severity or language, though parents of 7 of the 15 children participating in the study reported improvements in language.<sup>106, 107</sup> In a retrospective analysis of videotapes recorded during the study period, investigators found no significant group differences in verbal communication between children in the diet or control

groups or between children whose parents reported language improvements after the study period and those whose parents did not.

A 12-month RCT (high risk of bias) including children with urinary peptide abnormalities reported significant improvements (unblinded parent-rated questions from the Diagnosis of Psychotic Behavior in Children questionnaire) in communication, resistance to communication, social isolation, repetitive or challenging behavior, and overall impairment in children on a GFCF diet compared with those on a usual diet (p values  $\leq 0.007$ ).<sup>104, 105</sup> Children in the GFCF diet also improved significantly on tests of cognitive skills, motor skills, verbal and social communication, anxiety, and reaction to changes in environment and routine compared with control children (p values  $< 0.05$ ). Another high risk of bias RCT with 24-month followup of participants reported few differences in behavioral measures between children on a GFCF diet and those with no dietary restrictions;<sup>64, 65</sup> scores on the Autism Diagnostic Observation Schedule (ADOS) and Gilliam Autism Rating Scale improved significantly in participants in the GFCF group vs. no diet group at 12 months, but scores were not different on any measure in a subset of participants followed for 24 months.

### **Gluten-Free Diets**

One 6-week, high risk of bias RCT compared a gluten-free diet to a usual diet and reported significant improvements in gastrointestinal symptoms (stomachache, bloating, constipation) from baseline in the gluten-free diet group but not in the control group. Diarrhea did not improve significantly in either group. Stereotyped behavior, communication, social interaction, and ASD symptoms also improved from baseline in the gluten-free group (p values  $< 0.02$ ) but not in the control arm; differences in stereotyped behaviors and communication, but not social interaction, were significant between groups (p values  $\leq 0.005$ ). The study did not report other between-group comparisons.

### **Gluten-Free and Dairy-Free Diets**

In a small, low risk of bias trial comparing a gluten and dairy free diet with a diet including both gluten and dairy, scores on measures of challenging behavior (hyperactivity, irritability, inattention) did not differ between groups after 4 weeks of therapy.<sup>58</sup> Children in both groups had gastrointestinal symptoms (loose or hard stools, abdominal pain, p=NR).

### **Gluten and Casein Challenge Foods or Supplementation**

Two small RCTs (low<sup>129</sup> and moderate<sup>59</sup> risk of bias) evaluated “challenges” of gluten or casein containing foods, but evidence is inadequate to determine if short-term gluten- casein containing foods affect ASD symptoms or gastrointestinal function. One RCT randomized children who were maintaining GFCF diets to foods with gluten, gluten and casein, or placebo foods.<sup>60</sup> The study reported no significant group differences in measures of challenging behaviors or measures of sleep quality and stool frequency at any time point over the 30-week trial. Another RCT assessing effects of introducing gluten-casein containing foods versus placebo foods similarly reported no significant effects of added gluten or casein on behavior or gastrointestinal symptoms.<sup>59</sup>

### **Camel Milk**

A single RCT (high risk of bias) compared boiled or raw camel’s milk with cow’s milk and reported no significant differences in ASD severity between groups after 2 weeks of treatment.<sup>61</sup>

## Harms of Nutritional or Dietary Interventions

Studies that reported harms either reported no significant difference between the intervention group and the control group, or reported zero harms for each group. Appendix F includes detailed harms tables.

## Studies of Risperidone Adjuncts

### Key Points

- Though 14 RCTs with low or moderate risk of bias compared risperidone plus an adjunct medication with risperidone plus placebo, few compared the same adjunct agents. Studies thus provide little evidence to inform treatment decisions and can be considered primarily as pilot efficacy trials.
- Most studies reported improvements in irritability with combined treatment compared with placebo plus risperidone, but data were inadequate to assess effects for all comparisons and outcomes given the heterogeneity of agents (insufficient strength of evidence).

### Overview of the Literature

We identified 14 placebo-controlled RCTs addressing risperidone plus an adjunct medication (titrated to 0.5 to 3 mg/day based on body weight).<sup>89-100, 118, 124</sup> Two of these studies were included in our 2011 review.<sup>118, 124</sup> Study medications added to risperidone included celecoxib,<sup>94</sup> *Ginkgo biloba*,<sup>97</sup> memantine,<sup>95</sup> topiramate,<sup>98</sup> riluzole,<sup>91</sup> buspirone,<sup>92</sup> N-acetylcysteine,<sup>90, 93</sup> amantadine,<sup>96</sup> pioglitazone,<sup>99</sup> pentoxifylline,<sup>118</sup> galantamine,<sup>100</sup> minocycline,<sup>89</sup> and piracetam.<sup>124</sup> Studies were short-term ( $\leq 10$  weeks of treatment) with no longer term followup evaluation once treatment ended.

Studies included a total of 561 children ranging in age from 3 to 17 years. All studies were conducted in Iran.<sup>90-100, 118, 124</sup> We considered 11 studies to have low risk of bias<sup>90-100</sup> and two to have moderate risk of bias.<sup>118, 124</sup>

### Detailed Analysis

Despite the number of RCTs with low or moderate risk of bias, studies present little evidence to inform treatment decisions and can be considered primarily as pilot efficacy trials. As noted, all studies were short-term and lacked followup past the end of treatment. Studies included few participants (median 40 total/study) and few examined the same adjunct agent or outcomes besides the ABC Irritability subscale. Only two studies<sup>90, 93</sup> addressed the same outcomes with different doses of the same agent (N-acetylcysteine). All studies except one of *gingko biloba* added to risperidone reported significant improvements on the ABC-Irritability subscale in the adjunct groups compared with placebo plus risperidone; one study reporting only total ABC scores reported significant improvements in the adjunct group compared with placebo.<sup>124</sup> We present a brief summary of key outcomes in each study below; Appendix F includes detailed tables of outcomes and harms. Harms typically did not differ between groups.

**N-acetylcysteine.** Two studies<sup>90, 93</sup> compared the effect of different doses of N-acetylcysteine as an adjunctive therapy to risperidone vs. placebo plus risperidone in a total of 80 children with autistic disorder. By the end of treatment, the N-acetylcysteine groups had significantly greater reduction in irritability scores ( $p < 0.035$ ) than the placebo group in both the trials; in one RCT scores on the hyperactivity/noncompliance ( $p < 0.05$ ) subscales were also significantly improved

in the N-acetylcysteine group.<sup>90</sup> Other subscale scores did not differ between groups in either RCT. Adverse events were mild and transient, with a similar incidence in both trials.

**Celecoxib.** One RCT explored the effectiveness of adding celecoxib as an adjunct to risperidone vs. placebo plus risperidone in 40 children reported significant improvements on the ABC irritability, lethargy/social withdrawal, and stereotypy scales in the adjunct group compared with placebo plus risperidone.<sup>94</sup> Hyperactivity/noncompliance or inappropriate speech did not differ between groups. The frequency of adverse effects as reported by parents was similar between the two groups. By week 10, complete response (50% reduction in irritability subscale) was achieved by 11 of the children in the celecoxib group compared with four (20%) in the placebo group (p=0.02).

**Ginkgo Biloba.** In one RCT comparing *Ginkgo biloba* plus risperidone with risperidone plus placebo, investigators found no significant differences between groups on any of the ABC subscales. Side effects were similar between groups.

**Memantine.** One RCT reported significant reduction in ABC subscale scores for irritability, stereotypic behavior, and hyperactivity in the memantine adjunct group compared with risperidone plus placebo (all p<0.01).<sup>95</sup> No significant effects were found on the lethargy or inappropriate speech subscales. Frequency of side effects including extrapyramidal symptoms was similar between the two groups.

**Riluzole.** In one RCT including children with autistic disorder who responded suboptimally to previous medication, children treated with riluzole and risperidone had significantly greater improvement in four of the five ABC subscales (p<0.01) than those receiving placebo plus risperidone.<sup>91</sup> Based on CGI-I scores, complete response was achieved by 11 children (55%) in the riluzole group compared with five (25%) in the placebo group (p=0.05). Among the 16 side effects observed, increased appetite and weight gain were more frequently reported in the riluzole group versus the placebo group (p≤0.03). All other side effects occurred at a similar frequency in both groups.

**Buspirone.** More children receiving buspirone plus risperidone had a ≥30% reduction in irritability score (81.2% vs. 38.9%, p<0.01, RR=2.1) than those receiving placebo and risperidone. Investigators reported no serious adverse events in either group, but the odds ratio for increased appetite was 2.61 (61.1% with buspirone vs. 35.3% with placebo). Other commonly reported adverse events were drowsiness (11.1%) and fatigue (11.1%) in the buspirone group and dry mouth (5.9%) by the placebo group.

**Topiramate.** In one RCT children in the topiramate adjunct group had significantly greater reduction in ABC-C subscale scores for irritability, stereotypic behavior, and hyperactivity/noncompliance (all p=0.04) than those receiving placebo.<sup>98</sup> Frequencies of most side effects including extrapyramidal symptoms were similar, though somnolence (35% vs. 5%, p=0.04) and decreased appetite (35% vs. 5%, p=0.04) occurred more frequently in the topiramate-treated group than the placebo group.

**Amantadine.** In one RCT including children with severe disruptive symptoms, ABC-Irritability and Hyperactivity/Noncompliance scores were significantly improved in amantadine adjunct group compared with the placebo group ( $p \leq 0.03$ ).<sup>96</sup> By week 10, 17 (85%) of the children in the amantadine group compared with 13 (65%) in the placebo group had partial response (25% reduction in irritability subscale) ( $p=0.14$ ), while complete response (50% reduction in irritability score) was achieved by 7 (35%) vs. 3 (15%) in the amantadine and placebo groups respectively ( $p=ns$ ). None of the other ABC subscale scores differed between the groups by the end of treatment. Frequency of adverse effects did not differ between groups. Based on the improvement measured by CGI scale, a higher proportion of children in the amantadine group responded to treatment than those in the placebo group (50 % vs. 20%,  $p=0.047$ ), with two and eight children judged to have very much improved and much improved respectively in the amantadine group compared with one and three children in the placebo group.

**Pioglitazone.** In one RCT children receiving pioglitazone adjunct had significant improvement in the ABC Irritability ( $p=0.03$ ), Lethargy/social withdrawal ( $p=0.04$ ) and Hyperactivity/noncompliance ( $p=0.04$ ) subscale scores compared with the placebo group;<sup>99</sup> scores on other measures did not differ between groups. More children in the adjunct group also had a partial response ( $\geq 25\%$  reduction in irritability score) than did children receiving placebo (45% vs. 15%,  $p=0.04$ ). Nine children (45%) in the pioglitazone group had complete response ( $\geq 50\%$  reduction in irritability score) compared with 7 (35%) in the placebo group ( $p=ns$ ). Adverse events were mild and transient with no group differences in the frequency.

**Galantamine.** In a trial evaluating galantamine or placebo in addition to risperidone, children in the galantamine adjunct group showed significantly greater improvement in ABC-Irritability ( $p=0.017$ ) and Lethargy/social withdrawal ( $p=0.005$ ) subscales than the placebo group.<sup>100</sup> Reduction in other ABC subscale scores after treatment was similar between the groups. Sixteen children (80%) in the galantamine group had a complete response ( $\geq 50\%$  reduction in the irritability subscale score) compared with 10 (50%) in the placebo group ( $p=0.047$ ), while partial response ( $\geq 25\%$  reduction in the ABC-I subscale) was reported in 90% in the galantamine and 65% in the placebo group,  $p=0.058$ . The investigators noted no serious adverse events. Both groups reported weight gain by the end of the trial, with no significant group difference.

**Pentoxifylline.** Scores on the ABC-Irritability, Lethargy/Social Withdrawal, Stereotypic behavior, Hyperactivity/Noncompliance, and Inappropriate Speech subscales were significantly better for the pentoxifylline adjunct group compared with placebo ( $p \leq 0.0001$ ) in one RCT.<sup>118</sup> Frequency of side effects including extrapyramidal symptoms did not differ between groups.

**Piracetam.** Risperidone plus piracetam was associated with more improvement on the ABC-C total score than risperidone given with placebo in one RCT, with similar incidence of extrapyramidal symptoms and other adverse events.<sup>124</sup>

**Minocycline.** Improvements in ABC-Irritability and Hyperactivity scales were greater in children receiving minocycline+risperidone than in children receiving placebo+risperidone ( $p$  values  $\leq 0.003$ ), but scores on the other subscales did not differ significantly between groups in one RCT (low risk of bias).<sup>89</sup> Adverse events (including sedation, appetite changes, and gastrointestinal issues) did not differ between groups ( $p$  values=NS)



## Studies of Hyperbaric Oxygen Therapy

### Key Points

- Studies of hyperbaric oxygen using differing protocols reported conflicting results: no treatment effects in two RCTs and significant improvements in ASD symptoms in another.
- Data were inadequate to assess the effects of hyperbaric oxygen compared with placebo on ASD symptoms, language, or harms (insufficient strength of evidence).

### Overview of the Literature

We identified three RCTs with low<sup>67, 114</sup> and moderate<sup>66</sup> risk of bias addressing hyperbaric oxygen compared with a sham treatment. Studies were conducted in the United States<sup>67, 114</sup> and Thailand<sup>66</sup> and included a total of 150 children between 2 and 14 years old. Treatment duration ranged from 20 days to 15 weeks with followup immediately post-treatment.

### Detailed Analysis

Three RCTs of hyperbaric oxygen used different doses and reported inconsistent results (favorable effects associated with treatment in one and no significant effects in two). The RCTs included children with diagnoses of autistic disorder<sup>67, 114</sup> or autism.<sup>66</sup> Two studies used a 24 percent oxygen treatment<sup>67, 114</sup> and a third used 100 percent oxygen;<sup>66</sup> children continued concomitant treatments including behavioral and medical interventions instituted prior to the studies. Two studies of 80<sup>67</sup> or 20<sup>66</sup> hourly treatments reported no significant differences between groups on measures of symptom severity, language, and adaptive behavior.<sup>66, 67</sup> In a third RCT including 40 treatment sessions, clinician-rated overall CGI scores, parent-rated language and eye contact measures, the ABC-Irritability subscale, and the Autism Treatment Evaluation Checklist (ATEC) sensory scale improved significantly in the hyperbaric oxygen group compared with the placebo group. Other ABC or ATEC subscale scores did not differ significantly between groups.<sup>114</sup>

### Harms of Hyperbaric Oxygen

Studies typically noted that no significant harms occurred. One child had worsening asthma symptoms and discontinued treatment in one study,<sup>114</sup> while 11 children in another experienced middle ear barotrauma that did not lead to discontinuation of the treatment session or the study.<sup>66</sup> Across studies, one child withdrew due to seizures and one due to worsening asthma.

## Studies of N-acetylcysteine

### Key Points

- Two small RCTs of N-acetylcysteine reported few significant treatment effects and few clinically significant harms.
- N-acetylcysteine had no effect on social skills outcomes in two small RCTs; harms of this agent were not clinically significant. Our confidence in these conclusions is low (low strength of evidence). Data were inadequate to assess effects on other outcomes (insufficient strength of evidence).

## **Overview of the Literature**

Two RCTs with low<sup>78</sup> and moderate<sup>79</sup> risk of bias assessed N-acetylcysteine compared with placebo. Studies were conducted in the United States and Australia over 12 to 24 weeks and included a total of 123 children between 3 and 10 years old. Followup in both studies was immediately post-treatment.

## **Detailed Analysis**

In one 12-week RCT (low risk of bias) comparing the utility of N-acetylcysteine with placebo, children treated with N-acetylcysteine had significant improvement on the ABC-Irritability subscale as compared with placebo-treated children ( $p < 0.001$ );<sup>78</sup> but effects on other behavioral and social measures did not differ. A second 24-week RCT (moderate risk of bias) included 98 children randomized to N-acetylcysteine or placebo and reported no group differences on any outcome assessed including social communication, adaptive behavior, symptom severity, or repetitive behavior.<sup>79</sup> Table 19 outlines key outcomes.

**Table 19. Key outcomes in studies of N-acetylcysteine**

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow-Up Timepoint Post-Treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ± SD</b></p>	<p><b>Outcome Measure/Post-Treatment Scores, Mean ± SD</b></p>
<p>Dean 2016<sup>79</sup> RCT</p> <p>G1: N-acetylcysteine (500 mg/day), 48/34 G2: Placebo (ND),50 /37</p> <p>6 months/EOT</p> <p>Moderate ROB</p>	<p>SRS-Total Score G1: 102.9 ± 26.4 G2: 99.7 ± 24.8</p> <p>CCC-General Communication G1: 33.6 ± 13.1 G2: 34.7 ± 14.6</p> <p>CCC-Social Interaction Deviance G1: 3.1 ± 8.5 G2: 3.3 ± 6.7</p> <p>Repetitive Behavior Scale-Total Score G1: 28.5 ± 19.4 G2: 24.8 ± 14.1</p> <p>CGI-Severity G1: 4.1 ± 1 G2: 4.2 ± 1</p> <p>Developmental Behavior Checklist-Total Score G1: 57 ± 23.2 G2: 59 ± 27.6</p>	<p>SRS-Total Score G1: 92.1 ± 29.3 G2: 88.7 ± 27.7 G1 vs G2, p=ns</p> <p>CCC-General Communication G1: 34.7 ± 11.9 G2: 41.5 ± 16.5 G1 vs G2, p=ns</p> <p>CCC-Social Interaction Deviance Change Score G1: 0.05 ± 8.4 G2: -2.2 ± 8.2 G1 vs G2, p=ns</p> <p>Repetitive Behavior Scale-Total Score G1: 24.3 ± 24.3 G2: 20.8 ± 16.3 G1 vs G2, p=ns</p> <p>CGI-Severity G1: 3.9 ± 1 G2: 3.6 ± 1 G1 vs G2, p=ns</p> <p>Developmental Behavior Checklist-Total Score G1: 43.9 ± 25.2 G2: 48.2 ± 18 G1 vs G2, p=ns</p>
<p>Hardan 2012<sup>78</sup> RCT</p> <p>G1: N-acetylcysteine (900 mg up to 3 times/day), 15/134 G2: Placebo, 18/15</p> <p>12 weeks/EOT</p> <p>Low ROB</p>	<p>ABC Irritability G1: 16.9±7.9 G2: 14.8±9.6</p> <p>ABC Lethargy G1: 15.2±9.5 G2: 12.1±7.8</p> <p>ABC Stereotypy G1: 9.1±5.5 G2: 8.9±6.5</p> <p>ABC Hyperactivity G1: 23.4±9.0 G2: 23.8±9.3</p> <p>ABC Inappropriate Speech G1: 4.9±3.2 G2: 4.1±3.7</p>	<p>EOT</p> <p>ABC Irritability G1: 7.2±5.7 G2: 13.1±9.9 p&lt;.001</p> <p>ABC Lethargy G1: 11±9.4 G2: 8.3±7.7 p=.ns</p> <p>ABC Stereotypy G1: 5.6±5.7 G2: 8.0±7.0 p=ns</p> <p>ABC Hyperactivity G1: 12.4±11.4 G2: 21.0±11.5 p=ns</p>

<b>Author, Year Study Design</b>  <b>Groups (Dose), N Enrollment / N Final</b>  <b>Treatment Duration/Follow-Up Timepoint Post-Treatment</b>  <b>Risk of Bias</b>	<b>Outcome Measure/Baseline Scores, Mean ± SD</b>	<b>Outcome Measure/Post-Treatment Scores, Mean ± SD</b>
	RBS-R Stereotypies G1: 6.7±3.8 G2: 8.1±5.3  RBS Self-Injurious Behavior G1: 3.9±4.4 G2: 3.4±3.8  RBS Compulsions G1: 4.7±3.7 G2: 5.8±4.8  RBS Rituals G1: 5.3±3.7 G2: 6.6±4.5  RBS Sameness G1: 7.8±7.2 G2: 9.2±8.1  RBS Restricted G1: 4.7±3.4 G2: 5.2±3.7  SRS Total G1: 111.9±28.3 G2: 104.7±28.1  SRS Social Awareness G1: 12.7±3.4 G2: 13.5±3.7  SRS Social Cognition G1: 21.9±6.3 G2: 21.2±5.8  SRS Social Communication G1: 39.6±11.3 G2: 39.3±8.6  SRS Social Motivation G1: 16.6±6.3 G2: 16.9±6.5  SRS Autism Mannerisms G1: 21.7±5.6 G2: 21.4±7.3  CGI Severity G1: 5.1±0.7 G2: 5.3±0.8	ABC Inappropriate Speech G1: 2.5±2.6 G2: 3.6±3.6 p=ns  RBS Stereotypies G1: 4.6±3.4 G2: 6.9±5.2 p= .014  RBS Self Injurious Behavior G1: 2.2±2.3 G2: 3.0±3.6 p=ns  RBS Compulsions G1: 2.5±2.1 G2: 5.2±5.0 p=ns  RBS Rituals G1: 4.3±3.4 G2: 5.6±4.9 p=ns  RBS Sameness G1: 5.3±4.7 G2: 7.9±6.2 p=ns  RBS Restricted G1: 3.5±2.3 G2: 4.8±3.6 p=ns  SRS Total G1: 93.8±26.7 G2: 98.5±37.8 p=ns  SRS Social Awareness G1:11.5±3.3 G2: 13.4±4.7 p=ns  SRS social Cognition G1: 18.8±7.0 G2: 18.9±5.6 p=.037  SRS Social Communication

<b>Author, Year Study Design</b>  <b>Groups (Dose), N Enrollment / N Final</b>  <b>Treatment Duration/Follow-Up Timepoint Post-Treatment</b>  <b>Risk of Bias</b>	<b>Outcome Measure/Baseline Scores, Mean ± SD</b>	<b>Outcome Measure/Post-Treatment Scores, Mean ± SD</b>
		G1: 33.3±10.9 G2: 34.5±14.5 p=.ns  SRS Social Motivation G1: 13.0±4.7 G2: 14.5±7.0 p=ns  SRS Autism Mannerisms G1: 16.0±6.1 G2: 20.3±6.9 p=.045  CGI Severity G1: 4.5±0.8 G2: 4.9±0.9 p=ns  CGI Improvement G1: 2.9±1.1 G2: 3.2±.09 p=ns

ABC = Aberrant Behavior Checklist; CCC = Children’s Communication Checklist; CGI = Clinical Global Impression; EOT = end of treatment; RBS = Repetitive Behavior Scale; ROB = risk of bias; SRS = Social Responsiveness Scale

## Harms of N-acetylcysteine

Adverse events also did not differ between groups in either study, though one noted treatment discontinuation of one participant related to worsening of irritability.<sup>78</sup> Table 20 outlines harms.

**Table 20. Harms/adverse effects reported in studies of N-acetylcysteine**

Harm/Adverse Event	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
<b>N-acetylcysteine</b>		
Gastrointestinal symptoms <sup>78, 79</sup>	2 (23/48)	26.5%-100%
Agitation/nervousness/restlessness <sup>78</sup>	1 (3/14)	21.4%
EPS/impaired movement <sup>78</sup>	1 (3/14)	21.4%
Appetite decrease <sup>78</sup>	1 (2/14)	14.3%
Appetite increase <sup>78</sup>	1 (2/14)	14.3%
Skin changes <sup>79</sup>	1 (2/34)	5.9%
Asthma <sup>79</sup>	1 (1/34)	2.9%
Cysts – Unspecified <sup>79</sup>	1 (1/34)	2.9%
Infection/fever/cold/congestion symptoms <sup>78, 79</sup>	2 (20/48)	2.9%-28.6%
<b>Placebo</b>		
Appetite decrease <sup>78</sup>	1 (3/15)	20%
Drooling/increased saliva <sup>78</sup>	1 (2/15)	13.3%
Skin changes <sup>79</sup>	1 (2/37)	5.4%
Cysts – Unspecified <sup>79</sup>	1 (1/37)	2.7%
Agitation/nervousness/restlessness <sup>78, 79</sup>	1 (3/15)	6%-13%
EPS/impaired movement <sup>78</sup>	1 (3/15)	6%-13%
Gastrointestinal symptoms <sup>78, 79</sup>	2 (17/52)	6%-21%
Infection/fever/cold/congestion symptoms <sup>78, 79</sup>	2 (21/52)	2.7%-40%

EPS = extrapyramidal symptoms; N = number

## Studies of Tetrahydrobiopterin

### Key Points

- Two small RCTs reported inconsistent effects of tetrahydrobiopterin on symptom severity and few clinically significant harms.
- Tetrahydrobiopterin had no effect on symptom severity and was not associated with clinically significant harms. Our confidence in these conclusions is low (low strength of evidence). Data were inadequate to assess effects on other outcomes (insufficient strength of evidence).

### Overview of the Literature

Two RCTs with low<sup>53</sup> and moderate<sup>103</sup> risk of bias compared tetrahydrobiopterin and placebo. The studies included 56 children between 3 and 7 years old and ranged from 16 to 24 weeks duration with followup immediately post-treatment. Studies were conducted in the United States and Sweden.

### Detailed Analysis

In one 16-week RCT (low risk of bias) comparing tetrahydrobiopterin and including children with VABS developmental quotients of at least 50, children in the treatment arm had better language, adaptive behavior, and social interaction skills at baseline compared with placebo participants.<sup>53</sup> At followup immediately post-treatment, scores on the primary outcome, the CGI, were not significantly different between groups. Secondary outcomes favored the treatment group: children in the treatment group improved significantly more on the ABC Irritability, Lethargy, Stereotypy, Hyperactive and Inappropriate Speech scales; Social Responsiveness Scale

(SRS) total and subscale scores; and VABS composite and subscale measures than did children in the placebo group (p values <0.00).

In another 24-week crossover RCT (moderate risk of bias) including 12 boys, overall CARS scores did not differ significantly between group. In a post-hoc analysis grouping CARS variables into those assessing social interaction, communication, and stereotypy, children in the treatment group had significant improvement in social interaction (p=0.04) but not in the other categories.<sup>103</sup> Table 21 outlines key outcomes.

**Table 21. Key outcomes in studies of tetrahydrobiopterin**

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Timepoint Post-Treatment Risk of Bias	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
Klaiman 2013 <sup>53</sup> RCT  G1: Tetrahydrobiopterin (20mg/kg/day), 23/23 G2: Placebo (NA), 23/23  16 weeks/EOT  Low RoB	CGI-Severity [N (%)] Frequency of markedly, severely, or extremely ill G1: 10 (48) G2: 15 (68)  ABC-Irritability G1: 11.1 ± 7.7 G2: 11.9 ± 7.8  ABC-Social withdrawal/lethargy G1: 9.5 ± 7.5 G2: 16.2 ± 10.0  ABC-Stereotypy G1: 6.1 ± 3.9 G2: 6.1 ± 3.6  ABC-Hyperactivity G1: 21.5 ± 10.3 G2: 22.9 ± 11.6  ABC-Inappropriate speech G1: 3.7 ± 2.4 G2: 3.4 ± 4.1  SRS G1: 81.4 ± 10.3 G2: 83.6 ± 9.2  PLS G1: 77.8 ± 29.2 G2: 57.1 ± 25.7  VABS G1: 320.5 ± 47.9 G2: 274.4 ± 51.4	16 wks follow-up CGI-Severity [N (%)] Frequency of markedly, severely, or extremely ill G1: 7 (35) G2: 14 (64) G1 vs G2: p=ns  Improvement, frequency of very much or much improved G1: 5 (25) G2: 3 (14) G1 vs G2: p=ns  ABC-Irritability G1: 10.0 ± 7.8 G2: 10.8 ± 7.8 G1 vs G2: p=ns  ABC-Social withdrawal/lethargy G1: 5.2 ± 4.4 G2: 13.6 ± 7.5 G1 vs G2: p<0.01  ABC-Stereotypy G1: 5.4 ± 3.8 G2: 6.7 ± 4.5 G1 vs G2: p=ns  ABC-Hyperactivity G1: 18.2 ± 8.5 G2: 22.8 ± 10.3 G1 vs G2: p=ns  ABC-Inappropriate speech G1: 2.6 ± 1.9 G2: 3.9 ± 3.6 G1 vs G2: p=ns
Klaiman 2013 <sup>53</sup> RCT, continued  G1: Tetrahydrobiopterin (20mg/kg/day), 23/23 G2: Placebo (NA), 23/23		SRS G1: 76.7 ± 10.9 G2: 83.2 ± 10.4 G1 vs G2: p=ns  PLS

Author, Year Study Design Groups (Dose), N Enrollment / N Final Treatment Duration/Follow-Up Timepoint Post-Treatment Risk of Bias	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, Mean ± SD
16 weeks/EOT  Low RoB		G1: 84.0 ± 28.8 G2: 60.4 ± 25.4 G1 vs G2: p=0.01  VABS G1: 344.76 ± 50.0 G2: 294.9 ± 70.1 G1 vs G2: p=0.02
Danfors 2005 <sup>103</sup> RCT  G1: Tetrahydrobiopterin/Placebo (3mg/kg), 12 G2: Placebo/ Tetrahydrobiopterin (ND), 12  12 months/EOT  Moderate ROB	CARS-Total Score G1: 35.4 ± 2.6 G2: 37.4 ± 7.1  Social Interaction G1: 9 ± 0.6 G2: 10.8 ± 1.6	Points Decreased CARS-Total Score G1: 2.1 ± 2.1 G2: 2.1 ± 4.3 G1 vs G2, p=ns  Social Interaction G1: 1.6 ± 1.1 G2: 0.3 ± 1.4 G1 vs G2, p=0.04

ABC = Aberrant Behavior Checklist; CARS = Childhood Autism Rating Scale ; CGI = Clinical Global Impression; EOT = end of treatment; N = number; NR = not reported; NS = not significant; PLS = Preschool Language Scale; SRS = Social Responsiveness Scale; ROB = risk of bias; VABS = Vineland Adaptive Behavior Scales

## Harms of Tetrahydrobiopterin

Several children in both groups reported sleeping problems and behavioral issues, but investigators did not consider any harms to be clinically significant, and no child withdrew from either study due to adverse events. Table 22 outlines harms.



**Table 22. Harms/adverse effects reported in studies of tetrahydrobiopterin**

Harm/Adverse Event	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
<b>Tetrahydrobiopterin</b>		
Sleeping problems <sup>103</sup>	1 (4/5)	80%
Agitation/nervousness/restlessness <sup>103</sup>	1 (3/5)	60%
Challenging behavior <sup>53</sup>	1 (4/20)	22%
Hyperactivity <sup>53</sup>	1 (2/20)	9%
Insomnia <sup>53</sup>	1 (2/20)	9%
Skin changes <sup>53</sup>	1 (2/20)	9%
<b>Placebo</b>		
Sleeping problems <sup>103</sup>	1 (5/6)	83.3%
Agitation/nervousness/restlessness <sup>103</sup>	1 (3/6)	50%
Challenging behavior <sup>53</sup>	1 (4/22)	17%
Insomnia <sup>53</sup>	1 (4/22)	17%
GI symptoms <sup>53</sup>	1 (4/22)	17%
Repetitive behavior or language <sup>53</sup>	1 (2/22)	9%
Seizure <sup>53</sup>	1 (1/22)	4.5%
Hyperactivity <sup>53</sup>	1 (1/22)	4%

N = number

## Studies of Other Medical Interventions

### Key Points

- Most agents or interventions were addressed in only one study.
- While most studies reported some positive treatment effects on sleep, ASD symptoms, or language, data were inadequate to assess any comparisons given the heterogeneity of interventions (insufficient strength of evidence).

### Overview of the Literature

We categorized studies as “other” if we could not assess strength of evidence for interventions and outcomes reported (i.e., insufficient strength of evidence) and the studies did not fall under a broader category of intervention such as diet or nutritional supplements. Fourteen studies (13 RCTs and 1 retrospective cohort study) addressed other medical interventions.<sup>22, 23, 57, 68-75, 77, 100, 108, 115, 116, 123</sup>

Most agents or interventions were addressed in only one study. Two studies evaluated donepezil.<sup>77, 116</sup> Agents or interventions addressed in single studies included melatonin,<sup>68</sup> bumetanide,<sup>72</sup> transcranial stimulation (addressed in one multi-publication RCT<sup>69, 70</sup>), amantadine,<sup>115</sup> citalopram,<sup>22, 23</sup> divalproex,<sup>74</sup> oxytocin,<sup>71</sup> mecamlamine,<sup>73</sup> memantine,<sup>75</sup> prednisolone,<sup>123</sup> and levetiracetam.<sup>108</sup>

Three studies were included in our prior review,<sup>23, 115, 116</sup> including one RCT that now includes a followup analysis.<sup>22, 23</sup> We considered six studies to have low risk of bias,<sup>22, 23, 57, 73-75, 108</sup> seven to have moderate risk,<sup>68-72, 77, 115, 116</sup> and one to have high risk.<sup>123</sup>

Studies included a total of 829 children (median 39 total children/study) between the ages of 2 and 19 years receiving treatment for 4 days to 9 months. Two studies reported followup after the end of treatment (1-3 months post-treatment).<sup>71, 72</sup>

### Detailed Analysis

Despite the number of RCTs with low or moderate risk of bias, studies present little evidence to inform treatment decisions and can be considered primarily as pilot efficacy trials. Most

studies were short-term and lacked followup past the end of treatment. Studies included few participants and few examined the same agents. Two studies addressed donepezil but examined different outcomes. Harms reported in studies comparing these interventions were diverse, and their clinical significance is difficult to determine given the short-term nature of the studies and the typically low numbers of participants. Gastrointestinal symptoms including constipation, diarrhea, and abdominal pain occurred frequently as did agitation, nervousness, or restlessness and appetite changes. We present a brief summary of key effectiveness outcomes in each study below; Appendix F includes detailed tables of outcomes and harms.

**Donepezil.** Two RCTs (moderate risk of bias) of donepezil assessed differing outcomes and reported no effects on executive function and treatment-associated improvements in language. In an RCT comparing donepezil and placebo, changes between groups on measures of executive function did not differ significantly after 10 weeks of treatment, though each group generally improved on each measure over time.<sup>77</sup> In a 10-week open label extension, participants generally improved slightly on most measures (differences between baseline and 5 mg or 10 mg doses not significant). Scores on verbal and nonverbal problem solving skills and flexibility of thinking worsened over time (baseline vs. 10-mg dose,  $p \leq 0.004$ ). In another crossover RCT addressed in our prior review,<sup>11</sup> children receiving donepezil versus placebo improved on clinician-rated measures of receptive and expressive language and symptom severity after 6 weeks of treatment ( $p$  values  $< 0.05$ ).<sup>116</sup>

**Citalopram.** One low risk of bias RCT (reported in multiple publications) addressed the serotonin reuptake inhibitor citalopram and reported no significant effects on repetitive behavior and some positive effects on challenging behaviors compared with placebo.<sup>22, 23</sup> The original study was included in our 2011 review and now includes a followup study examining potential predictors of response to citalopram (see KQ2).<sup>22, 23</sup> The study (low risk of bias) focused on repetitive behavior outcomes in children with PDD and significant repetitive behavior. Investigators reported no significant differences between citalopram and placebo arms on measures of repetitive behavior, with similar baseline scores on the CYBOCS and similar improvements in each arm. The other measures of repetitive behavior, including the Repetitive Behavior Scale-Revised, also had similar improvements in each arm with no evidence for an effect of citalopram. The CGI-Improvement scale similarly showed no significant difference between the citalopram and the placebo arm. On the other hand, the primary measure of challenging behavior reported in this trial, the ABC-Irritability subscale, showed an advantage for citalopram with more improvement in the citalopram arm than for placebo.

**Memantine.** One low risk of bias RCT included a 12-week, placebo-controlled phase to determine safety and tolerability of memantine and a 48 week extension (6 weeks dose titration, with placebo participants moving to memantine followed by 42 weeks of maintenance treatment).<sup>75</sup> Both groups improved from baseline on caregiver-rated social skills (Social Responsiveness Scale) and on an unvalidated scale that measured symptom severity (Core Autism Treatment Scale-Improvement). Improvements were maintained over the extension period, but differences between groups at 12 weeks were not significant. Group differences on other measures of behavior and language (e.g., ABC, Children's Communication Checklist) were not statistically different between groups.

**Levetiracetam.** One 10-week, low risk of bias RCT reported no significant group differences in parent- or teacher-rated ABC scores, overall symptoms (CGI), impulsivity/hyperactivity, or repetitive behavior, though repetitive behavior improved in both groups from baseline.<sup>108</sup>

**Mecamylamine.** One low risk of bias, 14-week RCT randomized children to either mecamylamine in ascending doses (up to a maximum 5 mg/day) or placebo and reported no significant differences between groups on any of the outcome measures.<sup>73</sup>

**Divalproex Sodium.** In a 12-week RCT with low risk of bias including children with ASD and significant irritability or aggression, children receiving divalproex had greater improvements in the CGI-Irritability and ABC-Irritability scales ( $p$  values  $<0.05$ ), but scores on measures of aggression and repetitive behavior (Overt Aggression Scale-Irritability, CYBOCS) did not differ between groups.<sup>74</sup> In exploratory analyses changes in adaptive behavior or manic symptoms also did not differ between groups.

**Melatonin.** A crossover RCT with moderate risk of bias compared melatonin or placebo for 3 months followed by a 1-month washout and 3 months of either melatonin or placebo.<sup>68</sup> Sleep latency and total sleep were significantly reduced in the melatonin group compared with placebo ( $p \leq .004$ ), but night wakings did not differ between groups. Similarly, scores on the dysomnia scale of the Sleep Difficulties Questionnaire, but not the other sub-scales, were significantly lower for the treatment group compared with placebo ( $p = .041$ ). Scores on the Developmental Behavior Checklist were significantly different between groups (mean difference = 6.0,  $p = 0.05$ ), with lower scores (improved behavior) in the melatonin group.

**Bumetanide.** One RCT with moderate risk of bias compared bumetanide or placebo for 3 months followed by repeat evaluations 1 month after the end of treatment.<sup>72</sup> After the 3 month treatment period, CARS scores for participants in the treatment group declined from the severe range to medium or mild severity. At the 120 day followup, scores had shifted back toward pre-treatment values in both groups ( $p = ns$ ). CGI scores were significantly improved in the treatment group compared with placebo at 120 days ( $p = 0.02$ ), but ADOS total scores did not differ between groups. In analyses removing children with the most severe symptoms, ADOS scores improved significantly in the treatment group ( $p = 0.03$ ).

**Amantadine.** One moderate risk of bias RCT of amantadine reported no significant effect of daily amantadine over 4 weeks on parent-rated ABC behavior scores and clinician-rated CGI rating of overall improvement compared with placebo.<sup>115</sup> However, children in the amantadine arm improved significantly more than those receiving placebo in clinician-rated ABC Hyperactivity and Inappropriate Speech subscales.

**Oxytocin.** One RCT with moderate risk of bias including 38 boys with IQs of at least 80 and comorbid ADHD, oppositional defiant disorder, or anxiety compared four doses of nasal oxytocin or placebo over 5 days.<sup>71</sup> Children also received an emotion recognition training program and completed family interaction tasks both before and after oxytocin administration. No outcomes (social interaction, repetitive behavior, emotion recognition, ASD severity) differed between groups on blinded investigator-, parent-, and observation coder-ratings.

**Prednisolone.** In one retrospective study (high risk of bias) including children considered to have “regressive” autism (defined as clinically determined loss of age-appropriate language, communication, cognitive abilities and behavior), children who received prednisolone (mean treatment duration of 9.13±3.26 months, range=4-14 months) improved significantly more on a parent- and clinician-rated measure of receptive and expressive language developed for the study.<sup>123</sup> In followup of treated participants approximately 12 months after the end of treatment, participants with improved language (n=17) maintained or increased their improvements; three nonresponders continued to have no change in language in parent reports.

**Transcranial Stimulation.** One RCT with moderate risk of bias assessed transcranial direct current stimulation using electrodes attached to the scalp to provide positive and negative electrical currents to putatively affect activity in regions of the brain that may play a role in ASD symptoms.<sup>69, 70</sup> Investigators allocated study participants (all males) with mild to moderate ASD to either active stimulation (2 sessions of roughly 20 minutes) or sham simulation. At 7 days post-treatment, mean clinician-rated CARS scores and parent-rated ATEC total, social, sensory, and health and behavioral problem (but not language) scores were significantly improved in the treatment group compared with placebo (p values <0.05). Scores on the clinician-rated CGAS were also more improved in the treatment group (p<0.05) but CGI-Severity scores did not differ between groups. Investigators rated 45 percent of children receiving active treatment and 15 percent receiving sham treatment as “much improved” (p<0.05) and 10 percent in each arm as “much worse” (p=NS).

## KQ2. Modifiers of Treatment Outcomes

Understanding the degree to which child characteristics (i.e., age, specific ASD-related difficulties and skills), treatment factors (e.g., type, duration, intensity), and systems (e.g., family, community) influence response to treatments could improve targeting of treatments to the appropriate children and circumstances. While we sought modifying effects of child, provider, or intervention characteristics, few studies reported modifiers, and few were likely adequately powered to detect effects. We report modifying variables addressed in studies meeting our criteria as an indication of potential characteristics that may affect findings.

**Antipsychotics.** A sub-analysis of an 8-week RCT of risperidone vs. placebo<sup>34</sup> analyzed mediators and moderators of the decrease in irritability.<sup>29</sup> Baseline ABC-Irritability subscale score severity was the only significant moderator found. High severity was associated with greater improvement in irritability than was low severity in improvement with risperidone. Weight gain was the only significant mediator of response to risperidone. Greater weight gain was associated with less irritability improvement in the risperidone group. In an analysis of dose and compliance, better compliance was found to be associated with more improvement in the risperidone group and greater dose was associated with greater improvement.

In another post-hoc analysis of data from an extension of the 8-week trial of risperidone, younger age and better communication skills were associated with greater gains in communication but not with gains in daily living skills or socialization as measured on the VABS.<sup>37</sup> No child characteristics were associated with gains in adaptive behavior and gains in each domain of adaptive behavior (e.g., communication, socialization) appeared to contribute equally to gains in the overall adaptive behavior score. Reductions in aggression were also not associated with the magnitude of gains in adaptive behavior.

An additional analysis of this study analyzed the effect of initial severity of ASD on the efficacy of risperidone.<sup>110</sup> This study found that parent-, but not clinician-, efficacy of risperidone on irritability and lethargy was greater with higher baseline measurements of severity (moderate through severity) of challenging behaviors. Effects of baseline severity on clinician-rated ABC or CGI scores or parent ratings of other ABC scales (stereotypy, hyperactivity, inappropriate speech) were not statistically significant.

In secondary analyses of one RCT comparing aripiprazole and placebo, Caucasian children receiving aripiprazole had a relapse rate of 25.8 percent compared with 60.7 percent in the placebo group (HR=0.33, 95% CI: 0.14 to 0.78, p=0.01). Among non-White patients, the difference was not statistically significant. Age also did not interact significantly with relapse.<sup>48</sup> Finally, in one retrospective cohort study primarily assessing BMI change in children taking either risperidone or aripiprazole, investigators found no variables (baseline BMI or age, race, gender, intellectual disability, concomitant drug use, treatment duration) to be significant covariates of BMI Z-score change per year of treatment.<sup>122</sup>

**ADHD Medications.** In a double-blind cross-over trial of methylphenidate in 66 children,<sup>24-27</sup> authors found no effect of age, IQ, weight, or diagnosis on teacher- or parent-rated hyperactivity subscale scores, Swanson Nolan and Pelham rating scale (SNAP-IV), or CYBOCS scores. Children with Asperger syndrome/PDD-NOS (n=19) showed a trend of being more likely to be classified as responders to both placebo and methylphenidate than those with autism. Response to each dose of methylphenidate was significantly superior to placebo in the autism subgroup but not for the Asperger / PDD-NOS subgroup. In a later analysis assessing gene variants potentially associated with response, variations in seven genes (*SLC6A4*, *SLC6A3*, *DRD1*, *DRD3*, *DRD4*, *COMT* and *ADRA2A*) that influence monoaminergic signaling were significant predictors, though the study was not powered to correct for multiple comparisons.<sup>24</sup> In another RCT comparing guanfacine and placebo, cognitive skills were not significantly associated with treatment effects.<sup>46</sup>

**Other Agents.** Studies of other agents reported various potential modifiers of effects: Response to placebo (but not citalopram) was predicted by severity of disruptive behaviors, particularly hyperactivity, ASD severity and mood, and caregiver strain (p values  $\leq 0.012$ ) in one study.<sup>22, 23</sup> Children with higher baseline scores on these measures exhibited less response to placebo. In a trial of atomoxetine, scores on tests of inhibition control (go-no go task) and degree of distractibility by irrelevant information (focused-attention task) were not significantly correlated and did not correlate with changes in measures of ADHD symptoms.<sup>41-44</sup>

In a trial of divalproex, analyses suggested that children with abnormal epileptiform electroencephalogram (EEG) results were more likely to respond to divalproex than those with normal EEGs.<sup>74</sup> In analyses of treated children in this trial (n=16), children with higher blood levels of valproate (87-100 mcg/ml) had a better response rate, and higher dose was associated with a moderate effect on improvement scores (p values=NR).

Higher IQ was significantly correlated with improvements in social interaction in a post-hoc analysis in a crossover RCT comparing tetrahydrobiopterin and placebo.<sup>103</sup> Age or total CARS scores were not significantly associated with improvements. In a trial of buspirone, children with fewer brain abnormalities in positron emission tomography scans had significantly more behavioral improvement than those with fewer, as children with normal (not elevated) blood serotonin levels (p values  $\leq 0.04$ ); the serotonin association was not significant in multiple regression analysis.<sup>76</sup> In one RCT comparing hyperbaric oxygen and sham treatment, older age

(> 5 years) and lower baseline symptom severity as measured on the ADOS were associated with better outcomes.<sup>114</sup>

An RCT comparing active and sham transcranial stimulation reported that increased left frontal lobe activity as indicated by increases in peak alpha frequencies was associated with improvements in ATEC measures of social problems and health and behavior problems.<sup>69, 70</sup> Few of the included trials of diet or supplement interventions: one trial of gluten-free diet compared with a regular diet reported no significant correlations between baseline behavioral or gastrointestinal measures and outcomes.<sup>62</sup> In a trial of methyl-B12, improvement was positively correlated with increases in plasma levels of methionine and decreases in S-adenosylmethionine, and the ratio of these two levels ( $p$  values  $\leq 0.05$ ).<sup>87</sup>

No studies of risperidone adjuncts reported modifiers of effectiveness.

### **KQ3. Time to Effect of Interventions**

Information about early response to treatment, or lack thereof, could guide treatment selection, implementation, and modification; however, no studies reported data to assess time to effect of interventions. While several studies reported changes in the number of children responding to a given agent over time, studies did not provide data to determine the initiation of effects. One study of aripiprazole noted that clinically important improvements were seen within 8 weeks of treatment, but treatment was not associated with delayed relapse (return of significant symptoms by 16 weeks of treatment/placebo) compared with placebo.<sup>48</sup> In one study comparing risperidone and aripiprazole, improvement with aripiprazole was evident in the first 12 weeks of treatment without additional improvements at 24 weeks, while scores on measures in children taking risperidone improved at 12 weeks and continued to improve over the 24 week period.<sup>50</sup> The study does not indicate, however, when effects began to be observed. Another study assessing transcranial stimulation reported changes in peak alpha frequency immediately post-treatment in children receiving active versus sham stimulation (significant change from baseline in active treatment group and significant between group differences at some electrode sites), but the clinical effects of such changes are not clear.<sup>69, 70</sup>

### **KQ4. Evidence that Effects Measured at the End of Treatment Predict Long-Term Functional Outcomes**

Few studies provided data to address this KQ. Few studies had longer-term followup and those with more than 6 months of treatment or followup typically did not report functional outcomes. In one study, risperidone use was not associated with changes in IQ.<sup>28</sup> Changes from baseline to the end of study in class assignment (e.g., special education, regular classroom) were not significant.

### **KQ5. Effectiveness Across Environments or Contexts**

Seven studies reported teacher ratings of outcome measures that provide some information to address this KQ, but the limited results preclude conclusions. One RCT of omega-3 fatty acids reported no significant group differences in teacher ratings of challenging behaviors (parents also rated few measures as improved),<sup>80</sup> while another RCT of DHA supplementation versus placebo reported improvement in parent-rated social skills in children receiving placebo vs. those receiving DHA, while teachers rated communication as more improved in the treatment group compared with placebo.<sup>82</sup> An RCT of gluten- or casein- containing challenge foods introduced to

a gluten-free diet reported no statistically significant changes in behavior as rated by parents or teachers on the Connors scale.<sup>60</sup> An RCT of levetiracetam vs. placebo reported no significant group differences on any parent- or teacher- rated measures but also noted that teachers, but not parents, rated children in the placebo arm as more improved on irritability compared with the levetiracetam group ( $p=0.003$ ).<sup>108</sup>

RCTs of methylphenidate reported general agreement between parent and teacher ratings of hyperactivity.<sup>24-27, 45</sup> In one RCT, both parents and teachers considered hyperactivity and impulsive behavior to be significantly improved in the treatment group compared with placebo, but teachers (vs. parents) reported no significant group differences in inattention or oppositional behavior. Finally, one RCT of atomoxetine reported significant teacher-rated improvements in hyperactivity in the atomoxetine group compared with placebo, but teacher ratings of cognitive problems/inattention, oppositional behavior, or overall ADHD symptoms did not differ between groups.<sup>41-44</sup> In another RCT comparing atomoxetine alone, atomoxetine + parent training, placebo alone, and placebo + parent training, parents, but not teachers, rated children in active treatment groups as significantly improved on measures of ADHD, inattention, hyperactivity, and oppositional behavior.<sup>54, 55</sup>

## **KQ6. Drivers of Treatment Outcomes**

We did not identify studies that provided data to address this KQ.

# Discussion

## State of the Literature

We identified a total of 76 unique comparative studies, primarily (n=72) randomized controlled trials (RCTs), addressing medical interventions. Most studies were small (median 40 total participants/study) and addressed variable agents. Most studies had placebo comparators, while five (reported in multiple publications) compared a pharmaceutical agent to behavioral treatment or combined pharmaceutical and behavioral treatment.<sup>54-57, 120, 121</sup> Treatment length varied from four days to 24 months, with few studies (n=3) reporting longer term followup after the immediate intervention period.<sup>71, 72, 120</sup>

The methodologic rigor of studies increased substantially over those studies reported in our 2011 review of therapies for children with autism spectrum disorder (ASD).<sup>11</sup> Thirty-three studies in the current review have low risk of bias and 20 have moderate risk. While studies were generally well-conducted, evidence remains insufficient for most interventions given small sample sizes, lack of longer term followup, and heterogeneous agents and populations.

While most studies targeted challenging behaviors, only four (reported in multiple publications) explicitly included children with diagnosed comorbidities such as attention deficit hyperactivity disorder (ADHD).<sup>40-44, 71, 80</sup> Twenty-eight studies used variable criteria to define challenging behaviors, including specific cut-off scores on subscales of the Aberrant Behavior Checklist (ABC); parent-reported irritability; clinician observations of irritability or hyperactivity; or the presence of undefined “severe” behavioral symptoms. Other studies reported no specific indications.

Despite the limitations of the literature, some interventions have high strength of evidence. Specifically, the strength of evidence for the antipsychotics risperidone and aripiprazole is high for the amelioration of irritability in the short term ( $\leq 6$  months of treatment) for children with significant challenging behaviors at baseline. However, the strength of evidence is also high for significant side effects (e.g., extrapyramidal symptoms, weight gain). Longer term effectiveness is not as well studied, but uncontrolled open-label analyses have suggested some continued efficacy. In studies (reported in multiple publications), children receiving the psychostimulant methylphenidate had improvements in hyperactivity, but small sample sizes preclude firm conclusions about durability of effects.<sup>24-27, 45</sup> Two studies (in multiple publications) of atomoxetine also reported positive effects on hyperactivity, potentially with fewer adverse effects than methylphenidate.<sup>40-44</sup> Other studies of agents such as adjuncts to risperidone reported some positive effects but studies were small, often underpowered, and typically not replicated. Studies of nutritional supplements or specialized diets reported few positive effects as did studies of hyperbaric oxygen.

Despite the number of new studies, we can make few conclusions beyond those reached in our 2011 review. Evidence supports the effectiveness of antipsychotics in improving challenging behaviors, but with significant harms. Methylphenidate also improves hyperactivity but with significant harms. Evidence is promising for the ADHD medication atomoxetine. More studies have addressed combination approaches, but data are inadequate to draw conclusions. Data were limited and inconsistent for other interventions.



# Summary of Key Findings and Strength of the Evidence

## Key Question (KQ) 1. Benefits and Harms of Medical Treatments

### Studies of Antipsychotics

#### Key Findings

Studies of antipsychotics addressed either risperidone or aripiprazole and reported significant improvements in measures of challenging behavior in the short term (<6 months) in children receiving the medications compared with those receiving placebo. Harms of these agents, including extrapyramidal symptoms and weight gain, were also significant. Studies reporting longer term followup (up to 21 months for risperidone) suggest continued potential efficacy in many children but did not include control groups that would permit stronger conclusions. Studies comparing risperidone and aripiprazole reported few differences in effects on outcomes or harms.

#### Strength of the Evidence

Our confidence in the conclusion that risperidone and aripiprazole improve challenging behaviors in the short term (<6 months), with clinically significant harms, is high (high strength of evidence). Behaviors improved in the longer term ( $\geq 6$  months) with these agents compared with placebo, but our confidence in this conclusion is low (low strength of evidence) as few studies had longer-term followup.

In studies comparing risperidone and aripiprazole, BMI increased with both drugs over treatment durations of 6 months to more than 2 years, but group differences were not significant. We have low confidence in this conclusion given the few studies addressing this outcome (low strength of evidence). Other outcomes (e.g., challenging behaviors, attention) were not consistently addressed; thus we considered strength of evidence insufficient for all other intervention/outcome pairs. Table 23 outlines these findings.

**Table 23. Strength of evidence for effectiveness of antipsychotics versus placebo**

Intervention/ Outcome	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding  Strength of Evidence Grade
<b>Study Design</b>						
<b>Risk of Bias and Number of Studies (N Total)</b>						
<b>Risperidone vs. placebo</b>						
Challenging behavior ( $\leq 6$ months)  RCT: 2 low, <sup>34, 51, 52</sup> 1 moderate <sup>112, 113</sup> (N=274)	Low	Consistent	Direct	Imprecise	Undetected	<b>High SOE for short-term effectiveness of risperidone in improving challenging behavior compared with placebo</b>  Significant improvement in treatment group vs. placebo in 3 RCTs with 6-8 week treatment phases; improvement maintained in 2 RCTs with 6 months of treatment
Challenging behavior ( $> 6$ months)  RCT: 2 low, <sup>28, 102</sup> 1 moderate <sup>109</sup> (N=118)	Low	Consistent	Direct	Imprecise	Undetected	<b>Low SOE for effectiveness in the longer term</b>  Improvement maintained in 1 RCT with 6 months of treatment and in one open label extension with no comparison group with mean 21 months treatment duration; in another open label extension, more children relapsed with placebo vs. risperidone
Harms  RCT: 5 low, <sup>34, 49, 51, 52, 102, 130</sup> 4 moderate <sup>47, 101, 109, 112, 113</sup>  Retrospective cohort: 1 moderate <sup>122</sup> (N=334)	Low	Consistent	Direct	Imprecise	Undetected	<b>High SOE for clinically significant harms associated with risperidone</b>  Harms including weight gain, appetite changes, drowsiness, fatigue, extrapyramidal symptoms, drooling/hypersalivation, and gastrointestinal symptoms consistently reported
<b>Aripiprazole vs. Placebo</b>						
Challenging behavior ( $\leq 6$ months)  RCT: 2 low <sup>20, 21</sup> (N=316)	Low	Consistent	Direct	Precise	Undetected	<b>High SOE for short-term effectiveness of aripiprazole in improving challenging behavior compared with placebo</b>  Significant improvements in 2 short-term RCTs in treatment groups vs. placebo

Intervention/ Outcome  Study Design  Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding  Strength of Evidence Grade
Challenging behavior (≥6 months)  RCT: 2 low <sup>15, 20, 21, 48</sup>  (N=415)	Low	Inconsistent	Direct	Precise	Undetected	<b>Low SOE for longer term effectiveness in improving challenging behaviors</b>  In longer term followup, no differences in time to relapse of symptoms between aripiprazole and placebo groups in one 16 week RCT and continued improvements in ABC in one 52-week open label continuation with no control arm
Harms  RCT: 4 low, <sup>18, 20, 21, 48-50</sup>  Retrospective cohort: 1 moderate <sup>122</sup> (N=492)	Low	Consistent	Direct	Precise	Undetected	<b>High SOE for clinically significant harms associated with aripiprazole</b>  Harms including weight gain, appetite changes, somnolence, extrapyramidal symptoms, drooling/hypersalivation, infection, and gastrointestinal symptoms consistently reported
<b>Risperidone vs. Aripiprazole</b>						
BMI  RCT: 1 low <sup>50</sup> (N=37)  Retrospective cohort: 1 moderate <sup>122</sup> (N=142)	Medium	Consistent	Direct	Imprecise	Undetected	<b>Low SOE for no difference in effects on BMI</b>  BMI increased with both drugs over treatment durations of 6 months to more than 2 years, but group differences were not significant

N = number; RCT = randomized controlled trial; SOE = strength of evidence

## Studies of ADHD Medications

### Key Findings

Studies of methylphenidate, atomoxetine, and guanfacine reported improvements in hyperactivity and other challenging behaviors with treatment compared with placebo. Both RCTs addressing methylphenidate reported statistically significant improvements in hyperactivity in children treated with medium to high doses compared with placebo.<sup>24-27, 45</sup> Findings for oppositional behavior and social communication were inconsistent.

RCTs addressing atomoxetine reported statistically significant treatment-related improvements compared with placebo that were maintained over 20 weeks of open label, uncontrolled treatment in one study; inattention was statistically significantly improved in one study.<sup>40-44</sup> One small RCT of guanfacine reported improvements in hyperactivity, impulsiveness,

and attention.<sup>46</sup> Side effects were associated with all agents including aggressive behavior, gastrointestinal symptoms, irritability, and appetite changes.

### Strength of the Evidence

**Methylphenidate.** Methylphenidate vs. placebo improved hyperactivity and was associated with clinically significant harms (Table 24). Our confidence in these conclusions is low as studies were small and short term (low strength of evidence). Data were inadequate to assess effects on social communication and oppositional behavior (insufficient strength of evidence). Findings for oppositional behavior were inconsistent in two studies;<sup>25, 45</sup> thus, we could not assess the strength of evidence (insufficient). We considered the evidence inadequate to comment on potential effects on social communication or oppositional behavior (insufficient strength of evidence).

**Atomoxetine.** We found positive effects of atomoxetine compared with placebo on hyperactivity in children with ASD and ADHD in the short term (<6 months), with effects maintained over the longer term (≥6 months) (Table 24). Our confidence in this conclusion is low (low strength of evidence). Atomoxetine was associated with harms considered to be clinically moderate, and our confidence in this conclusion is low (low strength of evidence). Data were inadequate to assess effects on inattention as studies reported inconsistent findings (insufficient strength of evidence).

**Guanfacine.** Data were inadequate in this small study to draw conclusions about effects on any outcomes (insufficient strength of evidence).

**Table 24. Strength of evidence for effects of medications to treat ADHD**

Intervention/ Outcome	Study Design	Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding	Strength of Evidence Grade
<b>Methylphenidate vs. Placebo</b>									
Hyperactivity	RCT: 2 low <sup>24-27, 45</sup> (N=90)		Medium	Consistent	Direct	Imprecise	Undetected	<b>Low SOE for short-term (&lt;6 months) improvements in hyperactivity with methylphenidate compared with placebo</b>	Significant improvement with MPH compared with placebo on parent and teacher-rated measures; differential effect of dose not clear (little effect on 1 study and linear effect in another); SOE is low given small sample size and lack of long-term followup

Harms RCT: 2 low <sup>24-27, 45</sup> (N=90)	Me- dium	Consistent	Direct	Imprecise	Undetected	<b>Low SOE for association of methylphenidate with clinically significant harms</b>  Rates of children experiencing harms ranged from 0-75%; higher rates reported for repetitive behaviors or speech, loss of appetite, and irritability. Irritability responsible for withdrawals (n=6) in one RCT; SOE is low given small sample size
<b>Atomoxetine vs. Placebo</b>						
Hyperactivity RCT: 2 low, 1 moderate <sup>40-44, 54</sup> (N=163)	Me- dium	Consistent	Direct	Imprecise	Undetected	<b>Low SOE for improvements in hyperactivity in the short-term &lt;6 months) with atomoxetine vs. placebo</b>  Significant improvements in rating of hyperactivity in treatment group compared with placebo in both studies
Hyperactivity RCT: 2 low <sup>42-44, 54, 55, 131</sup> (N=106)	Me- dium	Consistent	Direct	Imprecise	Undetected	<b>Low SOE for improvements in hyperactivity in the longer-term ≥6 months) with atomoxetine vs. placebo</b>  Improvements in hyperactivity maintained in open label extensions
Harms RCT: 2 low, 1 moderate <sup>40, 42-44, 54, 55, 131</sup> (N=241)	Me- dium	Consistent	Direct	Imprecise	Undetected	<b>Low SOE for clinically moderate harms associated with atomoxetine</b>  No serious adverse events reported; most harms attenuated over open label extension phase

ADHD = attention deficit hyperactivity disorder; MPH = methylphenidate; N = number; RCT = randomized controlled trial; SOE = strength of evidence

## Studies of Combined Medical and Behavioral Treatments

### Key Findings

Three RCTs (2 low and 1 high risk of bias) and two nonrandomized trials (1 moderate and 1 high risk of bias) addressed different medical agents in combination with behavioral approaches. Atomoxetine plus parent training or atomoxetine alone were both associated with improvements in ADHD, inattention, hyperactivity, noncompliance, and overall symptom severity compared with placebo, with improvements maintained over 24 weeks for most treatment responders in one RCT.<sup>55, 132</sup> Differences between atomoxetine groups were not statistically significant for any outcome. Melatonin and melatonin plus cognitive behavioral therapy (CBT) both improved sleep-related outcomes in a second RCT.<sup>57</sup>

Folic acid plus Treatment and Education of Autistic and Related Communication Handicapped Children (TEACCH) treatment and folic acid alone both improved behaviors, with

no significant group differences in one nonrandomized trial.<sup>121</sup> In another RCT, bumetanide plus applied behavior analysis improved symptom severity and behavior more than applied behavior analysis alone.<sup>56</sup> In a final nonrandomized trial, stem cell transplantation plus rehabilitation therapy improved symptom severity, lethargy, and stereotypy more than umbilical cord blood cell transplant plus rehabilitation therapy or rehabilitation therapy alone.<sup>120</sup>

## **Strength of the Evidence**

Given that combination therapies were investigated in single studies, we could not make conclusions about their effects on any outcomes (insufficient strength of evidence).

## **Studies of Nutritional Supplements and Dietary Interventions**

### **Key Findings**

Three RCTs comparing omega-3 fatty acid supplementation with placebo reported no significant group differences in measures of challenging behavior; these studies did not consistently assess language and adaptive behavior outcomes, and no study reported clinically significant harms. While two RCTs addressed methyl B12 supplementation, results were inconsistent, with one study reporting positive effects on symptom severity<sup>87</sup> and another reporting no significant effects.<sup>83</sup>

Four RCTs (multiple publications) compared GFCF diets to either an unaltered diet or a diet that contained gluten and dairy and reported few differences in behavioral measures between children on restricted or unrestricted diets.<sup>63-65, 104-107</sup> One RCT comparing a gluten-free diet and regular diet reported significant improvements in gastrointestinal symptoms and behavior in the gluten-free group,<sup>62</sup> while another comparing a gluten and dairy-free diet to usual diet reported no significant effects.<sup>58</sup> Two RCTs evaluating “challenges” of gluten- or casein-containing foods reported no significant group differences in measures of challenging behavior,<sup>59, 60</sup> while a high risk of bias study evaluating antioxidant-rich camel’s milk reported no significant differences in ASD severity between children receiving boiled or raw camel’s milk or cow’s milk.<sup>61</sup>

Despite the number of RCTs with low or moderate risk of bias addressing other supplements or diets, data are also inadequate to determine effects on any outcome in the short- or long-term. Most studies were small and short-term (ranging from 1 week to 7 months, with 24 months of treatment in one study).

### **Strength of the Evidence**

Omega-3 fatty acid supplementation and placebo did not affect challenging behaviors. Our confidence in this conclusion is low (low strength of evidence for no effect) (Table 25). We also have low confidence in the conclusion that omega-3 supplementation was associated with minimal harms (low strength of evidence).

Data in two small studies of methyl-B12 were inadequate to draw conclusions (insufficient strength of evidence). Despite the number of RCTs with low or moderate risk of bias addressing other agents, evidence was inadequate to make conclusions about all clinical efficacy and harms outcomes because few, small, underpowered studies addressed each diet or supplement (insufficient strength of evidence).

While seven studies addressed variations of the GFCF diet, studies addressed different outcomes and different approaches to restricted and control diets; thus, data were inadequate to make conclusions about the body of evidence (insufficient strength of evidence). Data were

inadequate to allow conclusions about the relative effectiveness of other dietary interventions (e.g., camels' milk, gluten-containing challenge foods) compared with placebo (insufficient strength of evidence).

**Table 25. Strength of evidence for effects of omega-3 supplementation**

Intervention/ Outcome	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding  Strength of Evidence Grade
<b>Omega-3 fatty acids vs. Placebo</b>						
Challenging behaviors  RCT: 1 low, <sup>81</sup> 2 moderate <sup>80, 84</sup> N=119	Medium	Consistent	Direct	Imprecise	Undetected	<b>Low SOE for no effect on challenging behavior</b>  No significant differences between groups in three small, short-term RCTs
Harms  RCT: 1 low, <sup>81</sup> 2 moderate <sup>80, 84</sup> N=119	Medium	Consistent	Direct	Imprecise	Undetected	<b>Low SOE for minimal harms associated with supplementation</b>  No clinically significant harms reported in any study

N = number; RCT = randomized controlled trial; SOE = strength of evidence

## Studies of Risperidone Adjuncts

### Key Findings

Despite the number of RCTs with low or moderate risk of bias, studies present little evidence to inform treatment decisions and can be considered primarily as pilot efficacy trials. All studies were short-term and lacked followup past the end of treatment. Studies included few participants (median 40 total/study) and few examined the same adjunct agent or outcomes besides the ABC Irritability subscale. Only two studies<sup>90, 93</sup> addressed the same outcomes with different doses of the same agent (N-acetylcysteine). All studies except one of *Gingko biloba* added to risperidone reported significant improvements on the ABC-Irritability subscale in the adjunct groups compared with placebo or placebo plus risperidone; one study reporting only total ABC scores reported significant improvements in the adjunct group compared with placebo.<sup>124</sup>

### Strength of the Evidence

Data were inadequate to assess effects of risperidone plus adjunctive agents including amantadine, buspirone, celecoxib, memantine, riluzole, *Gingko biloba*, pioglitazone, or topiramate on any outcome assessed as no study addressed the same adjunctive agent (insufficient strength of evidence). Studies were also small (<50 children in any study) and short-term (8-10 weeks of treatment). While two RCTs addressing risperidone plus N-acetylcysteine reported improvements in irritability with the combination vs. risperidone plus placebo, evidence

is inadequate to comment on effects given the small number of participants (n=71 total), high attrition (15% to 30% across groups) and short-term nature (10 weeks each) of the studies (insufficient strength of evidence).

## Studies of Hyperbaric Oxygen Therapy

### Key Findings

Three RCTs of hyperbaric oxygen used different doses and reported inconsistent results (favorable effects associated with treatment in only one<sup>114</sup> and no significant effects in two<sup>66, 67</sup>).

### Strength of the Evidence

Data were inadequate to assess effects on outcomes given inconsistencies in outcome reporting (insufficient strength of evidence).

## Studies of N-acetylcysteine

### Key Findings

One RCT assessing N-acetylcysteine reported significant improvements in irritability (ABC-D) in treated children vs. those receiving placebo and no statistically significant effects on other measures of social skills or challenging behaviors.<sup>78</sup> Another RCT reported no significant treatment effects on any outcomes (symptom severity, social skills, repetitive behaviors).<sup>79</sup> Harms were not statistically significantly different between treatment and placebo groups.

### Strength of the Evidence

N-acetylcysteine had no effect on social skills outcomes in two small RCTs; harms of this agent were not clinically significant. Our confidence in these conclusions is low (low strength of evidence) (Table 26). Data were inadequate to assess effects on other outcomes including symptom severity given inconsistent findings in these two studies (insufficient strength of evidence).

**Table 26. Strength of evidence for effects of N-acetylcysteine**

Intervention/ Outcome	Study Design	Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding	Strength of Evidence Grade
<b>N-acetylcysteine vs. Placebo</b>									
Social skills			High	Consistent	Direct	Imprecise	Undetected	<b>Low SOE for lack of effect on social skills</b>	
RCT: 1 low, <sup>78</sup> 1 moderate <sup>79</sup> (N=127)									
No significant effects in either small, short-term RCT									



Harms RCT: 1 low, <sup>78</sup> 1 moderate <sup>79</sup> (N=127)	High	Consistent	Direct	Imprecise	Undetected	<b>Low SOE for minimal harms</b> No study reported harms considered clinically important
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N = number; RCT = randomized controlled trial; SOE = strength of evidence

## Studies of Tetrahydrobiopterin

### Key Findings

Outcomes were not consistent in two small RCTs of tetrahydrobiopterin.<sup>53, 103</sup> Changes in symptom severity were not significantly different between treatment and placebo groups; scores on other measures of challenging and adaptive behavior improved significantly in one study.<sup>53</sup> Investigators did not consider harms to be clinically significant.

### Strength of the Evidence

Tetrahydrobiopterin had no effect on symptom severity and was not associated with significant harms. Our confidence in these conclusions is low (low strength of evidence). Data were inadequate to assess effects on other outcomes including adaptive and challenging behavior (insufficient strength of evidence). Table 27 outlines findings.

**Table 27. Strength of evidence for tetrahydrobiopterin**

Intervention/ Outcome  Study Design  Risk of Bias and Number of Studies (N Total)	Study Limitations	Consistency	Directness	Precision	Reporting Bias	Finding  Strength of Evidence Grade
<b>Tetra- hydrobiopterin vs. Placebo</b>						
Symptom severity  RCT: 1 low <sup>53</sup> , 1 moderate <sup>103</sup> (N=54)	High	Consistent	Direct	Imprecise	Undetected	<b>Low SOE for lack of effect</b> No significant effects in either small, short-term RCT
Harms  RCT: 1 low <sup>53</sup> , 1 moderate <sup>103</sup> (N=54)	High	Consistent	Direct	Imprecise	Undetected	<b>Low SOE for minimal harms</b> No study reported harms considered clinically important

N = number; RCT = randomized controlled trial; SOE = strength of evidence

## Other Medical Interventions

### Key Findings

**Donepezil.** Two RCTs of donepezil assessed differing outcomes and reported no effects on executive function and treatment-associated improvements in language.<sup>11, 77</sup>

**Agents Addressed in Single Studies.** Studies of citalopram,<sup>22, 23</sup> and divalproex<sup>74</sup> reported positive effects on measures of challenging behavior associated with treatment compared with placebo. Measures of language or symptom severity improved more in treatment arms versus control arms in studies of prednisolone,<sup>123</sup> and transcranial stimulation,<sup>69, 70</sup> One study of amantadine reported significant improvements in hyperactivity relative to placebo.<sup>115</sup> One RCT reported improvements in time to fall asleep and sleep time with melatonin versus placebo,<sup>68</sup> and one of bumetanide compared with placebo reported positive effects of bumetanide on symptom severity.<sup>72</sup> Single studies of oxytocin<sup>71</sup> and mecamlamine<sup>73</sup> reported no significant treatment effects.

Harms reported in studies comparing these interventions were diverse, and their clinical significance is difficult to determine given the short-term nature of the studies and the typically low numbers of participants.

### **Strength of the Evidence**

Data were inadequate to make conclusions about the effects amantadine, bumetanide, divalproex, oxytocin, mecamlamine, prednisolone, citalopram, melatonin, and neurostimulation vs. placebo as no studies addressed the same agents (insufficient strength of evidence).

### **KQ2. Modifiers of Treatment Outcomes**

Few studies reported modifying characteristics, and no characteristics were consistent modifiers.

### **KQ3. Time to Effect of Interventions**

Few studies reported data to assess time to effect of interventions, and the lack of data precludes conclusions.

### **KQ4. Evidence That Effects Measured at the End of Treatment Predict Long-Term Functional Outcomes**

Few studies had longer-term followup and those few with 6 months or more of treatment or followup typically did not report functional outcomes.

### **KQ5. Effectiveness Across Environments or Contexts**

Five studies reported teacher ratings of outcome measures that provide some information to address this KQ, but the limited results preclude conclusions.

### **KQ6. Drivers of Treatment Outcomes**

We did not identify studies that provided data to address this KQ.

### **Findings in Relation to What Is Already Known**

We identified 16 recent (2010-present) systematic reviews or meta-analyses addressing medical interventions for children with ASD. Three reviews evaluated the antipsychotics

aripiprazole and risperidone; six evaluated multiple agents including antipsychotics; and seven evaluated agents including SSRIs, atomoxetine, gluten-free casein-free diets, omega-3 fatty acids, melatonin, and hyperbaric oxygen.

Overall, findings in these reviews generally aligned with the findings presented here, with high strength of evidence for short-term effectiveness of aripiprazole and risperidone to ameliorate challenging behaviors and high strength of evidence for adverse effects of each agent. Several reviews commented on atomoxetine as a promising agent, and one commented on melatonin to improve sleep problems. Reviews noted little evidence for gluten-free casein-free (GFCCF) diets, omega-3 fatty acids, hyperbaric oxygen, antiepileptic medications, selective serotonin reuptake inhibitors (SSRIs), and chelating agents.

Reviews generally considered studies of antipsychotics to have high quality and the quality of studies addressing stimulants and atomoxetine as moderate to high. Reviews generally considered studies addressing nutritional supplements, diets and hyperbaric oxygen as moderate to low quality. Reviews consistently commented on a lack of long term data and typically small sample sizes as limitations of the strength of the evidence.

## Antipsychotics

One Cochrane review of aripiprazole included two RCTs and reported significant short-term treatment-related improvements on irritability, hyperactivity, and repetitive movement with weight gain, sedation, drooling, and neurological side effects.<sup>133</sup> Another review including children with ASD (n=637), developmental disorders (n=68), or intellectual disability (n=50) noted that all of the 20 included randomized and observational studies reported significant treatment-related improvements in problem behaviors measured on the Clinical Global Impression (CGI) scale or ABC.<sup>134</sup> Most studies reported adverse effects including weight gain, sedation, and tremor. Both reviews noted a need for longer term studies to address durability of effects. One meta-analysis of risperidone (n=608 children) reported a mean effect size for risperidone of 1.09 across studies (1.14 for open label studies and 1.12 for placebo-controlled) using global outcome measures such as the Childhood Autism Rating Scale (CARS) and CGI.<sup>135</sup> The effect size for outcomes related to maladaptive behaviors such as irritability and aggression was 1.20.

## Reviews of Multiple Agents

**Agents To Treat Irritability and Problem Behaviors.** One review and meta-analysis addressed treatment of severe irritability and problem behaviors and included 11 RCTs that used the ABC-Irritability subscale in quantitative analyses. The review reported significant treatment effects for aripiprazole (effect size=0.9), risperidone (effect size=0.8), and N-acetylcysteine (effect size=0.7) compared with placebo.<sup>136</sup> Harms occurring with risperidone and aripiprazole included somnolence or sedation, and extrapyramidal symptoms occurred with aripiprazole and haloperidol. Aripiprazole, risperidone, and valproate caused greater weight gain compared with placebo (effect sizes of 3.1, 0.8, and 0.3, respectively). Investigators also noted smaller effects for clonidine, methylphenidate, tianeptine, venlafaxine, and naltrexone in studies that did not specifically target irritability and that atomoxetine and dextromethorphan were associated with improvements in hyperactivity and impulsivity on the ABC-Hyperactivity subscale.

**Psychotropic Medications.** One review of 17 different medications reported addressed in 33 RCTS reported little established evidence to support any medication.<sup>137</sup> Investigators considered

aripiprazole, risperidone, haloperidol to be have established evidence for treating irritability and hyperactivity (risperidone); irritability, hyperactivity, and stereotypy (aripiprazole); and unspecified behavioral symptoms (haloperidol). The review noted promising evidence for methylphenidate's effects on hyperactivity. Investigators considered evidence preliminary for the effects of risperidone on repetitive behavior and stereotypy, for the effects of atomoxetine and naltrexone on hyperactivity, and for pentoxifylline on irritability and social withdrawal. Investigators reported evidence as insufficient for all other agents (clonidine, guanfacine, olanzapine, divalproex, lamotrigine, levetiracetam, citalopram, fluoxetine, clomipramine, amantadine, naltrexone) on outcomes including social behavior, hyperactivity, and repetitive behavior.

**Agents To Treat ADHD Symptoms.** One review identified seven placebo-controlled trials of medications targeting ADHD symptoms in children with Pervasive Development Disorders (n=225 children) and reported that methylphenidate was significantly more effective than placebo in treating ADHD symptoms (effect size 0.67) and hyperactivity specifically (effect size=0.66).<sup>138</sup> Appetite decrease, insomnia, depressive symptoms, irritability, and social withdrawal occurred significantly more frequently in the treatment group versus placebo. The review reported no significant effects for clonidine versus placebo and significant improvements in ADHD symptoms and hyperactivity in children taking atomoxetine compared with placebo. Harms included nausea, decreased appetite, and sleep changes.

**Antiepileptic Medications.** One meta-analysis evaluated valproate, lamotrigine, levetiracetam, and topiramate in children with ASD.<sup>139</sup> In meta-analyses, single agents studied were not significantly different between treatment and placebo arms. One study of topiramate combined with risperidone reported improvements in irritability in the combination group compared with risperidone plus placebo. Two studies of valproate and one of levetiracetam reported no response to treatment as defined by CGI ratings. Discontinuation due to adverse effects did not differ between groups nor did the rate of total adverse events.

**Alzheimer's Medications.** One review addressed use of these medications for children and adults with ASD and included case reports and other observational studies and controlled trials.<sup>140</sup> Drugs assessed in children included donepezil, galantamine, rivastigmine, and memantine. Four uncontrolled and one controlled studies of donepezil reported treatment-associated improvements in ASD symptoms. All three studies of galantamine (2 RCTs and 1 case series) reported positive effects on core and associated ASD symptoms. One small case series addressing rivastigmine reported improvements in expressive language and ASD symptoms, and three studies (1 RCT, 2 case series) of memantine use in children also reported positive effects on irritability and associated symptoms with side effects including gastrointestinal symptoms, worsening behavior, and sedation. The review concluded that evidence is inconsistent and inconclusive but further study of some agents such as rivastigmine may be warranted.

**Predictors of Placebo Response.** One meta-analysis included data from 25 RCTs measuring outcomes with either the ABC, CGI, VABS, CARS, or Children's Yale-Brown Obsessive Compulsive Scale (CYBOCS) and reported a moderate but significant placebo response across studies (effect size=0.45, 95% CI: 0.34 to 0.56, p<0.001).<sup>141</sup> Investigators identified clinician-

completed outcome measures, level of response to active intervention, a pharmacologic active intervention (vs. diet, etc.), use of adjunctive treatment, and geographical location of the trial (greater response in Iran vs. United States) as significant moderators of the placebo response, with each factor associated with an increased response.

## Reviews of Other Agents

**Atomoxetine.** One review of atomoxetine included six studies (1 RCT) evaluating the agent for treatment of hyperactivity in children with ADHD (n=90).<sup>142</sup> All studies except one (which included children with “severe autistic disorder”) reported significant improvements in behavior in parent, teacher, and clinician ratings with treatment. Harms reported included gastrointestinal symptoms, somnolence, irritability, and weight loss; the review concluded that evidence suggests potential efficacy but small sample sizes and short-term studies limit conclusions.

**Hyperbaric Oxygen Therapy.** One review including eight studies (2 RCTs) reported little evidence for effects of hyperbaric oxygen in controlled trials, and some promising evidence in small case series.<sup>143</sup> Few studies reported any adverse effects at the pressure levels studied.

**SSRIs.** One Cochrane review included nine RCTs (5 including only children) evaluating (n=239 children) evaluating the SSRIs fluoxetine, fluvoxamine, fenfluramine, and citalopram.<sup>144</sup> The review reported no evidence for the effectiveness of SSRIs and potential evidence for harms.

**Omega-3 Fatty Acids.** One Cochrane review included two RCTs (n=37 children, predominately male with moderate to severe ASD symptoms) evaluating omega-3 fatty acids and reported no evidence for effects on social interaction, communication, hyperactivity, or stereotypy.<sup>145</sup>

**GFCF Diets.** One review included 32 studies, typically with high risk of bias, and noted scarce evidence for GFCF diets, with positive effects reported only in lower quality studies.<sup>146</sup> The review concluded that evidence for the effectiveness or harms of GFCF diets is limited and weak.

**Melatonin.** One review included 18 studies addressing melatonin for the treatment of sleep problems in ASD.<sup>147</sup> Thirteen observational studies reported improvements in sleep duration, night awakenings, or sleep onset latency, as did five RCTs. Investigators meta-analyzed RCT data and reported significant improvements on these measures with melatonin versus placebo. Harms associated with melatonin included drowsiness, gastrointestinal symptoms, and worsening behavior. No study reported serious adverse events.

**Chelation.** Though we did not identify studies addressing chelation agents in the current review, one Cochrane review addressed chelation therapy and included one RCT (n=49 children).<sup>148</sup> Investigators considered the study to have high risk of bias and noted that no evidence suggests efficacy for ASD symptoms.

## Applicability

By definition, ASD is heterogeneous. Characterizing a “typical” child with an ASD is not possible, although certain symptoms are central to the range of children within the autism spectrum. Individual therapies are developed and tested to ameliorate specific symptoms or

groups of symptoms, often in a fairly circumscribed subset of children. We provide details on the population, intervention, comparator, outcomes, and setting (PICOS) for each intervention addressed in more than one study in Appendix E to support translation of our findings and assessment of the applicability of each for differing circumstances and children.

Overall, study participants were generally recruited from specialty clinical service programs and represent nonprimary care populations. As such, families of these children may be seeking a higher level of care than those of the broader population of children with ASD based upon more severe or acute symptoms, including aggression or other challenging behaviors. Most studies of medical interventions targeted elementary school aged and older children with autism, with little data on the treatment of younger children. Most studies included majority male populations (consistent with the male prevalence of ASD).

Studies also included children with highly variable severity of challenging behaviors, ASD symptom severity, and cognitive impairment. Studies of pharmacological agents often sampled children with high levels of specific symptom patterns (e.g., children with severe challenging behavior at baseline where parents may be willing to pursue pharmacologic intervention and trial participation) who may not reflect the wider population of children with ASD in whom these challenges may not be present. Most of the studies reported including children with at least moderate level of severity of ASD. Studies of stimulants included children with cognitive impairment and with comorbidities including attention deficit hyperactivity disorder, oppositional defiant disorder, and obsessive compulsive disorder. Studies of other approaches had similarly heterogeneous populations. Dietary and nutritional studies included some younger children, with severity of autism not well described or the degree of intellectual functioning not well characterized in most studies. This heterogeneity in population characteristics may limit the generalizability of findings to children with differing levels of symptom expression or comorbidities but likely reflects the heterogeneity of the broader population of children with ASD

Studies addressed a variety of agents and typically reported use of concurrent medications or other therapies. Most agents studied are accessible in the United States, albeit with few receiving FDA approval for use. Comparators among non-placebo controlled studies varied, and few studies assessed the effect of concomitant behavioral or other therapies, though many children with ASD receive multiple interventions. The treatments studied may not adequately reflect the broad range of treatment combinations used in the general population of children with ASD.

As noted, few studies evaluated longer term treatment (>6 months); short treatment and followup periods limit our ability to understand potential longer term outcomes such as academic achievement or longer term harms. Overall, the heterogeneity of these studies parallels the heterogeneity of children with ASD, and some findings may be more applicable to children with specific levels of baseline severity or comorbidities. These limitations to generalizability likely reflect both the significant heterogeneity of ASD itself as well as its associated features, such as irritability. Thus, while there is a growing evidence base for treating certain symptoms in certain populations, these findings underscore the continued need for individualized treatment approaches that are informed by the emerging evidence base for benefits as well as harms of medical intervention, with careful consideration of symptom presentation and functioning level relative to study populations and applicability of the known literature.

## Implications for Clinical and Policy Decisionmaking

This review provides some evidence for decisionmaking about medical interventions for children with ASD. The clearest evidence favors the use of the antipsychotics risperidone and aripiprazole to address challenging behaviors in the short-term (<6 months); however, clinicians and caregivers must balance the significant harms of these agents. The significant side effect profiles make it clear that although these drugs are efficacious, caution is warranted regarding their use in patients without severe impairments or risk of injury. Few studies addressed longer term effects of these agents; thus, our confidence in longer term (>6 months) effectiveness is low. Studies of adjuncts to risperidone typically reported positive effects on challenging behaviors, but few studies addressed the same agents, precluding our ability to draw conclusions about their effectiveness.

Some evidence supports the use of methylphenidate and atomoxetine for hyperactivity, but few comparative studies addressed each agent, so our confidence in effects is limited. Given that many children with ASD are currently treated with medical interventions, strikingly little evidence exists to support clear benefit for most medical interventions, especially in the realm of interventions such as restrictive diets and supplements. Studies of nutritional supplements or specialized diets were typically underpowered and provided little evidence of effects of these approaches. Several agents were addressed in single studies, which limits conclusions about their effects.

Decisional dilemmas remain regarding characteristics of the child, family, or intervention that may modify effectiveness or predict which children may be most likely to benefit from a given approach. Similarly, the literature base is currently insufficient to inform our understanding of the time to effect of interventions, longer term effectiveness of interventions, generalizability of effects outside the treatment context, effectiveness and applicability to broader ASD populations, and components that may drive effectiveness.

## Limitations of the Comparative Effectiveness Review Process

We included studies published in English only and did not include unpublished data. We scanned a random sample of 150 non-English abstracts retrieved by our MEDLINE search. Most studies appeared to be case series, narrative reviews, basic science studies, or studies assessing etiology. Only two studies appeared to meet inclusion criteria; thus, given the high percentage of ineligible items in this scan (99%), we concluded that excluding non-English studies would not introduce significant bias into the review. We recognize that this preliminary scan did not address the entire corpus of ASD literature in other languages.

We also included only comparative studies of medical interventions with at least 10 children with ASD. To ensure comprehensive coverage of the literature, we included comparative studies with smaller sample size that would have been excluded in our 2011 review (which required a sample size of 30) in the present report. We did not conduct a *de novo* search for such studies but re-examined the excluded studies from the prior review. This approach may have overlooked relevant studies.

Given heterogeneity in treatment regimens, outcomes addressed in each study, and patient populations, we were limited in our ability to meta-analyze findings or identify potential subgroups that may respond more favorably to specific treatments. Finally, we used a nonvalidated tool to assess risk of bias, though we note that the tool evaluates similar constructs

to those assessed in tools such as that used by the Cochrane Collaboration, with the addition of ASD-specific domains.

## **Limitations of the Evidence Base**

As noted, studies in the review had small sample sizes and typically limited duration of intervention and followup after intervention, despite significant improvements in study design and execution over time. Populations across studies were heterogeneous in terms of challenging behaviors, ASD symptom severity, age, and comorbidities. Few studies addressed the same agent and outcomes, and few assessed potential factors that may modify effectiveness or drive effects of interventions. Many (n=63) studies also explicitly noted that concomitant interventions were held steady during the study treatment period; however, few studies reported specific analyses to control for or assess the effects of additional treatments.

Despite these limitations, investigators have made significant improvements in incorporating commonly used measures of symptom severity and behavior to facilitate comparisons across studies. Studies also typically described interventions fully, used standardized diagnostic processes and blinded assessors, and reported on the use or restriction of concomitant interventions.

## **Research Gaps and Areas for Future Research**

Improving research in this area should include methodologic considerations of power and sample size and durability of effects. Sample size and participant followup were frequently insufficient to allow firm conclusions. Duration of treatment and followup were generally short (<6 months); those studies with longer duration of treatment were typically open label extensions of RCTs and lacked control arms. While duration was typically short, retaining participants in studies, especially in placebo arms, is difficult when parents or children perceive little improvement in symptoms. Longer duration of treatment, however, is also important to rule out meaningful improvements in placebo groups and help inform our understanding of the placebo effect.

Few studies provided data on long-term outcomes after cessation of treatment. Future studies should extend the followup period and assess the degree to which outcomes are durable in “real world” situations. The literature includes many single studies of various agents. Studies of adjuncts to risperidone, for example, examined different adjunct agents, with some positive effects on challenging behaviors reported with most. Understanding which agents should be examined further is lacking. Another critical area for further research is identifying which children are likely to benefit from particular interventions. To date, studies have provided limited characterization of the subpopulation of children who experience positive response to medical interventions and limited characterization of the extent or type of behavioral challenges children experience at baseline.

Children with ASD also typically receive multiple types of therapies, but few studies addressed combinations of medical and behavioral or other categories of interventions or a medical treatment compared with a nonmedical treatment. Few attempted to account for potential effects on ongoing interventions. This not only limited our ability to interpret the effects of medical treatments in isolation but represents a significant gap for families and providers in choosing additional treatments that may bolster (or impair) the effects of behavioral, medication, or other therapies. Few studies (n=10) compared active treatments, and future



research to assess the comparative effectiveness of antipsychotics, ADHD medications, and other medications is necessary.

In addition, much of the medical intervention literature relies on baseline and outcome measures that have specific limits in understanding individualized response. Future research attempting to elucidate potential biobehavioral markers of response may prove useful. Research in understanding outcomes of importance to patients and caregivers, such as quality of life, is also lacking.

Harms reporting varied across studies; some studies amply described how harms were tracked, while others listed harms with no indication of how they were assessed (e.g., parent recall, checklist, clinician assessment during followup). This lack of reporting makes comparing harms across studies difficult. For instance, while studies of atomoxetine generally reported fewer harms than did studies of methylphenidate in children with ADHD symptoms, exploring differences in safety profiles is an important area for additional research.

## Conclusions

Risperidone and aripiprazole ameliorated challenging behaviors in the short term (<6 months), but had significant side effects. Methylphenidate and atomoxetine were also associated with improvements in hyperactivity in small, short-term RCTs (with uncontrolled open label extensions). Atomoxetine plus parent training was not more effective for hyperactivity than atomoxetine alone. Omega-3 fatty acid supplementation was not associated with improvements in challenging behaviors, and N-acetylcysteine and tetrahydrobiopterin were not associated with improvements in social skills and symptom severity, respectively. Some positive effects were reported with other agents studied (risperidone adjuncts, melatonin), but few studies addressed the same agent or outcomes. Data on longer term (>6 months) results and harms of interventions are lacking. Similarly, more research is needed to understand characteristics of the child or treatment that modify outcomes and whether effectiveness of interventions generalizes across different settings such as the home or school. Current evidence also does not inform our understanding of components of interventions that may drive effects. Some therapies hold promise and warrant further study, and the conduct of studies has improved considerably over time (i.e., growing number of randomized controlled trials and use of standardized measures). However, additional studies with larger, well-characterized populations over longer time frames, and that utilize transparent and rigorous methods that permit comparison across studies, would further inform decisionmaking.

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## Acronyms and Abbreviations

ABC	Aberrant Behavior Checklist
ADHD	attention deficit hyperactivity disorder
ADOS	Autism Diagnostic Observation Schedule
AHRQ	Agency For Healthcare Research And Quality
ASD	Autism Spectrum Disorder
ATEC	Autism Treatment Evaluation Checklist
BASC	Behavior Assessment System for Children
BMI	Body Mass Index
CARS	Childhood Autism Rating Scale
CBT	Cognitive Behavioral Therapy
CCC	Children's Communication Checklist
CER	Comparative Effectiveness Review
CGAS	Children's Global Assessment Scale
CGI	Clinical Global Impression
CI	Confidence Interval
CSBQ	Children's Social Behavior Questionnaire
CTRS	Connor's Teacher Rating Scales
CYBOCS	Children's Yale-Brown Obsessive Compulsive Scale
DHA	Docosahexanoic Acid
DSM-IV	Diagnostic Statistical Manual - IV
EEG	Electroencephalogram
EOT	End of Treatment
EPS	Extrapyramidal symptoms
EVT	Expressive Vocabulary Test
ES	Effect Size
FDA	Food and Drug Administration
FFA	Free Fatty Acid
G	Group
GFCF	Gluten Free, Casein Free (Diet)
IQ	Intelligence Quotient
kg	Kilograms
KQ	Key Question
mg	Milligram
MPH	Methylphenidate
n	Number
NA	Not Applicable
ND	No Data
NR	Not Reported
ns	Not Significant
ODD	Oppositional Defiant Disorder
OT/SI	Occupational Therapy With Sensory Integration
PDD	Pervasive Developmental Disorder
PDD-BI	Pervasive Development Disorder Behavioral Inventory
PDD-NOS	Pervasive Developmental Disorder – Not Otherwise Specified
PICOTS	Population, Intervention, Comparator, Outcome, Timing, Setting
PLS	Preschool Language Scale
PPVT	Peabody Picture Vocabulary Test
RBS	Repetitive Behavior Scale
RCT	Randomized, Controlled Trial
ROB	Risk of Bias
RR	Risk Ratio
RUPP	Research Units on Pediatric Psychopharmacology
SD	Standard Deviation
SNAP-IV	Swanson Nolan and Pelham rating scale
SOE	Strength of Evidence

SRS	Social Responsiveness Scale
SSRI	Selective Serotonin Reuptake Inhibitors
TEACCH	Treatment and Education of Autistic and Communication related handicapped Children
TEP	Technical Expert Panel
VABS	Vineland Adaptive Behavior Scales

# Appendix A. Search Strategies

**Table A-1. Treatment/intervention**

Interface: PubMed; Database: Medline

	<b>Search</b>	<b>Records</b>
1	"Child Development Disorders, Pervasive"[Mesh]	22690
2	(autistic[tiab] OR autism[tiab] OR asperger[tiab] OR asperger's[tiab] OR aspergers[tiab] OR pervasive development[tiab] OR pervasive developmental[tiab] OR pdd[tiab]) NOT medline[sb]	5613
3	#1 OR #2	28303
4	therapy[sh] OR therapeutics[mh] OR psychotherapy[mh] OR treatment outcome[mh]	7271756
5	(treatment[tiab] OR therapy[tiab] OR intervention[tiab] OR "control group"[tiab] OR randomized[tiab] OR outcome[tiab] OR randomized[tiab] OR efficacy[tiab] OR effectiveness[tiab] OR comparison[tiab] OR compared[tiab] OR trial[tiab] OR "pilot study"[tiab] ) NOT medline[sb]	794459
6	#4 OR #5	8058741
7	#3 AND #6	9859
8	(newspaper article[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])	5128288
9	#7 NOT #8	6801
10	#9 limited to ("2010/01/01"[Date - Publication] : "3000"[Date - Publication])	3894
Key: [mh] Medical Subject Heading; [tiab] title/abstract word; [pt] publication type; [sh] subheading; [dp] publication date; [la] language; [pt] publication type.		

**Table A-2. Medication**

Interface: EBSCOhost; Database: CINAHL

	<b>Search</b>	<b>Records</b>
1	(MH "Autistic Disorder")	10,856
2	(MH "Child Development Disorders") OR (MH "Child Development Disorders, Pervasive")	2,067
3	"autism"	8,856
4	#2 AND #3	511
5	#1 OR #4	11,134
6	(MH "Psychopharmacology") OR (MH "Central Nervous System Agents+")	92,105
7	(MM "Autistic Disorder/DT")	237
8	#6 OR #7	92,210
9	#5 AND #8	493
10	#9 limited to 2010-2015	215
11	#10 limited to English language	214



**Table A-3. Medication**

Interface: OVID; Database: EMBASE

	<b>Search</b>	<b>Results</b>
1	exp autism/	43068
2	exp autism/dt [Drug Therapy]	2497
3	exp *autism/dt [Drug Therapy]	1766
4	exp central nervous system agents/	1386129
5	exp *central nervous system agents/	734471
6	exp *autism/	28323
7	5 and 6	1213
8	3 or 7	2307
9	limit 8 to (english language and yr="2010")	116

# Appendix B. Screening and Risk of Bias Assessment Forms

## Medical and Sensory-Related Therapies for Children with Autism Spectrum Disorder Abstract Review Form

1. Addresses intervention approach and outcomes for young children (2-12 years) with ASD.

Yes  No  Cannot Determine

**If answer to question 1 is NO, this form is complete. Please submit and proceed to next abstract.**

2. Original research (does not include systematic reviews and meta-analyses)

Yes  No  Cannot Determine

3. Is this a comparative study (includes a treatment and comparison group)?

Yes  No  Cannot Determine

4. Addresses one of the following:

- Behavioral intervention involving training parents
- Sensory or auditory-focused intervention (e.g., sensory or auditory integration, weighted vest, therapeutic swinging, snoezelen room)
- Medical/pharmacologic intervention, including vitamins/supplements, hyperbaric oxygen, electroconvulsive therapy, transcranial magnetic stimulation
- Music therapy
- Educational intervention
- Complementary and alternative medicine (acupuncture, massage, etc.)
- Allied health intervention (non-sensory/auditory-related such as language, exercise, animal-assisted)
- Other behavioral intervention (e.g., social skills, CBT, early intensive intervention)
- Other
- Severe/challenging behavior (e.g., elopement, property destruction, self/other injury, severe aggression)
- Cannot determine

5. Eligible study size (at least 10 total participants in target population)

Yes  No  Cannot Determine

5a. Record total N with ASD:

## Medical and Sensory-Related Therapies for Children with Autism Spectrum Disorder Full Text Review Form

**1. Study population is children with autism between the ages of 2 and 12 years (mean+SD  $\leq$ 12 yrs, 11 months)**

Yes  No  Cannot Determine

**2. Original research (does not include systematic reviews and meta-analyses)**

Yes  No  Cannot Determine

**3. Is this a comparative study (includes a treatment and comparison group)?**

Yes  No  Cannot Determine

**4. Does this study address:**

- Medical intervention
- Sensory intervention
- Other intervention
- Not an intervention study

**5. Eligible study size (at least 10 total participants in RCT; 20 total participants in target population for observational studies)**

Yes  No  Cannot Determine

**5a. Record total N with ASD:**

\_\_\_\_\_

**6. Reports an outcome of interest for individuals with ASD:**

Yes  No  Cannot Determine

**Comments:**

\_\_\_\_\_

**If excluded, retain for review of references or background/contextual questions?**

Background  Review of References  Other

## Medical and Sensory-Related Therapies for Children with Autism Spectrum Disorder Risk of Bias Form

**1. Did the study employ a group design?**

Yes  No

**2. Were the groups randomly assigned?**

Yes  No  Comments \_\_\_\_\_

**3. Was there an appropriate comparison group?**

Yes  No or NR  Comments \_\_\_\_\_

**4. If an RCT, was randomization done correctly?**

Yes  No  NR  NA (non-RCT)

Comments \_\_\_\_\_

**5. Was a valid diagnostic approach for ASD used within the study, or were referred participants diagnosed using a valid approach?**

A. clinical DSM-IV/5-based diagnosis + ADI-R and/or ADOS

B. [clinical DSM-IV/5-based diagnosis + other] OR [ADOS + other, such as SRS, CARS, SCQ, CAST, ASSQ, OR STAT, MCHAT for under 30 months]

C. Only clinical DSM-IV/5-based diagnosis OR Only ADOS

D. Neither clinical DSM-IV/5-based diagnosis NOR ADOS

Comments \_\_\_\_\_

**6. Was the sample clearly characterized (e.g., information provided to characterize participants in terms of impairments associated with their ASD, such as cognitive or developmental level)?**

Yes  No or NR  Comments \_\_\_\_\_

**7. Were inclusion and exclusion criteria clearly stated?**

Yes  No or NR  Comments \_\_\_\_\_

**8. Do the authors report attrition?**

Yes  No  Comments \_\_\_\_\_

**9. Were characteristics of drop-out group evaluated for differences with the participant group as a whole?**

Yes  No or NR  NA or minimal attrition  
 Comments \_\_\_\_\_

**10. Was the intervention fully described?**

Yes  No or NR  Comments \_\_\_\_\_

**11. For behavioral/non-medical studies, was treatment fidelity monitored in a systematic way?**

Yes  No or NR  NA  
 Comments \_\_\_\_\_

**12. Did the authors measure and report adherence to the intended treatment process?**

Yes  No or NR  Comments \_\_\_\_\_

**13. Did the authors report differences in or hold steady all concomitant interventions?**

Yes  No or NR  Comments \_\_\_\_\_

**14. Did outcome measures demonstrate adequate reliability and validity (including interobserver reliability for behavior observation coding)?**

Yes  No or NR  Comments \_\_\_\_\_

**15. Were the primary & secondary outcomes clearly specified a priori?**

Yes  No or NR  Comments \_\_\_\_\_

**16. Were outcome data collected from sources appropriate to the target outcome (e.g. parent report, teacher report, direct behavior observation)?**

Yes  No or NR  Comments \_\_\_\_\_

**17. Were outcomes coded by individuals blinded to the intervention status of the participants?**

Yes  No or NR  Comments \_\_\_\_\_

**18. Was an appropriate statistical analysis used?**

Yes  No  Comments \_\_\_\_\_

**19. a. For RCTs, was there an intent-to-treat analysis?**

Yes  No  NA

Comments \_\_\_\_\_

**20. b. For negative studies, was a power calculation provided?**

Yes  No  NA

Comments \_\_\_\_\_

**21. c. Did the study correct for multiple testing?**

Yes  No  NA

Comments \_\_\_\_\_

**22. d. For observational studies, were potential confounders and effect measure modifiers captured?**

Yes  No  NA

Comments \_\_\_\_\_

**23. e. For observational studies, were potential confounders and effect measure modifiers handled appropriately?**

Yes  No  NA

Comments \_\_\_\_\_

**24. Were outcomes measured in at least one context outside of the treatment setting?**

Yes  No or NR  Comments \_\_\_\_\_

**25. Were outcomes measured in natural environments to assess generalization?**

Yes  No or NR  Comments \_\_\_\_\_

**26. Were follow-up measures of outcome conducted to assess maintenance of skills at least 3 months after the end of treatment?**

Yes  No or NR  NA

Comments \_\_\_\_\_

**27. Comments**

\_\_\_\_\_

# Appendix C. Excluded Studies

## Reasons for Exclusion

- X-1 Does not address interventions or outcomes of interest
- X-2 Not original research
- X-3 Does not include an appropriate comparison group
- X-4 Does not meet sample size criterion
- X-5 Not in English or not obtainable

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BACKGROUND  
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X-2  
X-3  
X-4

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## Appendix D. Risk of Bias Ratings

Table D-1. Risk of bias assessments

First Author Year	Group Design	Random Assignment	Appropriate Comparison Group	Correct Randomization	Systematic Diagnostic Approach	Clear Sample Characterization	Clear Inclusion/ Exclusion Criteria	Attrition Reported	Drop out Characteristics Evaluated	Intervention Fully Described	Treatment Fidelity Monitored	Treatment Adherence Measured and Reported	Concomitant Interventions Held Steady/ Reported	Outcome Measures Reliable and Valid	Primary Outcomes Specified <i>a priori</i>	Outcome Data Collected From Appropriate Sources	Outcomes Coded Blindly	Appropriate Statistical Analysis	Rating
Aman 2016 <sup>1</sup>	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	-	Low
Aman 2015 <sup>2-12</sup>	+	+	+	+	++	+	+	+	+	+	+	+	+	+	+	+	+	+	Low
Amatachaya 2015 <sup>13, 14</sup>	+	+	+	+	+	-	+	-	NA	+	NA	+	+	+	+	+	+	-	Moderate
Arnold 2012 <sup>15</sup>	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Low
Akhondzadeh 2010 <sup>16</sup>	+	+	+	+	-	-	+	NA	NA	+	NA	-	-	+	+	+	+	-	Moderate
Akhondzadeh 2008 <sup>17</sup>	+	+	+	+	-	-	+	+	NA	+	NA	-	+	+	+	+	+	+	Moderate
Arnold 2006 <sup>18</sup>	+	+	+	-	+	+	+	+	-	+	NA	-	+	+	+	+	+	-	moderate
Al Ayadhi 2013 <sup>19</sup>	+	+	+	-	+	-	-	+	NA	+	-	-	+	+	+	+	+	-	High
Asadabadi 2013 <sup>20</sup>	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Low
Bent	+	+	-	+	-	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Moderate

First Author Year	Group Design	Random Assignment	Appropriate Comparison Group	Correct Randomization	Systematic Diagnostic Approach	Clear Sample Characterization	Clear Inclusion/ Exclusion Criteria	Attrition Reported	Drop out Characteristics Evaluated	Intervention Fully Described	Treatment Fidelity Monitored	Treatment Adherence Measured and Reported	Concomitant Interventions Held Steady/ Reported	Outcome Measures Reliable and Valid	Primary Outcomes Specified a priori	Outcome Data Collected From Appropriate Sources	Outcomes Coded Blindly	Appropriate Statistical Analysis	Rating	
2014 <sup>21</sup>																				
Bent 2011 <sup>22</sup>	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	+	+	Low
Bertoglio 2010 <sup>23</sup>	+	+	+	-	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	-	Low
Chugani 2016 <sup>24</sup>	+	+	+	-	++	+	+	+	-	+	NA	+	+	+	+	+	+	-	-	Low
Cortesi 2012 <sup>25</sup>	+	+	+	+	++	+	+	+	+	+	NA	+	+	+	+	+	+	-	-	Low
Chez 2003 <sup>26</sup>	+	+	+	-	+	+	+	+	+	+	NA	-	+	+	+	+	+	-	-	Moderate
Dean 2016 <sup>27</sup>	+	+	+	+	+	+	+	+	-	+	NA	+	+	+	+	+	-	-	-	Moderate
Dadds 2014 <sup>28</sup>	+	+	+	-	+	+	+	+	-	+	NA	+	+	+	-	+	+	-	-	Low
Duffy 2014 <sup>29</sup>	+	-	-	NA	+	-	+	-	NA	+	NA	+	+	-	+	-	-	-	-	High
Findling 2014 <sup>30</sup>	+	+	+	-	++	+	+	+	-	+	NA	-	+	+	+	+	+	+	+	Low
Fahmy	+	+	+	-	-	+	+	+	-	+	NA	-	-	+	-	+	+	-	-	Moderate

First Author Year	Group Design	Random Assignment	Appropriate Comparison Group	Correct Randomization	Systematic Diagnostic Approach	Clear Sample Characterization	Clear Inclusion/ Exclusion Criteria	Attrition Reported	Drop out Characteristics Evaluated	Intervention Fully Described	Treatment Fidelity Monitored	Treatment Adherence Measured and Reported	Concomitant Interventions Held Steady/ Reported	Outcome Measures Reliable and Valid	Primary Outcomes Specified <i>a priori</i>	Outcome Data Collected From Appropriate Sources	Outcomes Coded Blindly	Appropriate Statistical Analysis	Rating	
2013 <sup>31</sup>																				
Ghaleiha 2016 <sup>32</sup>	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Low	
Ghalichi 2016 <sup>33</sup>	+	+	+	-	-	+	+	+	NA	+	NA	+	-	+	+	+	-	-	High	
Ghanizadeh 2014 <sup>34</sup>	+	+	+	-	++	+	+	+	-	+	NA	+	+	+	+	+	+	+	Low	
Geier 2011 <sup>35</sup>	+	+	+	-	-	-	-	+	-	+	NA	+	+	+	+	+	+	-	High	
Granpeesh 2010 <sup>36</sup>	+	+	+	-	++	-	+	+	-	+	NA	+	+	+	+	+	+	+	Low	
Ghaleiha 2015 <sup>37</sup>	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Low	
Ghaleiha 2013 <sup>38</sup>	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	+	Low	
Ghaleiha 2013 <sup>39</sup>	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Low	
Ghaleiha 2013 <sup>40</sup>	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	-	Low	
Ghanizadeh 2015 <sup>41</sup>	+	+	+	+	++	-	+	+	-	+	NA	-	+	+	+	+	+	+	Low	

First Author Year	Group Design	Random Assignment	Appropriate Comparison Group	Correct Randomization	Systematic Diagnostic Approach	Clear Sample Characterization	Clear Inclusion/ Exclusion Criteria	Attrition Reported	Drop out Characteristics Evaluated	Intervention Fully Described	Treatment Fidelity Monitored	Treatment Adherence Measured and Reported	Concomitant Interventions Held Steady/ Reported	Outcome Measures Reliable and Valid	Primary Outcomes Specified <i>a priori</i>	Outcome Data Collected From Appropriate Sources	Outcomes Coded Blindly	Appropriate Statistical Analysis	Rating
Ghanizadeh 2013 <sup>42</sup>	+	+	+	+	++	-	+	+	-	+	NA	-	+	+	+	+	+	+	Low
Hendren 2016 <sup>43</sup>	+	+	+	+	+	+	+	+	-	+	NA	+	-	+	+	+	+	-	Moderate
Handen 2015 <sup>44, 45</sup>	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	-	Low
Hyman 2015 <sup>46</sup>	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Low
Handen 2011 <sup>47</sup>	+	+	+	-	++	+	+	+	NA	+	NA	+	+	+	+	+	+	+	Low
Hollander 2010 <sup>48</sup>	+	+	+	-	++	+	+	+	-	+	NA	+	+	+	+	+	+	+	Low
Hardan 2012 <sup>49</sup>	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	-	Low
Hasanzadeh 2012 <sup>50</sup>	+	+	+	+	++	+	+	+	NA	+	NA	-	+	+	+	+	+	-	Low
Harrison 2006 <sup>51, 52</sup>	+	+	-	-	++	-	+	+	-	+	NA	-	-	+	+	+	+	-	Moderate
Johnson 2011 <sup>53</sup>	+	+	+	-	++	+	+	+	NA	+	NA	+	-	+	+	+	-	-	Moderate
King 2001 <sup>54</sup>	+	+	+	-	+	+	+	+	NA	+	NA	-	+	+	+	+	+	-	Moderate

First Author Year	Group Design	Random Assignment	Appropriate Comparison Group	Correct Randomization	Systematic Diagnostic Approach	Clear Sample Characterization	Clear Inclusion/ Exclusion Criteria	Attrition Reported	Drop out Characteristics Evaluated	Intervention Fully Described	Treatment Fidelity Monitored	Treatment Adherence Measured and Reported	Concomitant Interventions Held Steady/ Reported	Outcome Measures Reliable and Valid	Primary Outcomes Specified <i>a priori</i>	Outcome Data Collected From Appropriate Sources	Outcomes Coded Blindly	Appropriate Statistical Analysis	Rating
Kent 2013 <sup>55, 56</sup>	+	+	+	+	++	+	+	+	-	+	NA	-	+	+	+	+	+	+	Low
King 2013 <sup>57, 58</sup>	+	+	+	+	++	+	+	+	+	+	NA	+	+	+	+	+	+	+	Low
Klaiman 2013 <sup>59</sup>	+	+	+	+	++	-	+	+	-	+	NA	+	+	+	+	+	+	-	Low
Lamberti 2016 <sup>60</sup>	+	+	+	-	++	+	+	+	-	+	NA	-	-	+	+	+	-	+	Low
Lv 2013 <sup>61</sup>	+	-	-	NA	++	-	+	+	NA	+	NA	+	+	+	+	+	-	+	High
Lemonnier 2012 <sup>62</sup>	+	+	+	-	++	+	+	+	NA	+	NA	-	+	+	+	+	+	-	Moderate
Mankad 2015 <sup>63</sup>	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	-	Low
McCracken 2014 <sup>64-67</sup>	+	+	+	+	++	+	+	+	-	+	NA	-	+	+	+	+	+	+	Moderate
Mohammedi 2013 <sup>68</sup>	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	+	Low
Marcus 2011 <sup>69-75</sup>	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	+	Low

First Author Year	Group Design	Random Assignment	Appropriate Comparison Group	Correct Randomization	Systematic Diagnostic Approach	Clear Sample Characterization	Clear Inclusion/ Exclusion Criteria	Attrition Reported	Drop out Characteristics Evaluated	Intervention Fully Described	Treatment Fidelity Monitored	Treatment Adherence Measured and Reported	Concomitant Interventions Held Steady/ Reported	Outcome Measures Reliable and Valid	Primary Outcomes Specified <i>a priori</i>	Outcome Data Collected From Appropriate Sources	Outcomes Coded Blindly	Appropriate Statistical Analysis	Rating
Munasingh e 2010 <sup>76</sup>	+	+	+	-	-	-	+	+	-	+	NA	+	+	+	+	+	+	-	Moderate
Miral 2008 <sup>77</sup>	+	+	+	+	+	+	+	+	NA	+	NA	+	+	+	+	+	+	+	Moderate
Nikvarz 2016 <sup>78</sup>	+	+	+	+	+	-	+	+	-	+	NA	-	+	+	+	+	-	-	Moderate
Navarro 2015 <sup>79</sup>	+	+	+	+	++	+	+	+	NA	+	NA	+	-	+	+	+	+	-	Low
Nikoo 2014 <sup>80</sup>	+	+	+	+	+	+	+	+	-	+	NA	-	+	+	+	+	+	+	Moderate
Nagaraj 2006 <sup>81</sup>	+	+	+	+	+	+	+	+	-	+	NA	-	+	+	+	+	+	-	Moderate
Pusponegoro 2015 <sup>82</sup>	+	+	+	+	-	+	+	+	-	+	+	+	-	+	+	+	+	-	Moderate
Pearson 2013 <sup>83</sup>	+	+	+	-	++	+	+	+	NA	+	NA	+	+	+	+	+	+	+	Low
Rezaei 2010 <sup>84</sup>	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	+	Low
Rossignol	+	+	+	+	++	+	+	+	+	+	NA	-	+	+	+	+	+	-	Low

First Author Year	Group Design	Random Assignment	Appropriate Comparison Group	Correct Randomization	Systematic Diagnostic Approach	Clear Sample Characterization	Clear Inclusion/ Exclusion Criteria	Attrition Reported	Drop out Characteristics Evaluated	Intervention Fully Described	Treatment Fidelity Monitored	Treatment Adherence Measured and Reported	Concomitant Interventions Held Steady/ Reported	Outcome Measures Reliable and Valid	Primary Outcomes Specified <i>a priori</i>	Outcome Data Collected From Appropriate Sources	Outcomes Coded Blindly	Appropriate Statistical Analysis	Rating	
2009 <sup>85</sup>																				
Sun 2016 <sup>86</sup>	+	-	+	NA	+	+	+	+	-	+	NA	+	+	+	+	+	-	-	Moderate	
Sampanthavivat 2012 <sup>87</sup>	+	+	+	+	+	-	+	+	NA	+	NA	+	-	+	+	+	+	-	Moderate	
Shea 2004 <sup>88, 89</sup>	+	+	+	-	+	+	+	+	-	+	NA	+	+	+	+	+	+	-	Moderate	
Saad 2015 <sup>90</sup>	+	+	+	+	++	+	-	+	NA	+	NA	-	+	+	+	+	+	-	Moderate	
Scahill 2015 <sup>91</sup>	+	+	+	+	++	+	+	+	+	+	NA	+	+	+	+	+	+	+	Low	
Shan 2015 <sup>92</sup>	+	+	+	-	-	-	+	+	-	+	NA	-	-	+	-	+	-	-	High	
Troost 2005 <sup>93</sup>	+	+	+	-	++	+	+	+	NA	+	NA	-	+	+	+	+	+	+	Low	
Voigt 2014 <sup>94</sup>	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	+	Low	
Van der Meer 2013 <sup>95-98</sup>	+	+	+	+	++	+	+	+	NA	+	NA	+	+	+	+	+	+	-	Low	



First Author Year	Group Design	Random Assignment	Appropriate Comparison Group	Correct Randomization	Systematic Diagnostic Approach	Clear Sample Characterization	Clear Inclusion/ Exclusion Criteria	Attrition Reported	Drop out Characteristics Evaluated	Intervention Fully Described	Treatment Fidelity Monitored	Treatment Adherence Measured and Reported	Concomitant Interventions Held Steady/ Reported	Outcome Measures Reliable and Valid	Primary Outcomes Specified <i>a priori</i>	Outcome Data Collected From Appropriate Sources	Outcomes Coded Blindly	Appropriate Statistical Analysis	Rating
Wink 2014 <sup>99</sup>	+	-	+	NA	+	+	-	-	-	+	-	+	+	+	+	-	+	+	Moderate
Wright 2011 <sup>100</sup>	+	+	+	+	++	+	+	+	-	+	NA	+	+	+	+	+	+	-	Low
Whiteley 2010 <sup>101, 102</sup>	+	+	+	-	++	+	+	+	-	+	NA	+	+	+	+	+	-	-	Moderate
Wasserman 2006 <sup>103</sup>	+	+	+	-	++	+	+	+	-	+	NA	-	+	+	+	+	+	-	Low
Danfors 2005 <sup>104</sup>	+	+	+	-	+	+	+	+	NA	+	NA	+	-	+	+	+	+	+	Moderate
Knivsberg 2002 <sup>105, 4575</sup>	+	+	+	-	-	+	+	+	NA	-	NA	-	-	+	+	+	+	-	High

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## Appendix E. Applicability Summary Tables

**Table E-1. Antipsychotics**

Domain	Description of applicability of evidence compared to question
Population	Studies typically included participants recruited from non-primary care populations (university/academic-affiliated clinics, research centers), which may limit applicability to the wider population; participants in RCTs had an average age of roughly 9 years in the treatment and comparison groups and included a majority male subjects. In studies providing IQ data, the majority of subjects had IQs in the intellectual disability range. Studies reported use of concurrent medications but typically did not report on co-morbid conditions. Most of the studies report including children with at least moderate level of severity of ASD.
Intervention	Antipsychotics evaluated included risperidone and aripiprazole in dose ranges used in some children with ASD.
Comparators	RCTs compared treatment to placebo or to another medication (e.g., haloperidol, aripiprazole, memantine).
Outcomes	Studies primarily targeted outcomes related to problem behavior (irritability, hyperactivity) and repetitive behavior, which are significant concerns in the ASD population. Outcome measures used to assess change were appropriate; although the duration of studies was typically less than 6 months, and evaluation was typically immediately post-treatment. Some studies included open label, uncontrolled extensions. Studies reported adverse effects including sedation, weight gain, and extrapyramidal symptoms. Short-term harms and outcomes generally reflect longer-term outcomes measured over roughly 24 months.
Setting	Studies were conducted in the US, Canada, Iran, Italy, the Netherlands, Turkey, and India, primarily in academic clinics or research centers which may have yielded more selected populations.

ASD–Autism Spectrum Disorder; IQ–Intelligence Quotient; RCT–Randomized, Controlled Trial

**Table E-2. Medications to treat ADHD**

Domain	Description of applicability of evidence
Population	Studies included children 5 to 17 years old with autistic disorder; majority male. Studies typically included children with cognitive impairment (IQ or DQ $\leq$ 70) and comorbidities including ADHD, ODD, OCD, typically moderate to severe. Use of concomitant medications ranged from none to roughly a third of children in studies.
Intervention	Stimulants evaluated include different doses of methylphenidate, atomoxetine, and guanfacine.
Comparators	Placebo
Outcomes	Studies typically assessed outcomes in the short-term including hyperactivity/inattention, oppositional behavior, and social behaviors. The dose and type of medication were similar to reports in the literature; the duration of treatment across studies was 4 to 28 weeks with evaluation conducted immediately after treatment.
Setting	Studies were conducted in the US, The MPH trial included drug-free children in 5 academic outpatient clinics in the US and Netherlands, with clinic-based populations, likely representing a highly selected population.

ADHD–Attention Deficit/Hyperactivity Disorder; DQ–Developmental Quotient; MPH–methylphenidate; ODD–Oppositional Defiant Disorder; OCD–Obsessive Compulsive Disorder

**Table E-3. Nutritional supplements**

<b>Domain</b>	<b>Description of applicability of evidence</b>
Population	Studies included children ages 2-11 years with differing requirements for inclusion. Two omega-3 fatty acid studies targeted younger children (ages 3-8) with hyperactive behavior. The degree of intellectual disability was not well described in the studies.
Intervention	Nutritional supplements including omega-3 fatty acids, methyl B-12, peptizyde, N,N-dimethylglycine, digestive enzymes, docosahex-aenoic acid and levocarnitine.
Comparators	Comparator for all studies in this group was placebo.
Outcomes	Study outcomes included behavior, autism severity, communication, cognitive, and gastrointestinal symptoms and sleep disturbances. Data were collected using a wide range of assessment tools including CGI, ABC, CARS, SRS, BASC, GBRs, PDDBI, MCDI, PPVT, Stanford-Binet, hand muscle testing, ATEC, PIA-CV, Expressive Vocabulary test, Rescorla Language Development Survey, CBCL, and Childhood Psychiatric Rating Scale. Most studies were of 3 months duration (range 1 to 6 months). Outcomes were collected at end of treatment with no long term follow-up.
Setting	Five studies were conducted in the United States, two in Egypt and one each in the Netherlands and Australia

CGI-Clinical Global Impression; ABC-Aberrant Behavior Checklist; CARS-Childhood Autism Rating Scale; SRS-Social Responsiveness Scale; BASC-Behavioral Assessment System for Children; GBRs; Global Rating Scale; PDDBI-Pervasive Developmental Disorders Behavior Inventory; MCDI- MacArthur Communicative Development Inventory; PPVT-Peabody Picture Vocabulary Test; ATEC-Autism Treatment Evaluation Checklist; PIA-CV-Parent Interview for Autism-Clinical Version; CBCL-Child Behavior Checklist

**Table E-4. Dietary interventions**

<b>Domain</b>	<b>Description of applicability of evidence</b>
Population	Study participants ranged in age from 2 to 12 years, with no information available about co-morbidities, except one study that included children with severe maladaptive behavior. Severity of autism was not well described and the degree of intellectual disability was not well characterized in most studies. One GFCF study required participants to be concurrently enrolled in a comprehensive ABA program. Use of concomitant medications was not noted in most studies. One study recruited children with known allergies or food intolerances.
Intervention	Gluten-free casein-free diet, gluten-free diet, gluten dairy-free diet, raw and boiled camel milk.
Comparators	Comparators included gluten and dairy diet, gluten-containing challenge foods, usual diet, placebo and cow milk.
Outcomes	Outcomes included autism severity scores, problem behaviors including maladaptive behavior, sleep, and gastrointestinal symptoms. Assessments used in the studies included ADOS, CARS, Gilliam Autism Rating Scale (GARS), Ritvo-Freeman Real Life rating scales, ADHD-IV scale, Conner's Behavior Rating scale, VABS, Pervasive Developmental Disorder Behavior Inventory, sleep diaries, and Gastrointestinal symptom severity index.
Setting	Studies were conducted in academic medical centers located in the United States, Belgium, Denmark, Iran, Norway, and Saudi Arabia.

CARS-Childhood Autism Rating Scale; ADOS-Autism Diagnostic Observation Schedule; ADHD-IV-Attention Deficit/Hyperactivity Disorder-IV scale; VABS-Vineland Adaptive Behavior Scales; GFCF-Gluten-free, casein-free; ABA-Applied Behavioral Analysis

**Table E-5. Risperidone adjuncts**

<b>Domain</b>	<b>Description of applicability of evidence compared to question</b>
Population	Studies typically included participants with autism spectrum disorder (ASD) recruited from non-primary care populations (university/academic-affiliated clinics, research centers), which may limit applicability to the wider population; participants had an average age in a range between 3-16 years and included 17-23 subjects in the treatment arm to 14-24 in the placebo arm with more male subjects (73% in treatment groups and 75% in control). Three studies reported including subjects with cognitive impairment while majority did not mention the intellectual disability status. Most of the studies included subjects with severe disruptive symptoms and typically did not report comorbidity status or use of concomitant medications or therapies.
Intervention	Risperidone adjuncts evaluated included celecoxib, Ginkgo biloba, memantine, topiramate, riluzole, buspirone, N-acetyl cysteine, amantadine, pioglitazone, galantamine, pentoxifylline, and piracetam in children with ASD.
Comparators	Studies compared adjuncts to risperidone therapy to placebo added to risperidone.
Outcomes	Studies primarily targeted outcomes related to core and associated behavior symptoms (irritability, hyperactivity, lethargy/withdrawal, stereotypy and inappropriate speech) which are significant concerns in the ASD population along with global clinical improvement. Outcome measures used to assess change were appropriate; although the duration of studies was typically $\leq 10$ weeks and evaluation was typically immediately post-treatment.
Setting	All the studies were conducted in Iran and primarily in academic clinics or research centers which may have yielded more selected populations.

ASD-autism spectrum disorder

**Table E-6. Combination medical and behavioral treatments**

<b>Domain</b>	<b>Description of applicability of evidence</b>
Population	Studies included children between 3 and 14 years old. Across studies ASD symptoms were generally considered mild to moderate. In one study of atomoxetine plus parent training, children had concomitant ADHD symptoms.
Intervention	Atomoxetine plus/minus parent training, bumetanide plus applied behavioral analysis; cord blood or stem cell transplantation plus rehabilitation therapy; melatonin plus/minus cognitive behavioral therapy; folic acid plus TEACCH.
Comparators	Behavioral therapy alone, placebo.
Outcomes	Most studies assessed challenging behaviors (e.g., irritability, inattention, oppositional behavior) and symptom severity; one study evaluated cognitive skills and one evaluated sleep outcomes.
Setting	Studies were conducted in China, the US, and Italy and were recruited from research centers or clinics.

ADHD-Attention Deficit/Hyperactivity Disorder; ASD-autism spectrum disorder; TEACCH-Treatment and Education of Autistic and Communication-Related Handicapped Children

**Table E-7. N-acetylcysteine**

Domain	Description of applicability of evidence
Population	Studies included children between 3 and 10 years with participants recruited from the community in one study and from a clinic/hospital in another. Studies included children with and without intellectual disability. Treatment duration ranged from 12-24 weeks.
Intervention	N-acetylcysteine in doses of 500-900 milligrams.
Comparators	Placebo
Outcomes	Challenging behaviors, social and communication outcomes, adaptive behavior.
Setting	Studies were conducted in the US and Australia, with participants recruited from the community in one study and from a clinic/hospital in another.

**Table E-8. Tetrahydrobiopterin**

Domain	Description of applicability of evidence
Population	Studies included children between 3 and 7 years old. One study included only males. Treatment duration ranged from 16-24 weeks.
Intervention	Tetrahydrobiopterin at doses of 3 to 20 mg/kg of body weight.
Comparators	Placebo
Outcomes	The primary outcome in studies was symptom severity.
Setting	Studies were conducted in Sweden and the US with participants recruited from the community and clinic settings.

mg – milligrams; kg – kilograms

**Table E-9. Other--Hyperbaric oxygen therapy**

Domain	Description of applicability of evidence
Population	Studies included children ages 2-14 years with autism. The degree of disease severity was not well categorized. Participants were overwhelmingly male in the two studies that reported gender (84% and 93%) The degree of intellectual disability was not reported in any of the studies. Concomitant behavioral and medication interventions were reported in all studies.
Intervention	Hyperbaric oxygen therapy- dosages ranged from 24% to 100% oxygen.
Comparators	Comparators for these studies included treatments of room air, sham air and free air flow.
Outcomes	Study outcomes included autism severity and change in behavior. Assessment tools used in the studies included CGI (used in all three trials), ATEC, ADOS, SRS, ABC, VABS, VMI-5, BRIEF, PPVT-III, RBS and direct observation of toy play sessions. The number of treatment sessions ranged from 20 up to 80 one hour treatments occurring over a three up to 15 week period of time. Outcomes were collected at end of treatment with no long term follow-up.
Setting	Two studies were conducted in the United States and one was performed in Thailand. Participants in one study were recruited from a large community based ABA provider.

ABA – Applied Behavior Analysis; ABC – Abberant Behavior Checklist; ADOS - Autism Diagnostic Observation Schedule; ATEC – Autism Evaluation Checklist; BRIEF – Behavior Rating Inventory of Executive Function; CGI – Clinical Global Inventory; PPVT – Peabody Picture Vocabulary Test; RBS – Repetitive Behavior Scale; VABS – Vineland Adaptive Behavior Scale; VMI – Visual Motor Integration

**Table E-10. Other--Bumetanide**

<b>Domain</b>	<b>Description of applicability of evidence</b>
Population	Study participants ranged in age from 3 to 11 years with a wide range of disease severity among study participants. The Chinese study was restricted to younger children (2.5 to 6.5 years) who were concurrently enrolled in an ABA program. The degree of intellectual disability was not described. Concomitant medications were stopped prior to study entry in both studies. The placebo-controlled trial did allow use of melatonin.
Intervention	Bumetanide , 1 mg dose
Comparators	Placebo and no medical treatment in one study in which all participants were receiving ABA.
Outcomes	Outcomes included autism severity scores and symptoms. Assessments used in the studies included CARS, CGI, ADOS-G and ABC scales. Both studies were of 3 months duration. The placebo controlled trial also assessed subjects after a one month wash-out period post-intervention.
Setting	One placebo-controlled trial was conducted in France and the other study was done in China.

ABA-Applied Behavioral Analysis; CGI-Clinical Global Impression; CARS-Childhood Autism Rating Scale; ADOS-G-Autism Diagnostic Observation Schedule-Generic; ABC-Aberrant Behavior Checklist

**Table E-11. Other--Donepezil**

<b>Domain</b>	<b>Description of applicability of evidence</b>
Population	Studies included children 2 to 17 years old with autistic disorder; with majority being male children (>90%). One study reported a total ADOS score ranging from 10.2 to 11.2; with IQ ranging from 73-146 while the other did not exclude children based on intelligence or language development level. Studies allowed use of concomitant medications but did not include children with co-morbid conditions.
Intervention	The acetylcholinesterase inhibitor used was donepezil hydrochloride.
Comparators	The trial included a placebo controlled comparison group, which was an appropriate comparison group.
Outcomes	The trials ranged from 10 to 12 weeks in duration with the evaluation conducted immediately after treatment. Studies assessed outcomes in the short-term including expressive, receptive language, autistic behaviors and cognitive functioning. The dose used was similar to reports in the literature; treatment episodes were most commonly associated with mood swings, lability, diarrhea, headache and fatigue as side effects. One trial also evaluated the effect of age, IQ and autism severity on treatment response and found no significant group difference.
Setting	Both the trials were conducted in USA.

ADOS-Autism Diagnostic Observation Schedule; IQ – Intelligence Quotient

## Appendix F. Detailed Tables of Findings

**Table F-1. Key findings in studies of antipsychotics**

Author, Year Study Design	Mean Age, Years ± SD	Outcome Measure/Baseline Scores, Mean ±SD	Outcome Measure/Post- Treatment Scores, Mean ± SD
Groups (Dose), N Enrollment / N Final	Mean IQ ±SD		
Treatment Duration/Follow- Up Time Point Post- Treatment			
Risk Of Bias			
<b>Atomoxetine</b>			
Handen et al., 2015 <sup>1,2</sup> RCT  G1: Atomoxetine + Parent Training, up to 1.8 mg/kg/day, 32/ G2: Atomoxetine, up to 1.8 mg/kg/day, 32/ G3: Placebo + Parent Training, up to 1.8 mg/kg/day, 32/ G4: Placebo, up to 1.8 mg/kg/day, 32/  10 weeks/EOT  Low RoB	Age G1: 8 ± 1.9 G2: 8.6 ± 2.3 G3: 7.7 ± 1.5 G4: 8.2 ± 2.4  IQ (Stanford- Binet/Mullen Scales) G1: 83.3 ± 21.6 G2: 78.7 ± 25.9 G3: 77.9 2± 5.7 G4: 86.7 ± 23.7	SNAP-IV-Parent – ADHD G1: 2.21 ± 0.38 G2: 2.18 ± 0.44 G3: 2.22 ± 0.37 G4: 2.2 ± 0.52  SNAP-IV-Parent – Inattention G1: 2.28 ± 0.46 G2: 2.3 ± 0.43 G3: 2.23 ± 0.49 G4: 2.27 ± 0.51  SNAP-IV-Parent – Hyperactivity G1: 2.14 ± 0.49 G2: 2.07 ± 0.65 G3: 2.2 ± 0.48 G4: 2.13 ± 0.69  SNAP-IV-Parent – Oppositional Defiant Disorder G1: 1.33 ± 0.74 G2: 1.31 ± 0.65 G3: 1.37 ± 0.64 G4: 1.28 ± 0.82  SNAP-IV-Teacher – ADHD G1: 1.99 ± 0.46 G2: 2 ± 0.53 G3: 1.98 ± 0.52 G4: 1.96 ± 0.59  SNAP-IV-Teacher – Inattention G1: 2.13 ± 0.52	<b>10 weeks</b> SNAP-IV-Parent – ADHD G1: 1.23 ± 0.69 G2: 1.24 ± 0.56 G3: 1.45 ± 0.62 G4: 1.74 ± 0.86 G1 vs G4, p≤0.001; ES=0.98 G2 vs G4, p≤0.001; ES=0.80 G3 vs G4, p≤0.05; ES=0.57  SNAP-IV-Parent – Inattention G1: 1.3 ± 0.72 G2: 1.36 ± 0.61 G3: 1.45 ± 0.71 G4: 1.79 ± 0.84 G1 vs G4, p≤0.001; ES=1 G2 vs G4, p≤0.001; ES=0.84 G3 vs G4, p≤0.05; ES=0.60  SNAP-IV-Parent – Hyperactivity G1: 1.15 ± 0.74 G2: 1.12 ± 0.65 G3: 1.44 ± 0.72 G4: 1.69 ± 0.97 G1 vs G4, p≤0.01; ES=0.83 G2 vs G4, p≤0.001; ES=0.68 G3 vs G4, p≤0.05; ES=0.46

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow-Up Time Point Post-Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post-Treatment Scores, Mean ± SD</b></p>
		<p>G2: 2.15 ± 0.54 G3: 2.16 ± 0.46 G4: 2.28 ± 0.49</p> <p>SNAP-IV-Teacher – Hyperactivity G1: 1.86 ± 0.68 G2: 1.85 ± 0.72 G3: 1.81 ± 0.79 G4: 1.64 ± 0.9</p> <p>SNAP-IV-Teacher – Oppositional Defiant Disorder G1: 1.07 ± 0.73 G2: 1.21 ± 0.62 G3: 1.03 ± 0.76 G4: 1.04 ± 0.71</p> <p>ABC-Parent – Irritability G1: 17.88 ± 9.25 G2: 16 ± 9.74 G3: 18.16 ± 9.24 G4: 16.97 ± 8.36</p> <p>ABC-Parent – Social Withdrawal G1: 12.09 ± 7.68 G2: 12.53 ± 9.22 G3: 8.56 ± 5.69 G4: 12.09 ± 7.12</p> <p>ABC-Parent – Stereotypic Behavior G1: 5.81 ± 4.69 G2: 7.41 ± 5.5 G3: 5.34 ± 5.03 G4: 5.06 ± 5.2</p> <p>ABC-Parent – Hyperactivity G1: 29.94 ± 8.74 G2: 29.34 ± 9.52 G3: 31.31 ± 8.96</p>	<p>SNAP-IV-Parent – Oppositional Defiant Disorder G1: 0.96 ± 0.68 G2: 0.78 ± 0.52 G3: 0.7 ± 0.55 G4: 0.79 ± 0.5 p=NR</p> <p>SNAP-IV-Teacher – ADHD G1: 1.14 ± 0.82 G2: 1.49 ± 0.74 G3: 1.46 ± 0.82 G4: 1.4 p=NR 4 ± 0.85</p> <p>SNAP-IV-Teacher – Inattention G1: 1.3 ± 0.85 G2: 1.66 ± 0.78 G3: 1.64 ± 0.82 G4: 1.63 ± 0.98 p=NR</p> <p>SNAP-IV-Teacher – Hyperactivity G1: 0.98 ± 0.92 G2: 1.32 ± 0.92 G3: 1.28 ± 0.99 G4: 1.25 ± 0.92 p=NR</p> <p>SNAP-IV-Teacher – Oppositional Defiant Disorder G1: 0.71 ± 0.65 G2: 0.87 ± 0.77 G3: 0.56 ± 0.66 G4: 0.83 ± 0.84 p=NR</p> <p>ABC-Parent – Irritability</p>



<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow- Up Time Point Post- Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b></p>
		<p>G4: 31.22 ± 10.11</p> <p>ABC-Parent – Inappropriate Speech G1: 5.56 ± 3.17 G2: 5.53 ± 3.44 G3: 5.72 ± 2.7 G4: 5.69 ± 3.75</p> <p>ABC-Teacher – Irritability G1: 13.03 ± 10.85 G2: 12.96 ± 8.53 G3: 12.13 ± 9.62 G4: 14.71 ± 9.86</p> <p>ABC-Teacher – Social Withdrawal G1: 12.1 ± 9.92 G2: 11.23 ± 7.58 G3: 9.65 ± 8.03 G4: 11.06 ± 7.48</p> <p>ABC-Teacher – Stereotypic Behavior G1: 6.27 ± 5.21 G2: 6.84 ± 5.69 G3: 5.87 ± 4.19 G4: 6.32 ± 5.41</p> <p>ABC-Teacher – Hyperactivity G1: 24.37 ± 11 G2: 25.58 ± 1.08 G3: 24.29 ± 11.58 G4: 25.55 ± 12.99</p> <p>ABC-Teacher – Inappropriate Speech G1: 3.97 ± 3.59 G2: 4.42 ± 3.91 G3: 3.55 ± 2.96 G4: 4.71 ± 3.43</p>	<p>G1: 11.71 ± 8.96 G2: 10.31 ± 7.87 G3: 9.92 ± 7.94 G4: 12.95 ± 7.43 G1 vs G4, p=NR G2 vs G4, p=NR G3 vs G4, p≤0.05; ES=0.56</p> <p>ABC-Parent – Social Withdrawal G1: 7.46 ± 7.55 G2: 7.57 ± 7.8 G3: 3.64 ± 4.18 G4: 6.57 ± 4.46 p=NR</p> <p>ABC-Parent – Stereotypic Behavior G1: 2.21 ± 2.48 G2: 4.55 ± 5.16 G3: 2.76 ± 2.73 G4: 3.52 ± 4.45 p=NR</p> <p>ABC-Parent – Hyperactivity G1: 16.92 ± 11.17 G2: 15.55 ± 9.77 G3: 20.24 ± 11.16 G4: 24.24 ± 13.78 G1 vs G4, p≤0.01; ES=0.69 G2 vs G4, p≤0.01; ES=0.64 G3 vs G4, p=NR</p> <p>ABC-Parent – Inappropriate Speech G1: 3.58 ± 2.93 G2: 3.93 ± 3.51 G3: 3.92 ± 2.33 G4: 5.24 ± 4.15 G1 vs G4, p≤0.05;</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow- Up Time Point Post- Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b></p>
		<p>CGI-ADHD-S- Moderate G1: 9 (28) G2: 9 (28) G3: 7 (22) G4: 9 (28)</p> <p>CGI-ADHD-S- Marked G1: 19 (59) G2: 15 (47) G3: 18 (58) G4: 12 (38)</p> <p>CGI-ADHD-S- Severe/Extreme G1: 4 (13) G2: 8 (25) G3: 6 (19) G4: 11 (34)</p> <p>CGI- Noncompliance-S- Moderate G1: 2 (6) G2: 1 (3) G3: 1 (3) G4: 1 (3)</p> <p>CGI- Noncompliance-S- Marked G1: 19 (59) G2: 16 (50) G3: 17 (53) G4: 15 (47)</p> <p>CGI- Noncompliance-S- Severe/Extreme G1: 11 (35) G2: 15 (47) G3: 13 (41) G4: 16 (50)</p>	<p>ES=0.76 G2 vs G4, p=NR G3 vs G4, p≤0.05; ES=0.86</p> <p>ABC-Teacher – Irritability G1: 7.65 ± 7.74 G2: 8.97 ± 6.92 G3: 6.27 ± 7.4 G4: 12.6 ± 13.06 p=NR</p> <p>ABC-Teacher – Social Withdrawal G1: 7.59 ± 6.61 G2: 10.54 ± 7.63 G3: 7.93 ± 8.14 G4: 8.67 ± 10.4 p=NR</p> <p>ABC-Teacher – Stereotypic Behavior G1: 4.24 ± 5.84 G2: 5 ± 5.3 G3: 5.2 ± 5.48 G4: 5.4 ± 6.29 p=NR</p> <p>ABC-Teacher – Hyperactivity G1: 13.88 ± 11.13 G2: 20.64 ± 12.52 G3: 19 ± 12.84 G4: 20.67 ± 14.18 p=NR</p> <p>ABC-Teacher – Inappropriate Speech G1: 2.76 ± 2.97 G2: 3.89 ± 3.38 G3: 4.13 ± 3.38 G4: 4.13 ± 3.98 G1 vs G4, p=NR</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow- Up Time Point Post- Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b></p>
		<p>HSQ-Severity G1: 4.01 ± 1.7 G2: 3.69 ± 1.58 G3: 3.81 ± 1.49 G4: 3.99 ± 1.82</p> <p>SSQ-Severity G1: 3.67 ± 2.08 G2: 3.4 ± 1.93 G3: 3.23 ± 1.93 G4: 3.75 ± 2.29</p>	<p>G2 vs G4, p=NR G3 vs G4, p≤0.05; ES=0.61</p> <p>CGI-ADHD-I-1 or 2 G1: 15 (48.4) G2: 15 (46.9) G3: 9 (29) G4: 6 (19.4) p=NR</p> <p>CGI-ADHD-I-3 G1: 8 (25.8) G2: 11 (34.4) G3: 8 (25.8) G4: 5 (16.1) p=NR</p> <p>CGI-ADHD-I-4 G1: 6 (19.4) G2: 5 (15.6) G3: 12 (38.7) G4: 17 (54.8) p=NR</p> <p>CGI-ADHD-I-5 or 6 G1: 2 (6.5) G2: 1 (3.1) G3: 2 (6.5) G4: 3 (9.7) p=NR</p> <p>CGI- Noncompliance-I-1 or 2 G1: 10 (32.3) G2: 14 (43.8) G3: 12 (38.7) G4: 7 (22.6) p=NR</p> <p>CGI- Noncompliance-I-3 G1: 13 (41.9) G2: 14 (43.8)</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow- Up Time Point Post- Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b></p>
			<p>G3: 7 (22.6) G4: 7 (22.6) p=NR</p> <p>CGI- Noncompliance-I-4 G1: 7 (22.6) G2: 3 (9.4) G3: 7 (22.6) G4: 12 (38.7) p=NR</p> <p>CGI- Noncompliance-I-5 or 6 G1: 1 (3.2) G2: 1 (3.1) G3: 5 (16.1) G4: 5 (16.1) p=NR</p> <p>HSQ-Severity G1: 2.38 ± 1.97 G2: 1.8 ± 1.34 G3: 2.07 ± 1.52 G4: 3 ± 1.79 G1 vs G4, p≤0.05; ES=0.46 G2 vs G4, p≤0.01; ES=0.64 G3 vs G4, p=NR</p> <p>SSQ-Severity G1: 2.41 ± 2.26 G2: 3.06 ± 1.78 G3: 1.6 ± 1.43 G4: 3.04 ± 2.6 G1 vs G4, p=NR G2 vs G4, p=NR G3 vs G4, p≤0.05; ES=0.47</p>
<p>Handen et al., 2015<sup>1,2</sup> RCT</p>			<p><b>Open Label (20 weeks/Last</b></p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow- Up Time Point Post- Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b></p>
<p>G1a: Atomoxetine + Parent Training (responders) G2a: Atomoxetine (responders) G3a: Placebo + Parent Training (responders) G3b: Atomoxetine + Parent Training (placebo + PT nonresponders) G4a: Placebo (responders) G4b: Atomoxetine (placebo nonresponders)</p> <p>24 Week OLE</p> <p>Low RoB</p>			<p><b>Observation Carried Forward)</b></p> <p>SNAP-IV-Parent - ADHD G3b: 1.78 ± 0.65 G4b: 2. p=NR 18 ± 0.56</p> <p>SNAP-IV-Parent – Inattention G3b: 1.75 ± 0.75 G4b: 2.27 ± 0.5 p=NR</p> <p>SNAP-IV-Parent – Hyperactivity G3b: 1.8 ± 0.73 G4b: 2.08 ± 0.79 p=NR</p> <p>SNAP-IV-Parent – Oppositional Defiance Disorder G3b: 0.97 ± 0.72 G4b: 1.02 ± 0.76 p=NR</p> <p>HSQ-Severity G3b: 2.96 ± 1.94 G4b: 3.73 ± 1.78 p=NR</p> <p>ABC-Parent-Irritability G3b: 13.84 ± 10.3 G4b: 15.64 ± 9.38 p=NR</p> <p>ABC-Parent-Hyperactivity G3b: 28.26 ± 11.66 G4b: 30.23 ± 12.37 p=NR</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow- Up Time Point Post- Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b></p>
			<p><b>Open Label (24 weeks)</b></p> <p>SNAP-IV-Parent – Total Score G1a: 2.01 ± 0.34 G2a: 2.24 ± 0.35 G3a: 2.31 ± 0.08 G4a: 1.69 ± 0.21 p=NR</p> <p>HSQ-Severity G1a: 3.17 ± 1.77 G2a: 3.75 ± 1.34 G3a: 4.08 ± 1.51 G4a: 2.31 ± 1.71 p=NR</p>
<b>Risperidone</b>			
<p>Lamberti et al., 2016<sup>3</sup> RCT</p> <p>G1: Aripirazole (up to 15 mg/day), 22/19 G2: Risperidone (up tp 3 mg/day), 22/18</p> <p>24 weeks/EOT</p> <p>Low ROB</p>	<p>Age G1: 8.4 ± 2.9 G2: 7.9 ± 2.3</p> <p>IQ NR</p>	<p>CGI – Severity G1: 5.4 ± 0.5 G2: 5.5 ± 0.6</p> <p>CGAS – Total Score G1: 38 ± 8.3 G2: 31.42 ± 12.4</p> <p>ADHD Rating Scale – Total Score G1: 39.4 ± 2.8 G2: 37.4 ± 3.9</p> <p>CPRS – Hyperactivity G1: 5.7 ± 0.7 G2: 5.4 ± 0.7</p> <p>CPRS – Inattention G1: 5.4 ± 0.8 G2: 4.9 ± 0.9</p>	<p>CGI – Improvement G1: 3 ± 1.2 G2: 2.4 ± 0.7 G1 vs G2, p=ns</p> <p>CGAS – Total Score G1: 51.8 ± 9.8 G2: 42.7 ± 11.5 G1 vs G2, p=ns</p> <p>ADHD Rating Scale – Total Score G1: 26.7 ± 7.8 G2: 29.1 ± 3 G1 vs G2, p=ns</p> <p>CPRS – Hyperactivity G1: 3.4 ± 1.8 G2: 3.6 ± 1.2 G1 vs G2, p=ns</p> <p>CPRS – Inattention G1: 3.6 ± 1.5 G2: 3.8 ± 1 G1 vs G2, p=ns</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow- Up Time Point Post- Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b></p>
<p><sup>a</sup>Scahill 2015<sup>4</sup> RCT</p> <p>G1: Risperidone (2.5 mg/day), 57/55 G2: Placebo (NA), 27/26</p> <p>21 months/2 Years post-treatment</p> <p>Low RoB</p>	<p>Age G1: 8.6 ± 2.97 G2: 9.1 ± 2.58</p> <p>IQ ≥70 G1: 11 (23.9) G2: 6 (13.3)</p> <p>&lt;70 G1: 35 (76.1) G2: 39 (86.7)</p>	<p>ABC-Irritability G1: 27.22 ± 7.28 G2: 23.44 ± 7.24</p> <p>ABC-Social Withdrawal G1: 16.05 ± 8.55 G2: 18.52 ± 9.72</p> <p>ABC-Stereotypic Behavior G1: 10.5 ± 4.43 G2: 8.84 ± 5.22</p> <p>ABC- Hyperactivity/Noncomp liance G1: 34.3 ± 7.95 G2: 28.58 ± 10.4</p> <p>ABC-Inappropriate Speech G1: 5.71 ± 3.93 G2: 5.59 ± 4.03</p> <p>CYBOCS G1: 15.29 ± 3.15 G2: 16 ± 3.29</p> <p>CGI-Severity G1: 5.09 0.7 G2: 5.23 0.65</p> <p>VABS-Communication G1: 42.81 ± 14.75 G2: 44.21 ± 17.43</p> <p>VABS-Daily Living Skills G1: 38.56 ± 18.44 G2: 33.25 ± 15.2</p> <p>VABS-Social Skills G1: 47.4 ± 11.71 G2: 48.83 ± 18.19</p> <p>VABS-Motor Skills G1: 60.34 ± 19.86 G2: 56.88 ± 24.63</p>	<p><b>2 yrs post-treatment</b> ABC-Irritability G1: 14.82 ± 8.4 G2: 17.78 ± 10.82 G1 vs G2, p=0.0147</p> <p>ABC-Social Withdrawal G1: 8.43 ± 6.77 G2: 13.33 ± 8.73 G1 vs G2, p=0.0130</p> <p>ABC-Stereotypic Behavior G1: 6.02 ± 4.4 G2: 6.76 ± 5.37 G1 vs G2, p=0.0866</p> <p>ABC- Hyperactivity/Noncomp liance G1: 17.68 ± 10.16 G2: 23.38 ± 12.06 G1 vs G2, p=0.0020</p> <p>ABC-Inappropriate Speech G1: 3.86 ± 3.01 G2: 5.15 ± 4.24 G1 vs G2, p=0.0433</p> <p>CYBOCS G1: 11.67 ± 4.48 G2: 13.08 ± 4.6 G1 vs G2, p=0.3</p> <p>CGI-Severity G1: 4.4 ± 0.89 G2: 4.65 ± 1.09 G1 vs G2, p=0.3004</p> <p><b>7-38 mos follow-up</b> VABS-Communication G1: 43.19 ± 18.45 G2: 45.21 ± 21.09</p> <p>VABS-Daily Living Skills G1: 40.56 ± 20.3 G2: 38.54 ± 21.6</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow-Up Time Point Post-Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post-Treatment Scores, Mean ± SD</b></p>
		<p>VABS-Adaptive Behavior G1: 41.55 ± 15.63 G2: 38.58 ± 15.38</p> <p>IQ Tests G1: 50.52 ± 23.07 G2: 46.74 ± 30.57</p> <p>M-RLRS – Sensory Motor G1: 6.95 ± 4.28 G2: 4.76 ± 2.98</p> <p>M-RLRS – Social Relationships G1: 6.55 ± 4.29 G2: 6.28 ± 4.32</p> <p>M-RLRS – Affectual Responses G1: 6.13 ± 1.9 G2: 5.2 ± 1.94</p> <p>M-RLRS – Sensory Responses G1: 20.96 ± 9.06 G2: 19.24 ± 8.8</p> <p>M-RLRS – Language G1: 2.67 ± 4.31 G2: 4.92 ± 4.65</p>	<p>VABS-Social Skills G1: 50.63 ± 15.1 G2: 44.21 ± 18.07</p> <p>VABS-Motor Skills G1: 61.94 ± 15.72 G2: 63.06 ± 27.17</p> <p>VABS-Adaptive Behavior G1: 40.25 ± 15.51 G2: 38.96 ± 18.02</p> <p>IQ Tests G1: 48.73 ± 23.92 G2: 45.85 ± 32.22</p> <p>M-RLRS – Sensory Motor G1: 4.67 ± 3.06 G2: 4.2 ± 3.42</p> <p>M-RLRS – Social Relationships G1: 1.02 ± 4.23 G2: 2.4 ± 3.16</p> <p>M-RLRS – Affectual Responses G1: 3.49 ± 1.88 G2: 4.04 ± 1.88</p> <p>M-RLRS – Sensory Responses G1: 11.02 ± 7.1 G2: 14.8 ± 7.08</p> <p>M-RLRS – Language G1: -0.15 ± 3.99 G2: 1.96 ± 4.3</p>
<p><sup>a</sup>Scahill et al., 2015<sup>5</sup> RCT</p> <p>G1: Risperidone (up to 2.5 mg/kg), 49/43 G2: Placebo (NA), 52/38</p> <p>8 weeks/EOT</p>	<p>Age G1: 8.6 ± 2.97 G2: 9.1 ± 2.58</p> <p>IQ ≥70 G1: 11 (23.9) G2: 6 (13.3)</p>	<p>CYBOCS G1: 15.25 ± 3.25 G2: 14.8 ± 4.27</p>	<p><b>EOT</b> CYBOCS G1: 11.3 ± 3.77 G2: 14.1 ± 4.43 G1 vs G2, p=0.0005; ES=0.74</p>



<b>Author, Year Study Design</b>  <b>Groups (Dose), N Enrollment / N Final</b>  <b>Treatment Duration/Follow- Up Time Point Post- Treatment</b>  <b>Risk Of Bias</b>	<b>Mean Age, Years ± SD</b>  <b>Mean IQ ±SD</b>	<b>Outcome Measure/Baseline Scores, Mean ±SD</b>	<b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b>
Low RoB	<70 G1: 35 (76.1) G2: 39 (86.7)		
<sup>a</sup> Scahill et al., 2015 <sup>6</sup> RCT  G1: Risperidone (up to 2.5 mg/day), 49/49 G2: Placebo (NA), 52/52  8 weeks/EOT  Low RoB	Age G1: 7.5 ± 2.80 G2: 9.1 ± 2.58  IQ ≥70 G1: 23 (46.9) G2: 6 (13.3)  <70 NR	ABC-Social Withdrawal/Lethargy G1: 16.4 ± 8.2 G2: 16.1 ± 8.7	<b>EOT</b> ABC-Social Withdrawal/Lethargy G1 vs G2, p=0.05; ES=0.42
<sup>b</sup> Scahill et al., 2015 <sup>5</sup> RCT  G1: Risperidone (up to 3.5 mg/day), 49/47 G2: Risperidone + Parent Training (up to 3.5 mg/day + mean of 10.9 sessions), 75/70  8 weeks  Low RoB	Age G1: 7.5 ± 2.80 G2: 9.1 ± 2.58  IQ ≥70 G1: 23 (46.9) G2: 6 (13.3)  <70 NR	CYBOCS G1: 16.2 ± 2.47 G2: 14.8 ± 4.27	<b>EOT</b> CYBOCS G1: 11 ± 3.73 G2: 14.1 ± 4.43 G1 vs G2, p=0.0001; ES=0.88
Wink et al., 2014 <sup>7</sup> Retrospective Cohort  G1: Risperidone (2.23 mg/day), 72/72 G2: Aripiprazole (11.85 mg/day), 70/70  Varies/EOT  Moderate RoB	Age (at initiation) G1: 8.41 ± 3.59 G2: 9.74 ± 3.46  IQ NR	CGI-Severity NR	<b>EOT</b> CGI-Improvement G1: 3.2 ± 1.2 G2: 2.9 ± 1.2 G1 vs G2, p=ns

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow-Up Time Point Post-Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post-Treatment Scores, Mean ± SD</b></p>
<p><sup>b</sup>Kent et al., 2013<sup>8</sup> RCT</p> <p>G1: Risperidone (0.125-0.175 mg/day; low dose), 30/25 G2: Risperidone (1.25-1.75 mg/day; high dose), 31/25 G3: Placebo (NA), 35/27</p> <p>6 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 10 ± 3.4 G2: 9 ± 3.1 G3: 9 ± 2.6</p> <p>IQ Mental age G1 + G2 + G3: 5.5 yrs</p>	<p>ABC-Irritability G1: 27.1 ± 6.26 G2: 28.0 ± 7.81 G3: 28.9 ± 6.10</p> <p>CGI – Severity G1: 5.1 ± 0.92 G2: 5.0 ± 0.78 G3: 4.9 ± 0.67</p>	<p><b>EOT</b> Mean change in: ABC-Irritability G1: -7.4 ± 8.12 G2: -12.4 ± 6.52 G3: -3.5 ± 10.67 G1 vs G3: p=ns G2 vs G3: p&lt;0.001</p> <p>CGI – Severity G1: -0.4 ± 0.73 G2: -1.0 ± 0.78 G3: -0.3 ± 0.79 G1 vs G3: p=ns G2 vs G3: p&lt;0.001</p>
<p><sup>c</sup>Kent et al., 2013<sup>9</sup> RCT</p> <p>G1: Risperidone (0.125-0.175 mg/day; low dose)/Risperidone, 30/25 G2: Risperidone (1.25-1.75 mg/day; high dose)/Risperidone, 31/25 G3: Placebo/Risperidone (NA), 35/27</p> <p>6 weeks/End of open label trial</p> <p>Low RoB</p>	<p>Age G1: 10 ± 3.4 G2: 9 ± 3.1 G3: 9 ± 2.6</p> <p>IQ Mental age G1 + G2 + G3: 5.5 yrs</p>	<p>ABC-Irritability G1: 13.4 ± 3.99 G2: 14.4 ± 4.64 G3: 13.7 ± 2.66</p> <p>ABC-Hyperactivity G1: 30.1 ± 11.46 G2: 33.8 ± 9.75 G3: 31.4 ± 8.60</p> <p>ABC-Stereotypic Behavior G1: 9.3 ± 5.17 G2: 11.5 ± 5.06 G3: 10.5 ± 5.26</p> <p>ABC-Inappropriate Speech G1: 6.6 ± 3.49 G2: 7.5 ± 2.78 G3: 5.9 ± 3.42</p> <p>ABC-Social Withdrawal G1: 18.2 ± 9.71 G2: 21.4 ± 9.09 G3: 18.1 ± 10.16</p> <p>CYBOCS G1: 13.4 ± 3.99 G2: 14.4 ± 4.64 G3: 13.7 ± 2.66</p> <p>CGI-Severity G1: 5.1 ± 0.93</p>	<p><b>At OLE Endpoint</b> Mean change score ABC-Irritability G1: -13.2 ± 9.29 G2: -13 ± 10.55 G3: -11.8 ± 7.68</p> <p>ABC-Hyperactivity G1: -10.5 ± 12.42 G2: -12.3 ± 11.78 G3: -11.7 ± 8.54</p> <p>ABC-Stereotypic Behavior G1: -4.2 ± 6.51 G2: -4.6 ± 5.14 G3: -2.8 ± 4.12</p> <p>ABC-Inappropriate Speech G1: -1.8 ± 3.93 G2: -2.1 ± 3.07 G3: -1.5 ± 2.69</p> <p>ABC-Social Withdrawal G1: -8.3 ± 9.03 G2: -10.4 ± 8.57 G3: -6.9 ± 8.08</p> <p>CYBOCS G1: -4.1 ± 3.01 G2: -5.6 ± 4.66 G3: -5.3 ± 4.99</p>

<p>Author, Year Study Design</p> <p>Groups (Dose), N Enrollment / N Final</p> <p>Treatment Duration/Follow- Up Time Point Post- Treatment</p> <p>Risk Of Bias</p>	<p>Mean Age, Years ± SD</p> <p>Mean IQ ±SD</p>	<p>Outcome Measure/Baseline Scores, Mean ±SD</p>	<p>Outcome Measure/Post- Treatment Scores, Mean ± SD</p>
		<p>G2: 5 ± 0.75 G3: 4.9 ± 0.67</p>	<p>CGI-Severity G1: -1 ± 1.02 G2: -1.3 ± 1.17 G3:-0.9 ± 0.88</p> <p>CGI-Much or Very Much Improved G1: 14 (58) G2: 15 (60) G3: 20 (69)</p> <p>*% of patients with CGI-C ratings of “much” or “very much” improved at OLE endpoint was not significant among the 3 groups (p=0.684)</p> <p>*The percentage of patients with ABC-I response at OLE endpoint (defined as ‡ 25% improvement from DB baseline) was not statistically significantly different among the three groups ( p = 0.800).</p> <p><b>Mean change scores from baseline</b> ABC-Irritability G1: -7.4 ± 8.12 G2: -12.4 ± 6.52 G3: -3.5 ± 10.67 G1 Vs G3, p=0.164, ES=0.36 G2 Vs G3, p &lt;0.001, ES=0.94</p> <p>ABC-Hyperactivity G1: -10.5 ± 12.42 G2: -12.3 ± 11.78 G3: -11.7 ± 8.54 G1 Vs G3, p=0.008 G2 Vs G3, p=0.019</p> <p>ABC-Stereotypy G1: -4.2 ± 6.51</p>

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			<p>G2: -4.6 ± 5.14 G3: -2.8 ± 4.12 G1 Vs G3, p=ns G2 Vs G3, p=ns</p> <p>ABC-Inappropriate Speech G1: -1.8 ± 3.93 G2: -2.1 ± 3.07 G3: -1.5 ± 2.69 G1 Vs G3, p=ns G2 Vs G3, p=ns</p> <p>ABC-Social Withdrawal/Lethargy G1: -8.3 ± 9.03 G2: -10.4 ± 8.57 G3: -6.9 ± 8.08 G1 Vs G3, p=0.817 G2 Vs G3, p=0.004</p> <p><b>Change from baseline</b> CGI-Severity G1: -0.4 ± 0.73 G2: -1 ± 0.78 G3: -0.3 ± 0.79 G1 Vs G3, p=0.769, ES=0.08 G2 Vs G3, p&lt;0.001, ES=1.02</p> <p><b>EOT</b> CGI-Improvement – much or very much improved G1: 5 (17) G2: 18 (63) G3: 5 (15) G1 Vs G3, p=0.985 G2 Vs G3, p&lt;0.001</p> <p>CYBOCS NR</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow- Up Time Point Post- Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b></p>
<p><sup>b</sup>Scahill et al., <sup>6</sup>2013 RCT</p> <p>G1: Risperidone (up to 3.5 mg/day), 49/47 G2: Risperidone + Parent Training (up to 3.5 mg/day + mean of 10.9 sessions), 75/70</p> <p>8 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 7.5 ± 2.80 G2: 9.1 ± 2.58</p> <p>IQ ≥70 G1: 23 (46.9) G2: 6 (13.3)</p> <p>&lt;70 NR</p>	<p>ABC-Social Withdrawal/Lethargy G1: 17.1 ± 8.5 G2: 15.2 ± 9</p>	<p><b>EOT</b> ABC-Social Withdrawal/Lethargy NR</p>
<p><sup>a</sup>Shea et al., 2004<sup>10</sup> RCT</p> <p>G1: Risperidone (1 mg/mL), 24 G2: Placebo (NA), 28</p> <p>8 weeks/EOT</p> <p>Moderate RoB</p>	<p>Age G1: 7.4 ± 2.7 G2: 7.1 ± 2.1</p> <p>IQ - ≤84 G1: 19 (100) G2: 18 (75)</p> <p>IQ - &gt;84 G1: 0 (0) G2: 6 (25)</p>	<p>ABC-Irritability G1: 20.6 ± 8.1 G2: 21.6 ± 10.2</p> <p>ABC-Hyperactivity G1: 29.2 ± 9.5 G2: 33.6 ± 6.8</p> <p>ABC-Social Withdrawal/Lethargy G1: 14 ± 6.8 G2: 13.6 ± 8.6</p> <p>ABC-Stereotypy G1: 8.4 ± 5.8 G2: 9.4 ± 5.5</p> <p>ABC-Inappropriate Speech G1: 4.5 ± 3.7 G2: 4.5 ± 3.7</p> <p>Nisonger-Child Behavior Rating Form – Adaptive/Social G1: 3.8 ± 2.3 G2: 3.9 ± 2</p> <p>Nisonger-Child Behavior Rating Form – Compliant/Calm G1: 3.8 ± 2.7 G2: 6.2 ± 2.4</p> <p>Nisonger-Child Behavior Rating Form – Conduct Problem G1: 17.2 ± 8 G2: 21.5 ± 10.7</p>	<p><b>During Treatment (1 wk)</b> ABC-Irritability G1: 13.7 ± 9.1 G2: 16.9 ± 10.7</p> <p><b>During Treatment (2 wks)</b> ABC-Irritability G1: 10.3 ± 7.6 G2: 15.8 ± 10.8</p> <p><b>During Treatment (3 wks)</b> ABC-Irritability G1: 8.8 ± 7.3 G2: 14.4 ± 11.7</p> <p><b>During Treatment (5 wks)</b> ABC-Irritability G1: 8.8 ± 7.2 G2: 13.7 ± 11.1</p> <p><b>During Treatment (8 wks)</b> ABC-Irritability G1: 7.5 ± 6.4 G2: 13.8 ± 12.2</p> <p><b>EOT</b> ABC-Irritability G1: 7.2 ± 5.9 G2: 14.1 ± 11.3 G1 vs G2, p=0.002; ES = -0.7</p> <p>ABC-Hyperactivity</p>

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		<p>Nisonger-Child Behavior Rating Form – Hyperactive G1: 17.7 ± 5.6 G2: 19.6 ± 5.2</p> <p>Nisonger-Child Behavior Rating Form – Insecure/Anxious G1: 6.3 ± 6.7 G2: 8.7 ± 6.7</p> <p>Nisonger-Child Behavior Rating Form – Overly Sensitive G1: 6.7 ± 3.4 G2: 6.6 ± 3.4</p> <p>Nisonger-Child Behavior Rating Form – Self- Injury/Stereotypic G1: 4.5 ± 4.4 G2: 4.1 ± 4.4</p> <p>Nisonger-Child Behavior Rating Form – Self- Isolated/Ritualistic G1: 7.3 ± 4 G2: 7.8 ± 4.2</p> <p>VAS-Aggression G1: 86 ± 14.5 G2: 88.3 ± 9</p> <p>VAS- Defiance/Disobedience G1: 75 ± 47 G2: 94.8 ± 19.6</p> <p>VAS-Hyperactivity G1: 68.7 ± 28.6 G2: 96.3 ± 4.2</p> <p>VAS- Obsessive/Repetitive G1: 86.3 ± 19.4 G2: 98 ± 0</p>	<p>G1: 13.3 ± 8.7 G2: 26.4 ± 12.8 G1 vs G2, p=0.001; ES = -0.8</p> <p>ABC-Social Withdrawal/Lethargy G1: 4.7 ± 4.4 G2: 8.2 ± 8.9 G1 vs G2, p=0.020; ES = -0.5</p> <p>ABC-Stereotypy G1: 3.9 ± 4.2 G2: 6.9 ± 6.9 G1 vs G2, p=0.053; ES = -0.4</p> <p>ABC-Inappropriate Speech G1: 1.9 ± 2.2 G2: 3.1 ± 3.5 G1 vs G2, p=0.058; ES = -0.4</p> <p>CGI-I - much improved or very much improved G1: 14 (58.3) G2: 6 (21.4) G1 vs G2, p=0.008</p> <p>Nisonger-Child Behavior Rating Form – Adaptive/Social G1: 5.3 ± 2.4 G2: 4.3 ± 2.4 G1 vs G2, p=0.072</p> <p>Nisonger-Child Behavior Rating Form – Compliant/Calm G1: 8.7 ± 3.3 G2: 6.9 ± 2.9 G1 vs G2, p=0.072</p> <p>Nisonger-Child Behavior Rating Form – Conduct Problem G1: 6.5 ± 5.7 G2: 15.5 ± 11.9</p>

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		<p>VAS- Tantrums/Negative Mood G1: 80.8 ± 10.1 G2:81.2 ± 13.9</p>	<p>G1 vs G2, p=0.005</p> <p>Nisonger-Child Behavior Rating Form – Hyperactive G1: 9.4 ± 5.4 G2: 14.9 ± 8.4 G1 vs G2, p=0.021</p> <p>Nisonger-Child Behavior Rating Form – Insecure/Anxious G1: 3.2 ± 4.3 G2: 5.4 ± 4.8 G1 vs G2, p=ns</p> <p>Nisonger-Child Behavior Rating Form – Overly Sensitive G1: 2.8 ± 2.3 G2: 4.3 ± 3.3 G1 vs G2, p=0.029</p> <p>Nisonger-Child Behavior Rating Form – Self- Injury/Stereotypic G1: 2.2 ± 3.1 G2: 2.8 ± 3.9 G1 vs G2, p=ns</p> <p>Nisonger-Child Behavior Rating Form – Self- Isolated/Ritualistic G1: 2.4 ± 2.5 G2: 4.5 ± 5.5 G1 vs G2, p=0.078</p> <p>VAS-Aggression G1: 22.3 ± 20 G2: 63.4 ± 37.3 G1 vs G2, p=0.056</p> <p>VAS- Defiance/Disobedience G1: 60 ± 21.1 G2: 65.2 ± 25 G1 vs G2, p=ns</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow- Up Time Point Post- Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b></p>
			<p>VAS-Hyperactivity G1: 39.7 ± 19.7 G2: 80.5 ± 14.2 G1 vs G2, p=0.040</p> <p>VAS- Obsessive/Repetitive G1: 70 ± 16.8 G2: 48 ± 63.4 G1 vs G2, p=ns</p> <p>VAS- Tantrums/Negative Mood G1: 28 ± 20.9 G2:43.4 ± 28.8 G1 vs G2, p=0.496</p>
<p><sup>a</sup>Scahill et al., 2006<sup>11</sup> RCT</p> <p>G1: Risperidone (2.5 mg/day), 48/48</p> <p>16 weeks/end of 4 months</p> <p>Low RoB</p>	<p>G1: 5-16 yrs</p>	<p>VABS-Communication G1: 43.58 13.48</p> <p>VABS-Daily Living Skills G1: 39.42 18.06</p> <p>VABS-Socialization G1: 48.67 9.78</p> <p>VABS-Composite G1: 42.35 15.79</p>	<p><b>End of 4 month open label extension</b></p> <p>VABS-Communication G1: 45.21 18.85 d=0.11</p> <p>VABS-Daily Living Skills G1: 40.38 18.11 d=0.06</p> <p>VABS-Socialization G1: 5.5 12.94 d=0.14</p> <p>VABS-Composite G1: 42.06 13.53 d=-0.02</p>
<p><sup>a</sup>Scahill et al., 2005<sup>12</sup> RCT</p> <p>G1: Risperidone (2.5 mg/day), 49/49 G2: Placebo (NA), 52/42</p> <p>8 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1 + G2: 8.82 ± 2.69</p> <p>IQ NR</p>	<p>Ritvo-Freeman Real Life Rating Scales – Overall Score G1: 0.94 ± 0.36 G2: 1.03 ± 0.37</p> <p>VABS-Total Score G1: 33.26 ± 8.38 G2: 33.51 ± 8.29</p>	<p><b>4wks During Treatment</b></p> <p>Ritvo-Freeman Real Life Rating Scales – Overall Score G1: 0.54 ± 0.36 G2: 0.84 ± 0.39</p> <p><b>EOT (8 wks)</b></p> <p>Ritvo-Freeman Real Life Rating Scales – Overall Score G1: 0.45 ± 0.31 G2: 0.88 ± 0.4 G1 vs G2, ES=1.08</p>



<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow-Up Time Point Post-Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post-Treatment Scores, Mean ± SD</b></p>
			<p>VABS-Total Score G1: 20.34 ± 7.93 G2: 30.27 ± 8.87 G1 vs G2, ES=1.03, Group X time, p&lt;0.001</p>
<p><sup>a</sup>Scahill et al., 2005<sup>13</sup> RCT</p> <p>G1: Risperidone (2.5 mg/day), 63/63 G2: Placebo-Substitution (NA), NA</p> <p>4 weeks during open label extension/EOT</p> <p>Low RoB</p>	<p>Age G1 + G2: 8.82 ± 2.69</p> <p>IQ NR</p>	<p>End of initial 8 wks of med exposure</p> <p>CGI-I – Very much improved G1: 19 (30.2) G2: ND</p> <p>CGI-I – Much Improved G1: 42 (66.7) G2: ND</p> <p>CGI-I Minimally Improved G1: 0 (0) G2: ND</p> <p>CGI-I – No Change G1: 2 (3.2) G2: ND</p> <p>CGI-I – Worse G1: 0 (0) G2: ND</p> <p>CGI-I – Much Worse G1: 0 (0) G2: ND</p> <p>ABC-Irritability G1: 9.5 ± 6.8 G2: ND</p> <p>ABC-Social Withdrawal/Lethargy G1: 7.3 ± 5.4 G2: ND</p> <p>ABC-Stereotypy G1: 4.9 ± 4.3 G2: ND</p> <p>ABC-Hyperactivity</p>	<p><b>4 wks During Treatment</b></p> <p>CGI-I – Very much improved G1: 13 (20.6) G2: ND</p> <p>CGI-I – Much Improved G1: 38 (60.3) G2: ND</p> <p>CGI-I Minimally Improved G1: 7 (11.1) G2: ND</p> <p>CGI-I – No Change G1: 1 (1.6) G2: ND</p> <p>CGI-I – Worse G1: 20 (33.9) G2: ND</p> <p>CGI-I – Much Worse G1: 1 (1.6) G2: ND</p> <p><b>16 wks EOT</b></p> <p>CGI-I – Very much improved G1: 20 (33.9) G2: ND</p> <p>CGI-I – Much Improved G1: 31 (5.5) G2: ND</p> <p>CGI-I Minimally Improved G1: 5 (8.5)</p>

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		<p>G1: 15.1 ± 10 G2: ND</p> <p>ABC-Inappropriate Speech G1: 3.4 ± 3.6 G2: ND</p>	<p>G2: ND</p> <p>CGI-I – No Change G1: 1 (1.7) G2: ND</p> <p>CGI-I – Worse G1: 1 (1.7) G2: ND</p> <p>CGI-I – Much Worse G1: 1 (1.7) G2: ND</p> <p><b>EOT (Last Observation)</b> ABC-Irritability G1: 11.7 ± 8 G2: ND</p> <p>ABC-Social Withdrawal/Lethargy G1: 6.8 ± 5.9 G2: ND</p> <p>ABC-Stereotypy G1: 5.8 ± 4.7 G2: ND</p> <p>ABC-Hyperactivity G1: 15.8 ± 10.2 G2: ND</p> <p>ABC-Inappropriate Speech G1: 3.4 ± 3.2 G2: ND</p> <p><b>8 wks During Treatment</b> Relapse Rate G1: 10 (62.5) G2: 2 (12.5)</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow-Up Time Point Post-Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post-Treatment Scores, Mean ± SD</b></p>
<p><sup>c</sup>Shea et al., 2004<sup>14</sup> RCT</p> <p>G1: Risperidone (0.02 mg/kg/day), 39/39 G2: Placebo (NA), 38/38</p> <p>8 weeks/EOT</p> <p>Moderate RoB</p>	<p>Age G1: 7.6 ± 2.3 G2: 7.3 ± 2.3</p> <p>IQ – Normal G1: 3 (9.7) G2: 11 (31.4)</p> <p>IQ – Borderline G1: 6 (19.4) G2: 4 (11.4)</p> <p>IQ – Mild G1: 12 (38.7) G2: 8 (22.9)</p> <p>IQ – Moderate G1: 10 (32.3) G2: 12 (34.3)</p>	<p>ABC-Irritability G1: 18.9 ± 8.8 G2: 21.2 ± 9.7</p> <p>ABC-Hyperactivity G1: 13.7 ± 7 G2: 14.3 ± 8.2</p> <p>ABC-Social Withdrawal/Lethargy G1: 27.3 ± 9.7 G2: 30.9 ± 8.8</p> <p>ABC-Stereotypy G1: 4.6 ± 3.4 G2: 4.8 ± 3.7</p> <p>ABC-Inappropriate Speech G1: 7.9 ± 5 G2: 8.1 ± 5.6</p>	<p><b>Mean Change Score</b></p> <p>ABC-Irritability G1: -12.1 ± 5.8 G2: -6.5 ± 8.4 G1 vs G2, p≤0.001</p> <p>ABC-Hyperactivity G1: -8.6 ± 5.9 G2: -5.7 ± 6.9 G1 vs G2, p≤0.01</p> <p>ABC-Social Withdrawal/Lethargy G1: -14.9 ± 6.7 G2: -7.4 ± 9.7 G1 vs G2, p≤0.001</p> <p>ABC-Stereotypy G1: -2.6 ± 2.6 G2: -1.6 ± 3 G1 vs G2, p≤0.05</p> <p>ABC-Inappropriate Speech G1: -4.3 ± 3.8 G2: -2.4 ± 4 G1 vs G2, p≤0.05</p>
<p><sup>a</sup>Scahill et al., 2002<sup>15</sup> RCT</p> <p>G1: Risperidone (up to 2.5 mg/kg), 49/49 G2: Placebo (NA), 52/52</p> <p>8 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1 + G2: 8.82 ± 2.69</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 26.2 ± 7.9 G2: 25.5 ± 6.6</p> <p>ABC-Lethargy/Social Withdrawal G1: 16.4 ± 8.2 G2: 16.1 ± 8.7</p> <p>ABC-Stereotypic Behavior G1: 10.6 ± 4.9 G2: 9 ± 4.4</p> <p>ABC-Hyperactivity G1: 31.8 ± 9.6 G2: 32.3 ± 8.5</p> <p>ABC-Inappropriate Speech G1: 4.8 ± 4.1 G2: 6.5 ± 3.6</p>	<p><b>EOT</b></p> <p>ABC-Irritability G1: 11.3 ± 7.4 G2: 21.9 ± 9.5 G1 vs G2, p&lt;0.001; ES=1.2</p> <p>ABC-Lethargy/Social Withdrawal G1: 8.9 ± 6.4 G2: 12 ± 8.3 G1 vs G2, p=0.03, ES=0.4</p> <p>ABC-Stereotypic Behavior G1: 5.8 ± 4.6 G2: 7.3 ± 4.8 G1 vs G2, p&lt;0.001 ES=0.8</p> <p>ABC-Hyperactivity G1: 17 ± 9.7</p>

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		<p>CGI-S – Moderate G1: 9 (18) G2: 9 (18)</p> <p>CGI-S – Marked G1: 27 (55) G2: 28 (57)</p> <p>CGI-S – Severe G1: 12 (24) G2: 12 (24)</p> <p>CGI-S – Extreme G1: 1 (2) G2: 0 (0)</p>	<p>G2: 27.6 ± 10.6 G1 vs G2, p&lt;0.001</p> <p>ABC-Inappropriate Speech G1: 3 ± 3.1 G2: 5.9 ± 3.8 G1 vs G2, p=0.03. ES=0.3</p> <p>CGI-I – Much Improved or very much improved + 25% reduction on ABI-I G1: 34 (69) G2: 6 (12)</p>
<p>Nagaraj et al., 2006<sup>16</sup> RCT</p> <p>G1: Risperidone (0.5-1.0 mg/day), 19/19 G2: Placebo (NA), 20/20</p> <p>6 months/EOT</p> <p>Moderate RoB</p>	<p>Age, months G1: 57.95 ± 20.84 G2: 63 ± 20.12</p> <p>IQ – Borderline IQ G1: 9 (47.7) G2: 8 (40)</p> <p>IQ – Mild Retardation G1: 6 (31.6) G2: 5 (25)</p> <p>IQ – Moderate Retardation G1: 4 (21.1) G2: 7 (35)</p>	<p>CARS, median G1: 39.5 (32.5-46) G2: 38.5 (31.5-43)</p> <p>CGAS G1: 29.79 ± 7.27 G2: 32.65 ± 7.95</p>	<p><b>EOT</b> CARS, median G1: 32 (24.5-40.5) G2: 37.5 (30-42.5) G1 vs G2, p&lt;0.001</p> <p>CGAS G1: 40.94 ± 7.83 G2: 35.2 ± 9.38 G1 vs G2, p=0.035</p> <p>CARS (≥25% Improvement from Baseline) G1: 12 (63.2) G2: 0 (0)</p> <p>CGAS (≥25% Improvement from Baseline) G1: 17 (89.5) G2: 2 (10)</p> <p>Global Impression of Parents – Improvement to Some Extent G1: 9 (47.4) G2: 6 (30)</p> <p>Global Impression of Parents – Considerably Improved G1: 9 (47.4)</p>

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			<p>G2: 0 (0)</p> <p>Global Impression of Parents – Worsened G1: 1 (5.3) G2: 4 (20)</p> <p>Global Impression of Parents – No Change G1: 0 (0) G2: 9 (45)</p>
<p>Miral et al., 2008<sup>17</sup> RCT</p> <p>G1: Risperidone (1.2-4.0 mg/day), 15/13 G2: Haloperidol (1.0-5.7 mg/day), 15/15</p> <p>12 weeks/EOT</p> <p>Moderate ROB</p>	<p>Age G1: 10 ± 2.7 G2: 10.9 ± 2.9</p> <p>IQ NR</p>	<p>CGI-S-Mildly III G1: 0 (0) G2: 1 (6.7)</p> <p>CGI-S-Moderately III G1: 3 (20) G2: 2 (13.3)</p> <p>CGI-S-Markedly III G1: 4 (26.7) G2: 7 (46.7)</p> <p>CGI-S-Severely III G1: 5 (33.3) G2: 4 (26.7)</p> <p>CGI-S-Very Severely III G1: 1 (6.7) G2: 1 (6.7)</p> <p>ABC-Total Score G1: 85.6 ± 27.3 G2: 67.1 ± 25.1</p> <p>Ritvo-Freeman Real Life Rating Scales- Social G1: 0.62 ± 0.5 G2: 0.5 ± 0.41</p> <p>Ritvo-Freeman Real Life Rating Scales- Sensory Motor G1: 0.9 ± 0.52 G2: 0.69 ± 0.47</p> <p>Ritvo-Freeman Real Life Rating Scales-</p>	<p>CGI-I-Marked Improvement G1: 2 (15.4) G2: 0 (0) G1 vs G2, p=ns</p> <p>CGI-I-Moderate Improvement G1: 9 (69.2) G2: 9 (60) G1 vs G2, p=ns</p> <p>CGI-I-Slight Improvement G1: 2 (15.4) G2: 5 (33.3) G1 vs G2, p=ns</p> <p>CGI-I-No Change G1: 0 (0) G2: 1 (6.7)</p> <p>CGI degree of improvement G1 vs G2, p=ns</p> <p>ABC-Total Score G1: 36.8 ± 13.8 G2: 45.8 ± 20.2 G1 vs G2, p=0.0063</p> <p>Ritvo-Freeman Real Life Rating Scales- Social G1: -0.11 ± 0.38 G2: 0.02 ± 0.57 G1 vs G2, p=ns</p> <p>Ritvo-Freeman Real</p>

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		<p>Affect G1: 1.09 ± 0.41 G2: 1.05 ± 0.61</p> <p>Ritvo-Freeman Real Life Rating Scales-Sensory G1: 0.98 ± 0.46 G2: 0.86 0.44</p> <p>Ritvo-Freeman Real Life Rating Scales-Language G1: 0.52 ± 0.37 G2: 0.15 ± 0.44</p>	<p>Life Rating Scales-Sensory Motor G1: 0.36 ± 0.34 G2: 0.5 ± 0.44 G1 vs G2, p=ns</p> <p>Ritvo-Freeman Real Life Rating Scales-Affect G1: 0.54 ± 0.34 G2: 0.64 ± 0.48 G1 vs G2, p=ns</p> <p>Ritvo-Freeman Real Life Rating Scales-Sensory G1: 0.51 ± 0.25 G2: 0.58 ± 0.49 G1 vs G2, p=ns</p> <p>Ritvo-Freeman Real Life Rating Scales-Language G1: 0.04 ± 0.25 G2: -0.05 ± 0.5 G1 vs G2, p=ns</p>
<p>Troost et al., 2005<sup>18</sup> RCT</p> <p>G1: Risperidone (0.5-3.5 mg/day), 12/12 G2: Placebo (ND), 12/12</p> <p>8 weeks/EOT</p> <p>Low ROB</p>	<p>Age G1: 9.4 ± 3.4 G2: 8.7 ± 1.2</p> <p>Average or above-average IQ G1: 6 (50) G2: 9 (75)</p> <p>Borderline IQ G1: 4 (33) G2: 3 (25)</p> <p>Mild or Moderate Retardation G1: 2 (17) G2: 0 (0)</p>	<p>ABC-Irritability G1: 11.1 ± 8.1 G2: 12.7 ± 7.7</p> <p>ABC-Social Withdrawal/Lethargy G1: 5 ± 6 G2: 6.7 ± 6.9</p> <p>ABC-Stereotypic Behavior G1: 2.3 ± 3.2 G2: 4.7 ± 4.3</p> <p>ABC-Hyperactivity G1: 16.8 ± 11.5 G2: 15.8 ± 9.4</p> <p>ABC-Inappropriate Speech G1: 3.2 ± 3.2 G2: 2.3 ± 1.9</p>	<p>CGI-Minimally Improved G1: 5 (42) G2: 3 (25)</p> <p>CGI-Much Improvement G1: 3 (25) G2: 6 (50)</p> <p>CGI-Very Much Improved G1: 4 (33) G2: 3 (25)</p> <p>ABC-Irritability G1: 12.6 ± 9.8 G2: 20.3 ± 10.2 G1 vs G2, p=0.043</p> <p>ABC-Social Withdrawal/Lethargy G1: 2.8 ± 3.1 G2: 4.8 ± 3.5</p>

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			<p>G1 vs G2, p=ns</p> <p>ABC-Stereotypic Behavior G1: 3.3 ± 3.5 G2: 3.4 ± 4.6 G1 vs G2, p=0.305</p> <p>ABC-Hyperactivity G1: 18 ± 11.8 G2: 20.8 ± 12.1 G1 vs G2, p=0.118</p> <p>ABC-Inappropriate Speech G1: 3 ± 2.8 G2: 3 ± 2.3 G1 vs G2, p=0.303</p>
<b>Aripiprazole</b>			
<p>Findling et al., 2014<sup>19</sup> RCT</p> <p>G1: Aripiprazole (2-15 mg/day), 41/22 G2: Placebo (NA), 44/19</p> <p>16 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 10.1 ± 2.8 G2: 10.8 ± 2.8</p> <p>IQ G1: NR G2: NR</p>	<p>ABC-I – adjusted mean score NR</p> <p>CGI - improvement scale NR</p>	<p><b>EOT</b> Relapse rate G1: 35% G2: 52% G1 vs G2: p=ns</p> <p>Change scores in: ABC- I G1: 5.2 G2: 9.6 G1 vs G2: p=ns</p> <p>ABC- Hyperactivity G1: 5.0 G2: 10.3 G1 vs G2: p=0.041</p> <p>ABC- Stereotypy G1: 0.8 G2: 2.8 G1 vs G2: p=0.018</p> <p>ABC- Inappropriate speech G1: 0.6 G2: 2.1 G1 vs G2: p=0.013</p> <p>ABC- Social withdrawal G1: 0</p>

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			<p>G2: 1.5 G1 vs G2: p=ns</p> <p>CGI- I G1: 4.2 G2: 4.8 G1 vs G2: p=ns</p>
<p>Ghanizadeh et al., 2014<sup>20</sup> RCT</p> <p>G1: Aripiprazole (1.25-10 mg/day), 29/29 G2: Risperidone (0.25-3 mg/day), 30/30</p> <p>2 months/EOT</p> <p>Low RoB</p>	<p>Age G1: 9.6 ± 3.3 G2: 9.5 ± 4.6</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 26.2 ± 4.1 G2: 21.5 ± 7.4</p> <p>ABC-Hyperactivity G1: 37.1 ± 7 G2: 36 ± 6.2</p> <p>ABC-Lethargy G1: 27.5 ± 8.4 G2: 25.3 ± 8.9</p> <p>ABC-Stereotypy G1: 13.6 ± 5.7 G2: 13.2 ± 4.2</p> <p>ABC-Speech G1: 8.6 ± 3.1 G2: 8.9 ± 3.6</p>	<p><b>EOT</b></p> <p>ABC-Irritability G1: 14.6 ± 5.5 G2: 12.5 ± 5.4 G1 vs G2, p=ns</p> <p>ABC-Hyperactivity G1: 21.1 ± 9 G2: 19.1 ± 6.1 G1 vs G2, p=ns</p> <p>ABC-Lethargy G1: 17.3 ± 7.4 G2: 16.1 ± 6.9 G1 vs G2, p=ns</p> <p>ABC-Stereotypy G1: 8.2 ± 5 G2: 7.4 ± 3.9 G1 vs G2, p=ns</p> <p>ABC-Speech G1: 4.9 ± 2.3 G2: 5.7 ± 3.1 G1 vs G2, p=ns</p> <p>CGI-Improvement, n Much improved G1: 9 G2: 5</p> <p>Minimally improved G1: 7 G2: 12</p> <p>No change G1: 5 G2: 8</p> <p>Minimally worse G1: 3</p>



<b>Author, Year Study Design</b>  <b>Groups (Dose), N Enrollment / N Final</b>  <b>Treatment Duration/Follow- Up Time Point Post- Treatment</b>  <b>Risk Of Bias</b>	<b>Mean Age, Years ± SD</b>  <b>Mean IQ ±SD</b>	<b>Outcome Measure/Baseline Scores, Mean ±SD</b>	<b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b>
			G2: 2 G1 vs G2: p=ns
<sup>6</sup> Marcus et al., 2012 <sup>21</sup> RCT  G1: Aripiprazole (2-15 mg/kg; flexibly dosed study), 34/34 G2: Aripiprazole (5 mg/kg), 43/43 G3: Aripiprazole (10 mg/kg), 49/49 G4: Aripiprazole (15 mg/kg), 41/41 G5: Placebo (flexibly dosed study), 39/39 G6: Placebo (fixed-dose study), 37/37  8 weeks/EOT  Low RoB	Age G1: 9.5 ± 3.1 G2: 9.4 ± 3  IQ NR	Pediatric QoL- Combined Scales G1: 45 ± 2.9 G2: 41.5 ± 2.3 G3: 43.4 ± 2.1 G4: 38.3 ± 2.3 G5: 38.1 ± 2.7 G6: 42.8 ± 2.5	<b>EOT</b> Pediatric QoL- Combined Scales G1: 13.4 ± 1.9 G2: 14 ± 2.4 G3: 10.4 ± 2.2 G4: 18.7 ± 2.4 G5: 2 ± 1.8 G6: 10.6 ± 2.6
<sup>6</sup> Marcus et al., 2011 <sup>22</sup> RCT  G1: De Novo Subjects (2-15 mg/kg), 84/55 G2: Prior Placebo (2-15 mg/kg), 69/37 G3: Prior Aripiprazole (2-15 mg/kg), 169/107  52 weeks  Low RoB	Age 9.6 (mean)  IQ NR	CGI-Severity G1: 4.8 ± 1 G2: 4.2 ± 1 G3: 3.9 ± 1.1  ABC-Irritability G1: 23.2 ± 8.9 G2: 21.5 ± 9.8 G3: 15 ± 9.2  ABC-Lethargy/Social Withdrawal G1: 14.6 ± 8.6 G2: 11.3 ± 9.2 G3: 10.4 ± 8.9  ABC-Stereotypic Behavior G1: 8.1 ± 5.2 G2: 9.1 ± 5.6 G3: 6.4 ± 5.5  ABC-Hyperactivity G1: 28.4 ± 10.9 G2: 25.8 ± 13.2	<b>EOT</b> CGI-Severity G1: -1 ± 0.8 G2: -0.6 ± 1.2 G3: -0.1 ± 1  ABC-Irritability G1: -8 ± 10.1 G2: -6.1 ± 1.9 G3: 0.7 ± 10.2  ABC-Lethargy/Social Withdrawal G1: -6.4 ± 7.9 G2: -4.1 ± 7.2 G3: -2.3 ± 6.4  ABC-Stereotypic Behavior G1: -2.7 ± 3.1 G2: -1.9 ± 4.1 G3: -0.5 ± 4.4  ABC-Hyperactivity G1: -12.3 ± 8.5

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow- Up Time Point Post- Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b></p>
		<p>G3: 18.4 ± 12</p> <p>ABC-Inappropriate Speech G1: 5.8 ± 3.2 G2: 5.7 ± 4.2 G3: 4.2 ± 3.6</p> <p>CYBOCS G1: 12.6 ± 4.6 G2: 12.1 ± 4 G3: 10.4 ± 3.9</p>	<p>G2: -9.1 ± 11.5 G3: 0.6 ± 10.3</p> <p>ABC-Inappropriate Speech G1: -2 ± 2.5 G2: -1.8 ± 3 G3: -0.3 ± 2.4</p> <p>CYBOCS G1: -2.8 ± 3.5 G2: -2.6 ± 5.4 G3: 0.2 ± 4.1</p>
<p><sup>e</sup>Marcus et al., 2010<sup>23</sup> RCT</p> <p>G1: Aripiprazole (2-15 mg/kg; flexibly dosed study), 46/46 G2: Aripiprazole (5 mg/kg), 52/52 G3: Aripiprazole (10 mg/kg), 59/59 G4: Aripiprazole (15 mg/kg), 53/53 G5: Placebo (flexibly dosed study) 49/49 G6: Placebo (fixed-dose study) 49/49</p> <p>8 weeks/EOT</p> <p>Low RoB</p>	<p>Age Flexibly dosed study: 9.3 ± 2.9</p> <p>Fixed dose study: 9.7 ± 3.1</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 29.6 ± 1 G2: 28.3 ± 1 G3: 27.6 ± 0.9 G4: 28.3 ± 1 G5: 30.8 ± 1 G6: 26.9 ± 1</p> <p>ABC-Social Withdrawal/Lethargy G1: 19.9 ± 1.6 G2: 17.7 ± 1.4 G3: 16.8 ± 1.3 G4: 18.9 ± 1.4 G5: 18.1 ± 1.6 G6: 18 ± 1.5</p> <p>ABC-Stereotypic Behavior G1: 11.9 ± 0.9 G2: 11.4 ± 0.8 G3: 11.6 ± 0.8 G4: 10.7 ± 0.9 G5: 10.7 ± 0.8 G6: 10.7 ± 0.8</p> <p>ABC-Hyperactivity G1: 34.1 ± 1.4 G2: 33.1 ± 1.4 G3: 33.7 ± 1.3 G4: 32.2 ± 1.4 G5: 34.7 ± 1.4 G6: 31.1 ± 1.4</p> <p>ABC-Inappropriate Speech G1: 7 ± 0.6</p>	<p>Change score <b>EOT</b> ABC-Irritability G1: -12.9 ± 1.4 G2: -12.4 ± 1.4 G3: -13.2 ± 1.3 G4: -14.4 ± 1 G5: -5 ± 1.4 G6: -8.4 ± 1.4 G1 vs G6, p&lt;0.05 G2 vs G6, p&lt;0.05 G3 vs G6, p&lt;0.05 G4 vs G6, p&lt;0.05</p> <p>ABC-Social Withdrawal/Lethargy G1: -7.9 ± 1.2 G2: -5.8 ± 1.2 G3: -4.9 ± 1.1 G4: -7.9 ± 1.1 G5: -6.2 ± 1.1 G6: -5.2 ± 1.2 G5 vs G6, p=ns</p> <p>ABC-Stereotypic Behavior G1: -4.8 ± 0.6 G2: -4.5 ± 0.7 G3: -4.2 ± 0.6 G4: -4.5 ± 0.7 G5: -2 ± 0.6 G6: -1.8 ± 0.7 G1 vs G6, p&lt;0.05 G2 vs G6, p&lt;0.05 G3 vs G6, p&lt;0.05 G4 vs G6, p&lt;0.05</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow- Up Time Point Post- Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b></p>
		<p>G2: 5.8 ± 0.6 G3: 6.8 ± 0.5 G4: 6.3 ± 0.5 G5: 7 ± 0.6 G6: 5.9 ± 0.6</p>	<p>ABC-Hyperactivity G1: 12.7 ± 1.5 G2: -14 ± 1.6 G3: -13.3 ± 1.5 G4: -16.3 ± 1.6 G5: -2.8 ± 1.5 G6: -7.7 ± 1.7 G1 vs G6, p&lt;0.05 G2 vs G6, p&lt;0.05 G3 vs G6, p&lt;0.05 G4 vs G6, p&lt;0.05</p> <p>ABC-Inappropriate Speech G1: -2.5 ± 0.4 G2: -2 ± 0.5 G3: -1.8 ± 0.4 G4: -2.3 ± 0.4 G5: -0.4 ± 0.4 G6: -1.1 ± 5 G4 vs G6, p&lt;0.05</p>
<p><sup>e</sup>Marcus et al., 2009<sup>24</sup> RCT</p> <p>G1: Aripiprazole (2-15 mg/kg), 47/39 G2: Placebo (NA), 51/36</p> <p>8 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 9.7 ± 3.2 G2: 8.8 ± 2.6</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 29.6 ± 6.4 G2: 30.2 ± 6.5</p> <p>ABC- Hyperactivity/Noncomp liance G1: 34.1 G2: 34.7</p> <p>ABC-Stereotypic Behavior G1: 11.9 G2: 10.7</p> <p>ABC-Inappropriate Speech G1: 7 G2: 7</p> <p>CYBOCS G1: 12.8 G2: 13.7</p>	<p>Change Score <b>EOT</b> ABC-Irritability G1: -12.9 G2: -5 G1 vs G2, p&lt;0.001</p> <p>ABC- Hyperactivity/Noncomp liance G1: -12.7 G2: -2.8 G1 vs G2, p&lt;0.001</p> <p>ABC-Stereotypic Behavior G1: -4.8 G2: -2 G1 vs G2, p&lt;0.001</p> <p>ABC-Inappropriate Speech G1: -2.5 G2: -0.4 G1 vs G2, p&lt;0.001</p> <p>CYBOCS G1: -3.8 G2: -0.8</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (Dose), N Enrollment / N Final</b></p> <p><b>Treatment Duration/Follow- Up Time Point Post- Treatment</b></p> <p><b>Risk Of Bias</b></p>	<p><b>Mean Age, Years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome Measure/Baseline Scores, Mean ±SD</b></p>	<p><b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b></p>
			<p>G1 vs G2, p&lt;0.001</p> <p>CGI-Severity G1: -1.2 G2: -0.4</p> <p>CGI-I – Very much improved or much improved G1: 31 (67) G2: 8 (16)</p> <p>CGI-I – Minimally improved G1: 7 (15) G2: 10 (20)</p> <p>CGI-I – No change G1: 6 (13) G2: 22 (45)</p> <p>CGI-I – Minimally worse G1: 2 (4) G2: 5 (10)</p> <p>CGI-I – Much or very much worse G1: 0 (0) G2: 4 (8)</p>
<p><sup>a</sup>Marcus et al., 2009<sup>25</sup></p> <p>RCT</p> <p>G1: Aripiprazole (5 mg/kg), 53/44 G2: Aripiprazole (10 mg/kg), 59/49 G3: Aripiprazole (15 mg/kg), 54/47 G4: Placebo (NA), 52/38</p> <p>8 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 9 ± 2.8 G2: 10 ± 3.2 G3: 9.5 ± 3.1 G4: 10.2 ± 3.1</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 28.6 ± 7.6 G2: 28.2 ± 7.4 G3: 28.9 ± 6.4 G4: 28 ± 6.9</p> <p>ABC-Hyperactivity/Noncompliance G1: 33.1 ± 1.4 G2: 33.7 ± 1.3 G3: 32.2 ± 1.4 G4: 31 ± 1.4</p> <p>ABC-Stereotypic Behavior G1: 11.4 ± 0.8 G2: 11.6 ± 0.8 G3: 11.6 ± 0.8 G4: 10.7 ± 0.8</p>	<p>Change score <b>EOT</b> ABC-Irritability G1: -12.4 G2: -13.2 G3: -14.4 G4: -8.4 G1 v G4: p=0.032 G2 v G4: p=0.008 G3 v G4: p=0.001</p> <p>ABC-Hyperactivity/Noncompliance G1: -14 ± 1.6 G2: -13.3 ± 1.5 G3: -16.3 ± 1.6 G4: -7.7 ± 1.7 G1 v G4: p≤0.005 G2 v G4: p≤0.05</p>

<b>Author, Year Study Design</b>  <b>Groups (Dose), N Enrollment / N Final</b>  <b>Treatment Duration/Follow- Up Time Point Post- Treatment</b>  <b>Risk Of Bias</b>	<b>Mean Age, Years ± SD</b>  <b>Mean IQ ±SD</b>	<b>Outcome Measure/Baseline Scores, Mean ±SD</b>	<b>Outcome Measure/Post- Treatment Scores, Mean ± SD</b>
		ABC-Social Withdrawal/Lethargy G1: 17.7 ± 1.4 G2: 16.8 ± 1.3 G3: 18.9 ± 1.4 G4: 18 ± 1.5  ABC-Inappropriate Speech G1: 5.8 ± 0.6 G2: 6.8 ± 0.5 G3: 6.3 ± 0.5 G4: 5.9 ± 0.6  CYBOCS G1: 13.9 ± 0.6 G2: 13.5 ± 0.5 G3: 14.1 ± 0.5 G4: 13.7 ± 0.6  CGI-S G1: 5 ± 0.1 G2: 4.9 ± 0.1 G3: 5.1 ± 0.1 G4: 4.7 ± 0.1	G3 v G4: p≤0.001  ABC-Stereotypic Behavior G1: -4.5 ± 0.68 G2: -4.2 ± 0.63 G3: -4.5 ± 0.66 G4: -1.8 ± 0.69 G1 v G4: p≤0.005 G2 v G4: p≤0.05 G3 v G4: p≤0.005  ABC-Social Withdrawal/Lethargy G1: -5.8 ± 1.2 G2: -4.9 ± 1.1 G3: -7.9 ± 1.1 G4: -5.2 ± 1.2  ABC-Inappropriate Speech G1: -2 ± 0.5 G2: -1.8 ± 0.4 G3: -2.3 ± 0.4 G4: -1.1 ± 0.5  CYBOCS G1: -2.6 ± 0.5 G2: -2.4 ± 0.4 G3: -3.2 ± 0.5 G4: -1.7 ± 0.5 G1 v G4: p=NS G2 v G4: p=NS G3 v G4: p≤ 0.05  CGI-S G1: -0.9 ± 0.2 G2: -1 ± 0.1 G3: -1.1 ± 0.2 G4: -0.6 ± 0.2

<sup>a</sup>Publication in a larger RCT<sup>4-6, 11-13, 15, 26-30</sup>

<sup>b</sup>Publication in a larger RCT<sup>8, 9</sup>

<sup>c</sup>Publication in a larger RCT<sup>10, 14</sup>

<sup>d</sup>Publication in a larger RCT<sup>21-25, 31, 32</sup>

ABC-Aberrant Behavior Checklist; CGI-Clinical Global Impression; VABS-Vineland Adaptive Behavior Scale; CYBOCS-Children's Yale-Brown Obsessive Compulsive Scale; M-RLRS-Modified Real Life Rating Scale; EOT-End of Treatment; OLE-Open-label Extension; VAS-Visual Analog Scale; CGAS-Children's Global Assessment Scale

**Table F-2. Key findings in studies of methylphenidate**

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
<p><b>Mean IQ ±SD</b></p>			
<p>RUPP 2005<sup>33-36</sup> RCT</p> <p>G1: Methylphenidate - low dose (0.125 mg/kg), 66/45 G2: Methylphenidate - medium dose (0.250 mg/kg), 66/52 G3: Methylphenidate - high dose (0.500 mg/kg), 66/33 G4: Methylphenidate - optimal dose (NA), 66/58 G5: Placebo (NA), 66/46</p> <p>13 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1+G2+G3+G4+ G5: 7.5</p> <p>IQ NR</p>	<p><b>Overall ratings:</b> CGI severity sub- scale rating, n (%): Moderately ill: 20 (30.3)</p> <p>Markedly ill: 35 (52.0)</p> <p>Severely ill: 11 (16.7)</p> <p><b>Educational/cog- nitive/academic attainment:</b> Slosson IQ, mean ± SD (range): 62.6 ± 32.9 (16-135)</p> <p><b>Social skills:</b> VABS score, mean ± SD (range):†</p> <p>Socialization: 61.7 ± 16.7 (20-109)</p> <p><b>Communication/ language:</b> VABS Communication: 62.8 ± 21.8 (20-126)</p> <p><b>Adaptive behavior:</b> VABS composite: 56.2 ± 21.0 (20-109)</p> <p>VABS Daily living skills: 54.4 ± 19.8 (20-110)</p> <p><b>Problem behavior:</b> ABC score, parent- rated, mean ± SD (range):†</p> <p>Irritability: 16.9 ± 10.1 (0-41)</p> <p>Lethargy/social withdrawal: 12.1 ± 8.9 (0-33)</p>	<p><b>Overall ratings:</b> Responded to treatment, sub- jects completing cross-over phase, n (%): Total: 44 (76)</p> <p>Optimal/best treatment:† Placebo: 9 (20) Low: 11 (25) Medium: 14 (32) High: 10 (23)</p> <p>Response rate, by dose, n (%):† <b>G1:</b> 20/61 (33) <b>G2:</b> 27/77 (35) <b>G3:</b> 18/47 (38) <b>G5:</b> 12/61 (20) <b>G1/G5:</b> <i>P</i> = 0.18 <b>G2/G5:</b> <i>P</i> = 0.05 (including first medium dose) <b>G2/G5:</b> <i>P</i> = 0.06 (including first and second medium dose when applicable) <b>G3/G5:</b> <i>P</i> = 0.07</p> <p><b>Social skills:</b>^ Joint attention (n=33), mean ± SD</p> <p>Initiations: <b>G1:</b> 23.29 ± 16.62 <b>G2:</b> 20.85 ± 13.01 <b>G3:</b> 19.27 ± 14.23 <b>G4:</b> 25.09 ± 15.55 <b>G5:</b> 18.59 ± 12.03 <b>G1/G5:</b> <i>P</i> &lt; 0.05 <b>G2/G5:</b> <i>P</i> = NS <b>G3/G5:</b> <i>P</i> = NS</p>

<p>Author, Year Study Design</p> <p>Groups (dose), N enrollment / N final</p> <p>Treatment duration/Follow-up timepoint post-treatment</p> <p>Risk of Bias</p>	<p>Mean age, years ± SD</p> <p>Mean IQ ±SD</p>	<p>Outcome measure/Baseline scores, mean ±SD</p>	<p>Outcome measure/Post- treatment scores, mean ± SD</p>
		<p>Stereotypy: 7.6 ± 5.9 (0-21)</p> <p>Hyperactivity: 33.2 ± 8.7 (2-47)</p> <p>Inappropriate speech: 6.0 ± 4.1 (0-12)</p> <p>ABC score, teacher- rated, mean ± SD (range):†</p> <p>Irritability: 16.1 ± 9.4 (0-43)</p> <p>Lethargy/social withdrawal: 15.5 ± 10.9 (0-42)</p> <p>Stereotypy: 7.6 ± 5.1 (0-19)</p> <p>Hyperactivity: 30.9 ± 7.9 (16-45)</p> <p>Inappropriate speech: 5.8 ± 3.6 (0-12)</p> <p>SNAP-IV, parent- rated, mean ± SD:* ADHD: 39.82 ± 8.09</p> <p>Inattention: 20.21 ± 5.17</p> <p>Hyperactivity/ impulsivity: 19.61 ± 4.22</p> <p>Oppositional defiant disorder: 9.61 ± 6.19 SNAP-IV, teacher- rated, mean ± SD:*</p> <p>ADHD: 37.23 ± 7.04</p> <p>Inattention:</p>	<p><b>G4/G5: P &lt; 0.05</b></p> <p>Responses: <b>G1: 2.48 ± 1.45</b> <b>G2: 1.69 ± 1.42</b> <b>G3: 1.93 ± 1.48</b> <b>G4: 2.24 ± 1.69</b> <b>G5: 1.90 ± 1.71</b> <b>G1/G5: P &lt; 0.01</b> <b>G2/G5: P = NS</b> <b>G3/G5: P = NS</b> <b>G4/G5: P = NS</b></p> <p>Requesting: G1: 4.04 ± 2.25 G2: 3.81 ± 2.65 G3: 3.69 ± 3.27 G4: 4.13 ± 2.58 G5: 3.67 ± 2.40 G1/G5: P = NS G2/G5: P = NS G3/G5: P = NS G4/G5: P = NS</p> <p>Competing demands task (n=33), mean ± SD: Self-regulating behavior: G1: 19.77 ± 10.89 G2: 16.21 ± 9.03 G3: 15.80 ± 12.65 G4: 16.47 ± 13.91 G5: 12.47 ± 11.29 G1/G5: P = 0.09 G2/G5: P &lt; 0.01 G3/G5: P = NS G4/G5: P = 0.09</p> <p>Regulated affective state: G1: 12.91 ± 4.98 G2: 12.96 ± 3.85 G3: 11.67 ± 5.53 G4: 12.47 ± 4.99 G5: 9.57 ± 6.72 G1/G5: P = NS G2/G5: P &lt; 0.05</p>

<p>Author, Year Study Design</p> <p>Groups (dose), N enrollment / N final</p> <p>Treatment duration/Follow-up timepoint post-treatment</p> <p>Risk of Bias</p>	<p>Mean age, years ± SD</p> <p>Mean IQ ±SD</p>	<p>Outcome measure/Baseline scores, mean ±SD</p>	<p>Outcome measure/Post- treatment scores, mean ± SD</p>
		<p>19.30 ± 4.32</p> <p>Hyperactivity/ impulsivity: 17.93 ± 4.81</p> <p>Oppositional defiant disorder: 8.83 ± 5.19</p> <p>CYBOCS-PDD, clinician-rated, mean ± SD:* 13.30 ± 3.74</p> <p>VABS Maladaptive behaviors total: 29.2 ± 9.2 (13-51)</p> <p>Motor skills: 69.2 ± 17.8 (44-113)</p>	<p>G3/G5: P &lt; 0.05 G4/G5: P = 0.09</p> <p>Clean-up task (n=33), mean ± SD: Compliance behaviors: G1: 3.67 ± 4.87 G2: 3.67 ± 5.64 G3: 4.06 ± 4.55 G4: 3.94 ± 4.88 G5: 3.47 ± 5.41 G1/G5: P = NS G2/G5: P = NS G3/G5: P = NS G4/G5: P = NS</p> <p>Regulated affective state: G1: 8.10 ± 5.18 G2: 6.88 ± 4.86 G3: 6.65 ± 6.03 G4: 7.42 ± 5.05 G5: 7.33 ± 4.86 G1/G5: P = NS G2/G5: P = NS G3/G5: P = NS G4/G5: P = NS</p> <p>Repetitive behavior:† See notes Problem behavior: ABC- hyperactivity subscale score, mean ± SD:† Parent-rated: G1: 23.0 ± 11.29 G2: 20.6 ± 10.27 G3: 22.1 ± 9.67 G4: 17.2 ± 9.87 G5: 26.0 ± 9.90 G1/G5: P = 0.03 (es = 0.29) G2/G5: P &lt; 0.001 (es = 0.54) G3/G5: P = 0.003 (es = 0.40) G4/G5: P &lt;</p>



<p>Author, Year Study Design</p> <p>Groups (dose), N enrollment / N final</p> <p>Treatment duration/Follow-up timepoint post-treatment</p> <p>Risk of Bias</p>	<p>Mean age, years ± SD</p> <p>Mean IQ ±SD</p>	<p>Outcome measure/Baseline scores, mean ±SD</p>	<p>Outcome measure/Post- treatment scores, mean ± SD</p>
			<p>0.001 (es = 0.89)</p> <p>Teacher-rated: G1: 22.9 ± 12.84 G2: 23.6 ± 12.53 G3: 20.3 ± 11.94 G4: 20.1 ± 12.40 G5: 26.0 ± 11.66 G1/G5: P = 0.03 (es = 0.25) G2/G5: P = 0.008 (es = 0.20) G3/G5: P = 0.002 (es = 0.48) G4/G5: P &lt; 0.001 (es = 0.48)</p> <p>SNAP-IV inatten- tion, mean ± SD:*</p> <p>Parent-rated: G1: 14.58 ± 6.56 G2: 13.38 ± 6.48 G3: 14.30 ± 6.35 G4: 11.83 ± 6.02 G5: 15.59 ± 6.51 G1/G5: P = 0.15 (es = 0.15) G2/G5: P &lt; 0.001 (es = 0.34) G3/G5: P = 0.06 (es = 0.20) G4/G5: P &lt; 0.001 (es = 0.60)</p> <p>Teacher-rated: G1: 15.24 ± 6.34 G2: 14.27 ± 6.93 G3: 14.67 ± 6.88 G4: 13.98 ± 6.46 G5: 16.15 ± 6.10 G1/G5: P = 0.21 (es = 0.15) G2/G5: P &lt; 0.001 (es = 0.29) G3/G5: P = 0.02 (es = 0.23) G4/G5: P = 0.003 (es = 0.35)</p> <p>SNAP-IV</p>

<p>Author, Year Study Design</p> <p>Groups (dose), N enrollment / N final</p> <p>Treatment duration/Follow-up timepoint post-treatment</p> <p>Risk of Bias</p>	<p>Mean age, years ± SD</p> <p>Mean IQ ±SD</p>	<p>Outcome measure/Baseline scores, mean ±SD</p>	<p>Outcome measure/Post- treatment scores, mean ± SD</p>
			<p>hyperactivity/ impulsivity, mean ± SD:* Parent-rated: G1: 13.39 ± 5.87 G2: 12.19 ± 6.06 G3: 13.49 ± 6.41 G4: 10.80 ± 5.99 G5: 15.33 ± 5.81 G1/G5: P = 0.02 (es = 0.33) G2/G5: P &lt; 0.001 (es = 0.53) G3/G5: P = 0.01 (es = 0.30) G4/G5: P &lt; 0.001 (es = 0.77)</p> <p>Teacher-rated: G1: 12.76 ± 6.84 G2: 13.00 ± 6.71 G3: 11.45 ± 7.01 G4: 11.26 ± 6.26 G5: 14.41 ± 6.095 G1/G5: P = 0.08 (es = 0.24) G2/G5: P = 0.01 (es = 0.21) G3/G5: P = 0.005 (es = 0.42) G4/G5: P = 0.005 (es = 0.48)</p> <p>SNAP-IV oppositional defiant disorder, mean ± SD:* Parent-rated: G1: 6.77 ± 5.62 G2: 7.02 ± 5.90 G3: 7.53 ± 5.90 G4: 5.86 ± 4.70 G5: 7.69 ± 5.80 G1/G5: P = 0.14 (es = 0.16) G2/G5: P = 0.25 (es = 0.12) G3/G5: P = 0.66 (es = 0.03) G4/G5: P &lt; 0.001 (es = 0.35)</p>

<p>Author, Year Study Design</p> <p>Groups (dose), N enrollment / N final</p> <p>Treatment duration/Follow-up timepoint post-treatment</p> <p>Risk of Bias</p>	<p>Mean age, years ± SD</p> <p>Mean IQ ±SD</p>	<p>Outcome measure/Baseline scores, mean ±SD</p>	<p>Outcome measure/Post- treatment scores, mean ± SD</p>
			<p>Teacher-rated: G1: 5.89 ± 5.43 G2: 6.65 ± 5.10 G3: 6.75 ± 5.63 G4: 5.61 ± 4.85 G5: 7.02 ± 5.80 G1/G5: P = 0.11 (es = 0.20) G2/G5: P = 0.17 (es = 0.07) G3/G5: P = 0.35 (es = 0.05) G4/G5: P = 0.04 (es = 0.26)</p> <p>CYBOCS-PDD, clinician-rated, mean ± SD:* G1: 12.82 ± 4.15 G2: 12.31 ± 4.27 G3: 13.02 ± 4.11 G4: 12.13 ± 4.22 G5: 13.05 ± 3.46 G1/G5: P = 0.90 (es = 0.06) G2/G5: P = 0.21 (es = 0.19) G3/G5: P = 0.80 (es = 0.01) G4/G5: P = 0.08 (es = 0.24)</p> <p>Commonly occurring co- morbidities: SNAP-IV ADHD, mean ± SD:* Parent-rated: G1: 27.97 ± 11.62 G2: 25.57 ± 11.66 G3: 27.79 ± 11.63 G4: 22.63 ± 11.19 G5: 30.92 ± 11.55 G1/G5: P = 0.04 (es = 0.25) G2/G5: P &lt;</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
			<p>0.001 (es = 0.46) G3/G5: P = 0.02 (es = 0.27) G4/G5: P &lt; 0.001 (es = 0.73)</p> <p>Teacher-rated: G1: 28.00 ± 12.12 G2: 27.27 ± 12.21 G3: 26.12 ± 12.64 G4: 25.24 ± 11.53 G5: 30.57 ± 11.84 G1/G5: P = 0.10 (es = 0.21) G2/G5: P = 0.001 (es = 0.27) G3/G5: P = 0.005 (es = 0.36) G4/G5: P = 0.003 (es = 0.46)</p>
<p>Pearson et al., 2013<sup>37</sup> RCT</p> <p>G1: Methylphenidate - low dose (0.14-0.21 mg/kg), 24/24 G2: Methylphenidate - medium dose (0.24-0.35 mg/kg), 24/24 G3: Methylphenidate - high dose (0.27-0.48 mg/kg), 24/24 G4: Placebo (NA), 24/24</p> <p>4 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1+G2+G3+G4: 8.8 ± 1.6 IQ NR</p>	<p><b>Parent Ratings</b> CPRS NR</p> <p>CPRS-ADHD scale G1+G2+G3+G4: 76.4 ± 6.7</p> <p>SNAP-IV NR</p> <p>ACTeRS NR</p> <p>ABC NR</p> <p>SCQ NR</p> <p><b>Teacher Ratings</b> CTRS NR</p> <p>CTRS-ADHD scale G1+G2+G3+G4: 67.2 ± 8.7</p> <p>SNAP-IV NR</p>	<p><b>EOT Parent Ratings</b> CPRS – CGI Total G1: 61.9 ± 11.7 G2: 59.9 ± 9.8 G3: 55.8 ± 9.3 G4: 66.8 ± 12.7 G4 vs G2, p&lt;0.05</p> <p>G4 vs G3, p&lt;0.05</p> <p>G1 vs G3, p&lt;0.05</p> <p>CPRS – Oppositional G1: 53.1 ± 15.3 G2: 53.8 ± 12.4 G3: 49.8 ± 11.4 G4: 59.2 ± 16 ANOVA p-value for all groups, p&lt;0.05</p> <p>CPRS – Cognitive</p>

<p>Author, Year Study Design</p> <p>Groups (dose), N enrollment / N final</p> <p>Treatment duration/Follow-up timepoint post-treatment</p> <p>Risk of Bias</p>	<p>Mean age, years ± SD</p> <p>Mean IQ ±SD</p>	<p>Outcome measure/Baseline scores, mean ±SD</p>	<p>Outcome measure/Post- treatment scores, mean ± SD</p>
		<p>ACTeRS NR</p>	<p>Problems/Inattention G1: 67.7 ± 11.6 G2: 63.9 ± 12.5 G3: 60 ± 11.7 G4: 70.3 ± 12.8 G4 vs G2, p&lt;0.05  G4 vs G3, p&lt;0.05  G1 vs G3, p&lt;0.05  CPRS – Hyperactivity G1: 62.6 ± 12.2 G2: 62.1 ± 12 G3: 58.3 ± 10.2 G4: 70.8 ± 15.2 G4 vs G2, p&lt;0.05  G4 vs G3, p&lt;0.05  CPRS – ADHD Index G1: 64.9 ± 9.3 G2: 62.3 ± 10 G3: 59.9 ± 10.5 G4: 70.1 ± 11.9 G4 vs G2, p&lt;0.05  G4 vs G3, p&lt;0.05  SNAP-IV – Inattentive/Hyper active G1: 26 ± 11.1 G2: 22.8 ± 9.6 G3: 21.6 ± 9.6 G4: 31.6 ± 11 G4 vs G2, p&lt;0.05  G4 vs G3, p&lt;0.05  ACTeRS – Attention G1: 12.4 ± 5.3 G2: 13.4 ± 5</p>

<p>Author, Year Study Design</p> <p>Groups (dose), N enrollment / N final</p> <p>Treatment duration/Follow-up timepoint post-treatment</p> <p>Risk of Bias</p>	<p>Mean age, years ± SD</p> <p>Mean IQ ±SD</p>	<p>Outcome measure/Baseline scores, mean ±SD</p>	<p>Outcome measure/Post- treatment scores, mean ± SD</p>
			<p>G3: 14 ± 4.2 G4: 10.9 ± 4.7 G4 vs G3, p=ns</p> <p>ACTeRS – Hyperactivity G1: 13.3 ± 4.5 G2: 12 ± 4 G3: 12 ± 4.3 G4: 15.7 ± 4.5 G4 vs G2, p&lt;0.05</p> <p>G4 vs G3, p&lt;0.05</p> <p>ACTeRS – Social Skills G1: 13.3 ± 4.4 G2: 12 ± 3.7 G3: 14 ± 4.3 G4: 12.8 ± 4.5 G2 vs G3, p&lt;0.05</p> <p>ACTeRS – Oppositional G1: 7.8 ± 5.6 G2: 6.8 ± 4 G3: 6.6 ± 2.6 G4: 8.4 ± 5.3 G4 vs G2, p&lt;0.05</p> <p>ABC-Irritability G1: 10 ± 9.2 G2: 8.2 ± 8.1 G3: 7.2 ± 6.9 G4: 12.6 ± 10.4 G4 vs G3, p&lt;0.05</p> <p>ABC-Social Withdrawal/Leth argy G1: 7.3 ± 5.6 G2: 8.1 ± 5.9 G3: 8.5 ± 6.6 G4: 9.3 ± 8.1 p=ns</p> <p>ABC-Stereotypy G1: 4.3 ± 4.5 G2: 4 ± 3.8 G3: 3.5 ± 3.8</p>

<p>Author, Year Study Design</p> <p>Groups (dose), N enrollment / N final</p> <p>Treatment duration/Follow-up timepoint post-treatment</p> <p>Risk of Bias</p>	<p>Mean age, years ± SD</p> <p>Mean IQ ±SD</p>	<p>Outcome measure/Baseline scores, mean ±SD</p>	<p>Outcome measure/Post- treatment scores, mean ± SD</p>
			<p>G4: 4.9 ± 5.4 p=ns</p> <p>ABC- Hyperactivity G1: 18.1 ± 10.5 G2: 14.5 ± 7.7 G3: 14.5 ± 9.2 G4: 24.1 ± 13 G4 vs G2, p&lt;0.05</p> <p>G4 vs G3, p&lt;0.05</p> <p>ABC- Inappropriate Speech G1: 4.3 ± 3.2 G2: 4 ± 3.1 G3: 3.9 ± 3.1 G4: 5.2 ± 3.1 G4 vs G2, p&lt;0.05</p> <p>G4 vs G3, p&lt;0.05</p> <p>SCQ – Total G1: 14.2 ± 6.6 G2: 15.2 ± 6.2 G3: 13.4 ± 6.2 G4: 15.5 ± 6.1 ANOVA p-value for all groups, p&lt;0.05</p> <p><b>Teacher Ratings</b> CTRS – CGI- Total G1: 63.4 ± 12.8 G2: 62.4 ± 12.5 G3: 59.3 ± 12.7 G4: 75.6 ± 11.5 G4 vs G2, p&lt;0.05</p> <p>G4 vs G3, p&lt;0.05</p> <p>G1 vs G3, p&lt;0.05</p> <p>CTRS- Oppositional</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
			<p>G1: 56.6 ± 13.2 G2: 58.1 ± 15.4 G3: 55.1 ± 13.5 G4: 65.1 ± 19.5 p=ns</p> <p>CTRS-Cognitive Problems/Inatten tion G1: 58.3 ± 10.7 G2: 57.8 ± 9.5 G3: 59.3 ± 11.1 G4: 63 ± 11.2 G4 vs G2, p&lt;0.05 G4 vs G3, p&lt;0.05 G1 vs G3, p&lt;0.05</p> <p>CTRS- Hyperactivity G1: 59.9 ± 13.6 G2: 59.9 ± 11.4 G3: 57.7 ± 11.3 G4: 70.3 ± 13.5 G4 vs G2, p&lt;0.05 G4 vs G3, p&lt;0.05 G1 vs G3, p&lt;0.05</p> <p>CTRS-ADHD Index G1: 63.1 ± 11.2 G2: 63.6 ± 10.4 G3: 61.5 ± 13 G4: 72.8 ± 12 G4 vs G2, p&lt;0.05 G4 vs G3, p&lt;0.05 G1 vs G3, p&lt;0.05</p> <p>SNAP-IV – Inattentive/Hyper active G1: 24.7 ± 10.9</p>



<p>Author, Year Study Design</p> <p>Groups (dose), N enrollment / N final</p> <p>Treatment duration/Follow-up timepoint post-treatment</p> <p>Risk of Bias</p>	<p>Mean age, years ± SD</p> <p>Mean IQ ±SD</p>	<p>Outcome measure/Baseline scores, mean ±SD</p>	<p>Outcome measure/Post- treatment scores, mean ± SD</p>
			<p>G2: 23.7 ± 11.1 G3: 21.8 ± 11.6 G4: 32.7 ± 12.4 G4 vs G2, p&lt;0.05</p> <p>G4 vs G3, p&lt;0.05</p> <p>G1 vs G3, p&lt;0.05</p> <p>ACTeRS – Attention G1: 14.3 ± 6.2 G2: 13.7 ± 5.5 G3: 15.9 ± 8.5 G4: 11.3 ± 4 G4 vs G3, p&lt;0.05</p> <p>ACTeRS – Hyperactivity G1: 11.8 ± 5.6 G2: 12.8 ± 5.5 G3: 11.2 ± 5 G4: 18.7 ± 5.2 G4 vs G2, p&lt;0.05</p> <p>G4 vs G3, p&lt;0.05</p> <p>G1 vs G3, p&lt;0.05</p> <p>ACTeRS – Social Skills G1: 19.2 ± 4.2 G2: 16.7 ± 4 G3: 18.5 ± 5.8 G4: 15.8 ± 3.6 p=ns</p> <p>ACTeRS – Oppositional G1: 7.6 ± 3.5 G2: 9.2 ± 5.5 G3: 7.1 ± 2.1 G4: 10.6 ± 5.8 G4 vs G3, p&lt;0.05</p> <p>CGI-Severity (clinician 1) G1: 4 ± 0.81</p>

<p>Author, Year Study Design</p> <p>Groups (dose), N enrollment / N final</p> <p>Treatment duration/Follow-up timepoint post-treatment</p> <p>Risk of Bias</p>	<p>Mean age, years ± SD</p> <p>Mean IQ ±SD</p>	<p>Outcome measure/Baseline scores, mean ±SD</p>	<p>Outcome measure/Post- treatment scores, mean ± SD</p>
			<p>G2: 3.8 ± 0.82 G3: 3.8 ± 0.74 G4: 4.8 ± 0.61 G4 vs G2, p&lt;0.05</p> <p>G4 vs G3, p&lt;0.05</p> <p>G1 vs G3, p&lt;0.05</p> <p>CGI- Improvement (clinician 1) G1: 2.8 ± 1.3 G2: 2.4 ± 1.3 G3: 2.1 ± 1.2 G4: 4 ± 0.81 G4 vs G2, p&lt;0.05</p> <p>G4 vs G3, p&lt;0.05</p> <p>G1 vs G3, p&lt;0.05</p> <p>CGI-Severity (clinician 2) G1: 4 ± 0.72 G2: 4 ± 0.62 G3: 3.9 ± 0.74 G4: 4.7 ± 0.76 G4 vs G2, p&lt;0.05</p> <p>G4 vs G3, p&lt;0.05</p> <p>G1 vs G3, p&lt;0.05</p> <p>CGI- Improvement (clinician 2) G1: 2.8 ± 1.4 G2: 2.6 ± 1.3 G3: 2 ± 1 G4: 4.1 ± 0.95 G4 vs G2, p&lt;0.05</p> <p>G4 vs G3, p&lt;0.05</p> <p>G1 vs G3,</p>

<b>Author, Year Study Design</b>  <b>Groups (dose), N enrollment / N final</b>  <b>Treatment duration/Follow-up timepoint post-treatment</b>  <b>Risk of Bias</b>	<b>Mean age, years ± SD</b>  <b>Mean IQ ±SD</b>	<b>Outcome measure/Baseline scores, mean ±SD</b>	<b>Outcome measure/Post- treatment scores, mean ± SD</b>
			p<0.05

ABC-Aberrant Behavior Checklist; CGI-Clinical Global Impression; VABS-Vineland Adaptive Behavior Scale; CYBOCS-PDD-Children's Yale-Brown Obsessive Compulsive Scale Modified for Pervasive Developmental Disorder; EOT-End of Treatment; VBS-Visual Analog Scale; CGAS-Children's Global Assessment Scale; SNAP-IV- ; ADHD-Attention Deficit/Hyperactivity Disorder; CPRS-Conners Parent Rating Scale; ACTeRS-ADD-H Comprehensive Teacher Rating Scale; CTRS-Conners Teacher Rating Scale; SCQ-Social Communication Questionnaire

**Table F-3. Key findings in studies of nutritional interventions**

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
<p>Sun et al., 2016<sup>38</sup> RCT</p> <p>G1: TEACCH+folic acid, 44/44 G2: TEACCH alone, 22/22</p> <p>3 months/EOT</p> <p>Moderate ROB</p> <p>(Note: Discussed in section on combined treatments in main report)</p>	<p>Age (months) G1: 57.23 ± 15.06 G2: 51.75 ± 12.72</p> <p>IQ NR</p>	<p>ABC - Total Score G1: 54.55 ± 26.58 G2: 67.59 ± 27.6</p> <p>CARS – Total Score G1: 33.86 ± 7.08 G2: 33.41 ± 6.04</p> <p>ATEC – Total Score G1: 48.68 ± 21.43 G2: 57.36 ± 20.38</p> <p>PEP – Cognitive Verbal/Preverbal G1: 12 ± 3 G2: 12.95 ± 2.38</p> <p>PEP – Expressive Language G1: 11.41 ± 3.41 G2: 11.91 ± 2.86</p> <p>PEP – Receptive Language G1: 12.36 ± 2.42 G2: 13.32 ± 1.96</p> <p>PEP – Fine Motor G1: 11.8 ± 1.79 G2: 11.91 ± 2</p> <p>PEP – Gross Motor G1: 12.07 ± 1.78 G2: 12.36 ± 1.92</p> <p>PEP – Visual Motor Imitation G1: 11.55 ± 2.17 G2: 12 ± 2.16</p> <p>PEP – Affective Expression G1: 11.8 ± 2.06 G2: 10.95 ± 2.3</p> <p>PEP – Social Reciprocity G1: 10.36 ± 2.08 G2: 10.5 ± 1.87</p>	<p>ABC - Total Score G1: 39.4 ± 26.73 G2: 46.18 ± 22.71 G1 vs G2, p=ns</p> <p>CARS – Total Score G1: 29.34 ± 5.52 G2: 30.82 ± 5.06 G1 vs G2, p=ns</p> <p>ATEC – Total Score G1: 36.3 ± 17.49 G2: 46.36 ± 18.56 G1 vs G2, p=0.052</p> <p>PEP – Cognitive Verbal/Preverbal G1: 14.2 ± 1.97 G2: 13.91 ± 2.79 G1 vs G2, p=ns</p> <p>PEP – Expressive Language G1: 13.07 ± 3.19 G2: 13.14 ± 2.87 G1 vs G2, p=ns</p> <p>PEP – Receptive Language G1: 13.75 ± 1.4 G2: 13.73 ± 1.75 G1 vs G2, p=ns</p> <p>PEP – Fine Motor G1: 12.48 ± 1.68 G2: 13 ± 1.75 G1 vs G2, p=ns</p> <p>PEP – Gross Motor G1: 12.77 ± 0.99 G2: 13.09 ± 1.31 G1 vs G2, p=ns</p> <p>PEP – Visual Motor Imitation G1: 12.27 ± 1.48 G2: 13.64 ± 1.97 G1 vs G2, p=ns</p> <p>PEP – Affective</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
		<p>PEP – Characteristic Motor Behaviors G1: 11.98 ± 2.39 G2: 11.95 ± 2.3</p> <p>PEP – Characteristic Verbal Behaviors G1: 8 ± 3.58 G2: 9.05 ± 2.9</p> <p>PEP – Communication G1: 35.77 ± 8.21 G2: 38.18 ± 6.71</p> <p>PEP – Motor G1: 35.41 ± 5.18 G2: 36.27 ± 5.54</p> <p>PEP – Maladaptive Behavior G1: 42.14 ± 7.84 G2: 42.45 ± 7.31</p> <p>PEP – Problem Behaviors G1: 8.25 ± 2.36 G2: 8.27 ± 2.39</p> <p>PEP – Personal Self-Care G1: 11.7 ± 2.41 G2: 12.09 ± 2.24</p> <p>PEP – Adaptive Behaviors G1: 11.14 ± 2.36 G2: 11.36 ± 2.63</p>	<p>Expression G1: 11.98 ± 2.25 G2: 12.45 ± 1.26 G1 vs G2, p=ns</p> <p>PEP – Social Reciprocity G1: 11.3 ± 2.09 G2: 11.64 ± 1.65 G1 vs G2, p=ns</p> <p>PEP – Characteristic Motor Behaviors G1: 11.66 ± 2.58 G2: 12.59 ± 2.26 G1 vs G2, p=ns</p> <p>PEP – Characteristic Verbal Behaviors G1: 9.64 ± 3.72 G2: 10.5 ± 2.65 G1 vs G2, p=ns</p> <p>PEP – Communication G1: 41.02 ± 5.91 G2: 40.77 ± 7.04 G1 vs G2, p=ns</p> <p>PEP – Motor G1: 37.52 ± 3.79 G2: 38.73 ± 4.69 G1 vs G2, p=ns</p> <p>PEP – Maladaptive Behavior G1: 44.57 ± 9.59 G2: 47.18 ± 6.53 G1 vs G2, p=ns</p> <p>PEP – Problem Behaviors G1: 9.05 ± 2.9 G2: 9 ± 2.65 G1 vs G2, p=ns</p> <p>PEP – Personal Self-Care G1: 12.34 ± 1.7 G2: 12.41 ± 2.48 G1 vs G2, p=ns</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
			<p>PEP – Adaptive Behaviors G1: 12.32 ± 2.59 G2: 11.77 ± 2.51 G1 vs G2, p=ns</p>
<p>Mankad et al., 2015<sup>39</sup> RCT</p> <p>G1: Omega-3 fatty acid (3.5 mL/day), 19/18 G2: Placebo, 19/19</p> <p>6 months/EOT</p> <p>Moderate RoB</p>	<p>Age G1: 3.5 ± 1.1 G2: 3.8 ± 1.0</p> <p>IQ NR</p>	<p>Baseline scores NR</p>	<p><b>Change from Baseline</b></p> <p>PDDBI – Autism Composite G1: -4.5 G2: -6.4 G1 vs G2: p=ns</p> <p>BASC – Externalizing G1: 3.2 G2: -3.0 G1 vs G2: p=0.02</p> <p>CGI G1: NR G2: NR G1 vs G2:p=ns</p> <p>VABS G1: 2.8 G2: -0.2 G1 vs G2: p=ns</p> <p>Preschool Language Scale (PLS4) G1: 0.7 G2: -0.6 G1 vs G2: p=ns</p>
<p>Saad et al., 2015<sup>40</sup> RCT</p> <p>G1: Digestive enzymes (15 mL/day), 51/47 G2: Placebo (NA), 50/45</p> <p>3 months/EOT</p> <p>Moderate RoB</p>	<p>Age G1: 5.94 ± 2.01 G2: 5.87 ± 2.12</p> <p>IQ NR</p>	<p>CARS G1: 36.1 ± 3.7 G2: 35.3 ± 4.0</p> <p>GBRS Child's General Behavior G1: 3.01 ± 1.3 G2: 3.50 ± 0.7</p> <p>Nighttime sleeping G1: 3.89 ± 1.3 G2: 3.84 ± 1.0</p>	<p><b>EOT</b></p> <p>CARS G1: 31.2 ± 1.2 G2: 35.5 ± 2.8 G1 vs G2: p=0.034</p> <p>GBRS Child's General Behavior G1: 5.5 ± 0.75 G2: 3.39 ± 1.01 G1 vs G2:, p&lt;0.001</p> <p>Nighttime sleeping</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
		<p>Gastrointestinal symptoms G1: 3.79 ± 0.61 G2: 4.02 ± 0.28</p> <p>Daytime wetting G1: 3.86 ± 0.67 G2: 3.92 ± 0.83</p> <p>Nighttime wetting G1: 4.60 ± 0.97 G2: 3.92 ± 0.6</p>	<p>G1: 4.02 ± 1.20 G2: 3.98 ± 0.89 G1 vs G2: p=ns</p> <p>Gastrointestinal symptoms G1: 6.03 ± 0.56 G2: 4.02 ± 0.23 G1 vs G2: p&lt;0.001</p> <p>Daytime wetting G1: 3.97 ± 0.88 G2: 4.03 ± 1.04 G1 vs G2: p=ns</p> <p>Nighttime wetting G1: 4.23 ± 1.25 G2: 4.09 ± 0.64 G1 vs G2: p=ns</p>
<p>Bent et al., 2014<sup>41</sup> RCT</p> <p>G1: Omega-3 fatty acid (1.3g/day), 29/29 G2: Placebo, 28/28</p> <p>6 weeks/EOT</p> <p>Moderate RoB</p>	<p>Age, months G1: 88.2 ± 12.3 G2: 85 ± 13.2 mos</p> <p>IQ NR</p>	<p>ABC- Hyperactivity Parent Ratings G1: 28.4 ± 8.4 G2: 28.1 ± 7.6</p> <p>ABC-Hyperactivity Teacher Ratings G1: 18.1 ± 12.0 G2: 14.6 ± 4</p> <p>ABC-Irritability Parent G1: 20.0 ± 8.9 G2: 16.8 ± 8.3</p> <p>ABC-Irritability Teacher G1: 14.3 ± 9.8 G2: 9.4 ± 9.3</p> <p>ABC-Stereotypy Parent G1: 8.0 ± 6.0 G2: 5.4 ± 4.7</p> <p>ABC-Stereotypy Teacher G1: 5.1 ± 4.8 G2: 3.7 ± 4.1</p> <p>ABC-Lethargy Parent G1: 12.2 ± 8.8 G2: 8.8 ± 4.2</p>	<p><b>Mean change score</b> ABC – Hyperactivity Parent G1: -5.3 ± 7.2 G2: -3.4 ± 7.5 G1 vs G2: p=ns</p> <p>ABC- Hyperactivity Teacher G1: -2.6 ± 8.0 G2: -1.0 ± 10.0 G1 vs G2: p=ns</p> <p>ABC-Irritability Parent G1: -2.0 ± 6.9 G2: -2.1 ± 4.4 G1 vs G2: p=ns</p> <p>ABC-Irritability Teacher G1: -1.3 ± 8.6 G2: -0.2 ± 6.8 G1 vs G2: p=ns</p> <p>ABC-Stereotypy Parent G1: -2.0 ± 3.7 G2: -0.5 ± 2.6 G1 vs G2: p=0.05</p> <p>ABC-Stereotypy Teacher</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
		<p>ABC-Lethargy Teacher G1: 9.9 ± 8.9 G2: 8.3 ± 7.1</p> <p>ABC-Inappropriate speech Parent G1: 7.0 ± 3.4 G2: 5.8 ± 2.8</p> <p>ABC-Inappropriate speech Teacher G1: 4.2 ± 3.9 G2: 3.1 ± 3.3</p> <p>SRS-total G1: 89.7 ± 12.7 G2: 88.3 ± .7</p> <p>CGI-S G1: 3.8 ± 1.0 G2: 4.0 ± 0.79</p>	<p>G1: -1.0 ± 4.2 G2: -0.7 ± 3.2 G1 vs G2: p=ns</p> <p>ABC-Lethargy Parent G1: -2.1 ± 4.2 G2: 0.1 ± 2.6 G1 vs G2: p=0.01</p> <p>ABC-Lethargy Teacher G1: -2.5 ± 7.9 G2: -1.6 ± 5.5 G1 vs G2: p=ns</p> <p>ABC-Inappropriate speech Parent G1: -0.6 ± 2.7 G2: -0.9 ± 2.2 G1 vs G2: p=ns</p> <p>ABC-Inappropriate speech Teacher G1: -1.0 ± 2.6 G2: -0.1 ± 5.5 G1 vs G2: p=ns</p> <p>SRS-total G1: -2.6 ± 8.3 G2: -6.1 ± 7.8 G1 vs G2:p=ns</p> <p>CGI-S G1: NR G2: NR</p>
<p>Voigt et al., 2014<sup>42</sup> RCT</p> <p>G1: Docosahexaenoic acid (DHA) (500 mg/day), 24/19 G2: Placebo, 24/15</p> <p>6 months/EOT</p> <p>Moderate RoB</p>	<p>Age G1: 5.8 ± 1.8 G2: 6.5 ± 2.2</p> <p>IQ NR</p>	<p>CGI-I Parent NR</p> <p>BASC – Parent G1: 26.5 ± 7.1 G2: 30.3 ± 9.1</p> <p>BASC – Teacher G1: 32.2 ± 7.6 G2: 38.5 ± 4.3</p>	<p>CGI-I Parent <b>3 months</b> G1: 4/21 (19) G2: 5/16 (31) G1 vs G2: p=ns</p> <p><b>6 months</b> G1: 5/18 (28) G2: 2/13 (15) G1 vs G2: p=ns</p> <p>CGI-I Investigator <b>3 months</b> G1: 1/17 (6)) G2: 0/13 (0) G1 vs G2: p=ns</p>



<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
			<p><b>6 months</b> G1: 0/18 (0) G2: 1/14 (7) G1 vs G2: p=ns</p> <p><b>EOT</b> BASC – Parent G1: 26.3 ± 6.8 G2: 33.3 ± 9.7 G1 vs G2: p=0.04</p> <p>BASC – Teacher G1: 33.6 ± 9.3 G2: 34.0 ± 5.6 G1 vs G2: p=0.02</p>
<p>Al-Ayadhi et al., 2013<sup>43</sup> RCT</p> <p>G1: Raw camel milk (500 mL/day), 24/24 G2: Boiled camel milk (500 mL/day), 25/25 G3: Cow milk (500 mL/day), 11/11</p> <p>2 weeks/EOT</p> <p>High RoB</p>	<p>Age 2-12</p> <p>IQ NR</p>	<p>CARS – total score G1: 37.63 ± 6.31 G2: 36.82 ± 3.27 G3: 34.18 ± 3.25</p>	<p><b>EOT</b> CARS – total score G1: 34.54 ± 5.19 G2: 33.8 ± 4.91 G3: 34.41 ± 3.25 p=NR</p>
<p>Fahmy et al. 2013<sup>44</sup> RCT</p> <p>G1: Levocarnitine, 16/16 G2: Placebo, 14/14</p> <p>6 months/EOT</p> <p>Moderate RoB</p>	<p>Age (months) G1: 69 (29-103) G2: 68.5 (32- 98)</p> <p>IQ NR</p>	<p>CARS – Mild/Moderate Severity G1: 1 (6.3) G2: 9 (64.3)</p> <p>CARS – Severe G1: 15 (93.80) G2: 5 (35.7)</p> <p>CARS-Total Score G1: 45.25 ± 6.191 G2: 36.71 ± 5.594</p>	<p><b>EOT</b> Mild/Moderate Severity G1: 9 (56.3) G2: 9 (64.3) G1 vs G2, p=ns</p> <p>CARS – Severe G1: 7 (43.8) G2: 5 (35.7) G1 vs G2, p=ns</p> <p>CARS-Total Score G1: 37.06 ± 5.882 G2: 34.71 ± 4.631 G1 vs G2, p&lt;0.001</p>
<p>Bent et al., 2011<sup>45</sup> RCT</p> <p>G1: Omega-3 fatty acid (1.3 g/day), 14/13 G2: Placebo, 13/12</p> <p>12 weeks/EOT</p>	<p>Age, months G1: 70.2 ± 22 G2: 69.8 ± 17</p> <p>IQ G1: 77.5 ± 27 G2: 77.5 ± 17</p>	<p>ABC –Hyperactivity G1: 16.8 ± 13 G2: 20.3 ± 8</p> <p>PPVT G1: 72.2 ± 28 G2: 85.8 ± 12</p> <p>EVT</p>	<p><b>Mean change score</b> ABC – Hyperactivity G1: 2.7 ± 4.8 G2: 0.3 ± 7.2 G1 vs G2: p=ns</p> <p>PPVT G1: 2.7 ± 11.6 G2: 1.9 ± 12.4</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
<p>Low RoB</p>		<p>G1: 70.8 ± 33 G2: 86.4 ± 14</p> <p>SRS G1: 76.9 ± 11 G2: 79.0 ±</p> <p>BASC-Externalizing G1: 53.8 ± 13 G2: 66.3 ± 25</p> <p>BASC- Internalizing G1: 43.3 ± 10 G2: 50.1 ± 9</p> <p>BASC-Behavioral G1: 60.9 ± 14 G2: 65.4 ± 3</p> <p>BASC- Adaptive skill G1: 29.8 ± 9 G2: 31.9 ± 9</p> <p>BASC-Hyperactivity G1: 61.8 ± 17 G2: 64.6 ± 7</p>	<p>G1 vs G2: p=ns</p> <p>EVT G1: 2.2 ± 7.6 G2: 5.8 ± 5.7 G1 vs G2: p=ns</p> <p>SRS G1: -0.9 ± .5 G2: 1.7 ± 7.2 G1 vs G2: p=ns</p> <p>BASC-Externalizing G1: 0.1 ± 6.7 G2: 6.6 ± 30.4 G1 vs G2: p=ns</p> <p>BASC-Internalizing G1: 0.3 ± 6.6 G2: -2.9 ± 7.6 G1 vs G2: p=ns</p> <p>BASC-Behavioral G1: -1.1 ± 6.1 G2: -2.0 ± 4.9 G1 vs G2: p=ns</p> <p>BASC-Adaptive skill G1: 1.8 ± 6.8 G2: 0.8 ± 7.1 G1 vs G2: p=ns</p> <p>BASC-Hyperactivity G1: 2.1 ± 6.3 G2: 1.2 ± 5.8 G1 vs G2: p=ns</p>
<p>Geier, et al., 2011<sup>46</sup> RCT</p> <p>G1: Levocarnitine (50 mg/kg/day), 19/16 G2: Placebo, 11/11</p> <p>3 months/EOT</p> <p>High RoB</p>	<p>Age: G1: 6.3 ± 2.4 G2: 6.7 ± 1.6</p> <p>IQ NR</p>	<p>CARS G1: 35.7±5.3 G2: 38.2±6.0</p> <p>CGI G1: 2.0 G2: 2.0</p> <p>Hand Muscle Testing G1: 32.7±13.9 G2: 35.3±13.2</p> <p>ATEC Total G1: 55.1±23.3 G2: 62.8±31.7</p>	<p><b>EOT</b> CARS G1: 33.8±5.8 G2: 38.4±6.3 p=.02</p> <p>CGI G1: 1.5±0.63 G2: 2.09±0.7 p= .03</p> <p>Hand Muscle Testing G1: 34.3±16.7 G2: 35.1±7.5 p= ns</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
		<p>ATEC Speech G1: 9.9±6.3 G2: 10.5±6.4</p> <p>ATEC Sociability G1: 12±7.1 G2: 11.9±7.7</p> <p>ATEC Cognitive G1: 12.7±6.1 G2: 14.4±7.6</p> <p>ATEC Health/Behavior G1: 20.5±8.1 G2: 26±14.8</p>	<p>ATEC Total G1: 40.1±22.8 G2: 56±27.6 p= ns</p> <p>ATEC Speech G1: 7.8±5.9 G2: 10.9±7.2 p= ns</p> <p>ATEC Sociability G1: 8.3±5.9 G2: 10.8±8.4 p=ns</p> <p>ATEC Cognitive G1: 9.2±5.5 G2: 14.9±7.3 p=.009</p> <p>ATEC Health/Behavior G1: 14.8±7.9 G2: 19.5±10.9 p=ns</p>
<p>Bertoglio et al., 2010<sup>17</sup> RCT</p> <p>G1: Methyl B12 (64.5 µg/kg) G2: Placebo Crossover design N=30 total</p> <p>12 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1 + G2: 3-8</p> <p>IQ NR</p>	<p>CGIS NR</p>	<p>No significant group difference in behavior measures</p> <p><b>EOT</b> CGIS Improvement (≥1 point) n (%) G1+G2: 9 (30) 3 received placebo first and 6 received active treatment</p> <p>CBCL improvement (≥5 points): G1+G2: 3 (10)</p> <p>ABC improvement (≥5 points): G1+G2: 5 (16.7)</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
<p>Munasinghe et al., 2010<sup>48</sup> RCT</p> <p>G1: Digestive enzyme supplement- Peptizyde (up to 2 capsules/day) G2: Placebo (360 mg/day) Crossover design N=43 total</p> <p>3 months/EOT</p> <p>Moderate RoB</p>	<p>Age, months G1 + G2: 5.78 ± 1.77</p> <p>IQ NR</p>	<p>GBRS G1+G2: 4</p> <p>ARS G1+G2: 4</p> <p>LDS NR</p>	<p><b>EOT</b></p> <p>Food variety score G1: 4.42 ± 0.62 G2: 4.06 ± 0.45 p= 0.02</p> <p>Parent Behavior score G1: 4.29 ± 0.79 G2: 4.11 ± 0.73 p = ns</p> <p>GI symptoms score G1: 4.01 ± 0.68 G2: 3.87 ± 0.36 p = ns</p> <p>Sleep Quality score G1: 3.95 ± 0.75 G2: 3.87 ± 0.56 p = ns</p> <p>Therapist engagement score G1: 4.59 ± 0.96 G2: 4.43 ± 0.55 p = ns</p> <p>LDS Vocabulary percentile score G1: 56.95 ± 28.6 G2: 55.59 ± 28.6 p = ns</p> <p>LDS Sentence length percentile score G1: 62.38 ± 26.2 G2: 63.91 ± 24.9 p = ns</p>
<p>Hendren et al., 2016<sup>49</sup> RCT</p> <p>G1: Methyl B-12 (75 µg/kg every 3 days), 28/27 G2: Placebo (75 µg/kg every 3 days), 29/23</p> <p>8 weeks/EOT</p> <p>Moderate ROB</p>	<p>Age (months) G1: 67 ± 16 G2: 58 ± 14</p> <p>IQ-Stanford Binet G1: 64 ± 18 G2: 67 ± 20</p>	<p>CGI-Severity G1: 5.2 ± 0.7 G2: 5.1 ± 0.6</p> <p>ABC-Hyperactivity G1: 25 ± 10.1 G2: 22.4 ± 11.5</p> <p>ABC-Inappropriate Speech G1: 4.2 ± 3.2 G2: 2.9 ± 3.2</p>	<p><b>Change Score</b></p> <p>CGI-Improvement G1: 2.4 ± 0.8 G2: 3.1 ± 0.8 G1 vs G2, p=0.005</p> <p>ABC-Hyperactivity G1: -0.9 ± 4.8 G2: -3.9 ± 7.1 G1 vs G2, p=ns; ES=- 0.48</p> <p>ABC-Inappropriate</p>

<b>Author, Year Study Design</b>	<b>Mean age, years ± SD</b>	<b>Outcome measure/Baseline scores, mean ±SD</b>	<b>Outcome measure/Post- treatment scores, mean ± SD</b>
<b>Groups (dose), N enrollment / N final</b>	<b>Mean IQ ±SD</b>		
<b>Treatment duration/Follow-up timepoint post-treatment</b>			
<b>Risk of Bias</b>			
		ABC-Irritability G1: 15.2 ± 10.4 G2: 11.1 ± 8.4  ABC-Social Withdrawal/Lethargy G1: 15 ± 9.1 G2: 14.2 ± 8.5  ABC-Stereotypic Behavior G1: 7.1 ± 4.6 G2: 7.4 ± 5.1  SRS-Total Score G1: 90 ± 13.7 G2: 83.5 ± 10.6	Speech G1: 0.3 ± 1.4 G2: -0.3 ± 1.6 G1 vs G2, p=ns; ES=- 0.43  ABC-Irritability G1: -0.1 ± 3.7 G2: -2.6 ± 4.3 G1 vs G2, p= 0.08; ES=-0.61  ABC-Social Withdrawal/Lethargy G1: -1.9 ± 5.8 G2: -1.2 ± 7.1 G1 vs G2, p=ns; ES=0.12  ABC-Stereotypic Behavior G1: -0.3 ± 2.2 G2: 0.3 ± 3.2 G1 vs G2, p=ns; ES=0.23  SRS-Total Score G1: -1.6 ± 7.7 G2: -4.1 ± 7.7 G1 vs G2, p=ns; ES=- 0.32

ABC-Aberrant Behavior Checklist; CGI-Clinical Global Impression; VABS-Vineland Adaptive Behavior Scale; EOT-End of Treatment; PDDBI-Pervasive Developmental Disorders Behavior Inventory; BASC-Behavior Assessment System for Children; CARS-Childhood Autism Rating Scale; GBRS-Global Rating Scale; SRS-Social Responsiveness Scale; PPVT-Peabody Picture Vocabulary Test; EVT-Expressive Vocabulary Test; ATEC-Autism Treatment Evaluation Checklist; CGIS-Clinical Global Impressions Scale; CBCL-Child Behavior Checklist; GBRS-Global Rating Scale; ARS-Additional Rating Scale; LDS-Language Development Survey

**Table F-4. Key findings in studies of specialized diets**

<b>Author, Year Study Design</b>	<b>Mean age, years ± SD</b>	<b>Outcome measure/Baseline scores, mean ±SD</b>	<b>Outcome measure/Post- treatment scores, mean ± SD</b>
<b>Groups (dose), N enrollment / N final</b>	<b>Mean IQ ±SD</b>		
<b>Treatment duration/Follow-up timepoint post-treatment</b>			
<b>Risk of Bias</b>			

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
<p>Hyman et al., 2016<sup>50</sup> RCT</p> <p>Gluten-free/casein-free diet followed by weekly challenges of gluten, casein, gluten and casein and placebo G1: gluten G2: casein G3: gluten and casein G4: placebo Crossover study n=14</p> <p>12 weeks/EOT</p> <p>Low RoB</p>	<p>Age 3.78 ± 0.60</p> <p>IQ NR</p>	<p>LS means</p> <p><b>Day before challenge</b></p> <p>Conners- research asst rater G1: 6.65 ± 2.38 G2: 5.71 ± 2.18 G3: 5.32 ± 2.13 G4: 6.17 ± 3.01</p> <p>Conners- teacher G1: 8.50 ± 3.72 G2: 8.29 ± 3.73 G3: 6.89 ± 2.40 G4: 8.84 ± 5.92</p> <p>Conners- parent G1: 6.10 ± 3.53 G2: 6.48 ± 3.99 G3: 5.79 ± 4.17 G4: 5.71 ± 3.50</p> <p>Day before challenge: NR</p> <p><b>Day of challenge</b></p> <p>Sensory motor G1: 0.34 ± 0.27 G2: 0.32 ± 0.28 G3: 0.31 ± 0.37 G4: 0.33 ± 0.30</p> <p>Social relationships G1: -0.30 ± 0.24 G2: -0.30 ± 0.21 G3: -0.27 ± 0.17 G4: -0.20 ± 0.16</p> <p>Affectual relationships G1: 0.08 ± 0.12 G2: 0.09 ± 0.13 G3: 0.05 ± 0.11 G4: 0.09 ± 0.11</p> <p>Sensory responses G1: 0.25 ± 0.14 G2: 0.26 ± 0.19 G3: 0.21 ± 0.14 G4: 0.30 ± 0.19</p> <p>Language G1: -0.07 ± 0.31 G2: -0.04 ± 0.27 G3: -0.03 ± 0.30</p>	<p><b>EOT</b></p> <p>LS means</p> <p><b>Day after challenge</b></p> <p>Conners- research asst rater G1: 5.57 ± 1.61 G2: 6.19 ± 2.47 G3: 6.73 ± 3.24 G4: 6.55 ± 2.83 p=ns</p> <p>Conners- teacher G1: 7.76 ± 3.08 G2: 7.42 ± 2.79 G3: 7.19 ± 2.81 G4: 7.43 ± 3.88 p=ns</p> <p>Conners- parent G1: 6.75 ± 3.69 G2: 6.31 ± 3.75 G3: 7.15 ± 4.42 G4: 7.15 ± 4.25 p=ns</p> <p><b>Day after challenge</b></p> <p>Sensory motor G1: 0.28 ± 0.29 G2: 0.29 ± 0.22 G3: 0.43 ± 0.42 G4: 0.32 ± 0.21 p=ns</p> <p>Social relationships G1: -0.27 ± 0.21 G2: -0.28 ± 0.18 G3: -0.30 ± 0.19 G4: -0.26 ± 0.16 p=ns</p> <p>Affectual relationships G1: 0.04 ± 0.06 G2: 0.11 ± 0.13 G3: 0.09 ± 0.15 G4: 0.07 ± 0.09 p=ns</p> <p>Sensory responses G1: 0.29 ± 0.17 G2: 0.27 ± 0.16 G3: 0.26 ± 0.17</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
		<p>G4: 0.00 ± 0.24</p> <p><b>Day before challenge</b> Minutes of sleep G1: 631 ± 67.3 G2: 627 ± 76.6 G3: 616.7 ± 48.3 G4: 693 ± 56.4</p> <p>Number of wakings G1: 0.34 ± 1.53 G2: 0.10 ± 0.30 G3: 0.11 ± 0.40 G4: 0.08 ± 0.27</p>	<p>G4: 0.32 ± 0.18 p=ns</p> <p>Language G1: -0.03 ± 0.25 G2: -0.03 ± 0.25 G3: -0.07 ± 0.32 G4: 0.00 ± 0.25 p=ns</p> <p><b>Day after challenge</b> Minutes of sleep G1: 646 ± 69.1 G2: 641 ± 68.2 G3: 633 ± 70.7 G4: 641 ± 61.3 p=ns</p> <p>Number of wakings G1: 0.20 ± 0.58 G2: 0.03 ± 0.16 G3: 0.17 ± 0.45 G4: 0.05 ± 0.22 p=ns</p>
<p>Navarro et al., 2015<sup>51</sup> RCT</p> <p>G1: "gluten-dairy containing (GD(+)) diet", 6/6 G2: gluten-dairy free (GD(-)) diet, 6/6</p> <p>4 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 6 (6-7) G2: 5.5 (4-7)</p> <p>IQ G1: 55 (52-88) G2: 79 (76-97)</p>	<p>ABC-Irritability G1: 19.77 ± 15.15 G2: 10.50 ± 8.55</p> <p>ABC- Hyperactivity G1: 23.20 ± 11.28 G2: 22.17 ± 7.31</p> <p>Connors Parent Rating Scale-Revised- Cognitive Problems/Inattention G1: 12.17 ± 7.11 G2: 15.83 ± 3.82</p>	<p><b>EOT</b> ABC-Irritability G1: 16.0 G2: 14.50 G1 vs G2, p= NR</p> <p>ABC-Hyperactivity G1: 26.5 G2: NR</p> <p>Connors Parent Rating Scale-Revised G1: 21 G2: NR</p>
<p>Pusponegoro et al., 2015<sup>52</sup> RCT</p> <p>G1: Gluten-casein, 38/24 G2: Placebo, 36/26</p> <p>7 days/EOT</p> <p>Moderate RoB</p>	<p>Age, median (range) G1: 5.4 (4.8- 6.7) G2: 5.1 (4.3- 6.1)</p> <p>IQ NR</p>	<p>Pervasive Developmental Disorder Behavior Inventory – Approach Withdrawal problems composite</p> <p>AWPC G1: 56.96 ± 11.72 G2: 57.08 ± 11.46</p> <p>Gastrointestinal</p>	<p><b>EOT</b> Pervasive Developmental Disorder Behavior Inventory - Approach Withdrawal problems composite</p> <p>AWPC G1: 39.38 ± 2.89 G2: 39.63 ± 3.05 G1 vs G2: p=ns</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
		<p>Symptom Severity Index, median G1: 0 G2: 0</p>	<p>Gastrointestinal Symptom Severity Index, median (range) G1: 3 (0-9) G2: 0 (0-7) G1 vs G2: p=ns</p>
<p>Whiteley et al., 2010<sup>53,746</sup> RCT</p> <p>G1: Gluten and casein-free diet, 38/26 G2: No diet, 34/29</p> <p>24 months/EOT</p> <p>Moderate RoB</p>	<p>Age, months G1: 94.2 [IQR 76.6-118.0] G2: 96.4 [IQR 76.3-120.3]</p> <p>IQ NR</p>	<p>ADOS-Communication G1: 1.13 G2: 1.00</p> <p>ADOS-Social G1: 1.18 G2: 1.22</p> <p>ADOS-Repetitive G1: 0.46 G2: 0.36</p> <p>GARS-Social G1: 6.96 G2: 6.41</p> <p>GARS-Communication G1: 7.23 G2: 7.28</p> <p>GARS-Stereotyped G1: 6.81 G2: 6.76</p> <p>VABS-Communication G1: 66.46 G2: 62.45</p> <p>VABS-Social G1: 64.58 G2: 64.03</p> <p>VABS-Daily Living G1: 59.88 G2: 55.55</p> <p>ADHD-IV scale- Inattention G1: 11.96 G2: 11.21</p>	<p><b>8 months</b> ADOS-Communication G1: 0.87 G2: 1.07 G1 vs G2: p=ns</p> <p>ADOS-Social G1: 1.09 G2: 1.30 G1 vs G2: p=ns</p> <p>ADOS-Repetitive G1: 0.35 G2: 0.34 G1 vs G2: p=ns</p> <p>GARS-Social (<b>8 mos</b>) G1: 5.88 G2: 6.34</p> <p>GARS- Social (<b>12 mos</b>) G1: 5.38 G2: 6.00 G1 vs G2: p=ns</p> <p>GARS-Communication (<b>8 mos</b>) G1: 6.00 G2: 6.76</p> <p>GARS-Communication (<b>12 mos</b>) G1: 5.74 G2: 5.81 G1 vs G2: p=ns</p> <p>GARS-Stereotyped (<b>8 mos</b>) G1: 5.85 G2: 5.97</p>



<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
		<p>ADHD-IV scale- Hyperactivity G1: 10.31 G2: 10.79</p>	<p><b>GARS-Stereotyped (12 mos)</b> G1: 5.35 G2: 5.37 G1 vs G2: p=ns</p> <p><b>VABS-Communication (8 mos)</b> G1: 66.69 G2: 63.46</p> <p><b>VABS-Communication (12 mos)</b> G1: 67.38 G2: 64.07 G1 vs G2: p=ns</p> <p><b>VABS-Social (8 mos)</b> G1: 66.12 G2: 65.39</p> <p><b>VABS-Social (12 mos)</b> G1: 60.42 G2: 61.21 G1 vs G2: p=ns</p> <p><b>VABS-Daily Living (8 mos)</b> G1: 62.92 G2: 55.18</p> <p><b>VABS-Daily Living (12 mos)</b> G1: 63.35 G2: 53.96 G1 vs G2: p=ns</p> <p><b>ADHD-IV scale- Inattention (8 mos)</b> G1: 9.81 G2: 11.52</p> <p><b>ADHD-IV scale- Inattention (12 mos)</b> G1: 9.77 G2: 11.11 G1 vs G2: p=ns</p> <p><b>ADHD-IV scale- Hyperactivity (8 mos)</b> G1: 8.27</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
			<p>G2:10.62</p> <p>ADHD-IV scale- Hyperactivity(12 mos) G1: 8.62 G2:10.00 G1 vs G2: p=ns</p>
<p>Knivsberg et al., 2002<sup>54, 55</sup> RCT</p> <p>G1: Gluten and Casein free diet, 10/10 G2: Normal Diet, 10/10</p> <p>12 months/EOT</p> <p>Moderate ROB</p>	<p>Age (months) G1: 91 (62-120) G2: 86 (59-127)</p> <p>IQ NR</p>	<p>Leiter R-Nonverbal Cognitive Level G1: 81 ± 35.9 G2: 84.6 ± 36.6</p> <p>Parent Questionnaire ND</p> <p>DPBC-Communication and Interaction G1: 3.9 ± 0.9 G2: 4.3 ± 1.3</p> <p>DPBC-Resistance to Communication and Interaction G1: 2.5 1 G2: 2.3 1.7</p> <p>DPBC-Social Interaction and Isolation G1: 7.6 ± 1.7 G2: 7.1 ± 2.8</p> <p>DPBC-Unusual and Bizarre Behavior G1: 4.9 ± 1.5 G2: 4.5 ± 1.6</p> <p>DPBC-Autistic Behavior G1: 12.5 ± 2.2 G2: 11.5 ± 3.9</p>	<p>Leiter R-Nonverbal Cognitive Level G1: 86.7 ± 38.5 G2: 74.3 ± 31.4 G1 vs G2, p=0.004</p> <p>Parent Questionnaire- Attention G1 vs G2, p&lt;0.028</p> <p>Parent Questionnaire- Social and Emotional Factors G1 vs G2, p&lt;0.004</p> <p>Parent Questionnaire- Communicative Factors G1 vs G2, p&lt;0.007</p> <p>Parent Questionnaire- Cognitive Factors G1 vs G2, p&lt;0.019</p> <p>Parent Questionnaire- Sensory/Motor Factors G1 vs G2, p=ns</p> <p>DPBC-Communication and Interaction G1: 6.2 ± 1.1 G2: 4.5 ± 1.6 G1 vs G2, p&lt;0.004</p> <p>DPBC-Resistance to Communication and Interaction G1: 0.2 ± 0.4 G2: 1.9 ± 1.4 G1 vs G2, p&lt;0.004</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
			<p>DPBC-Social Interaction and Isolation G1: 3 ± 1.4 G2: 6.2 ± 2.9 G1 vs G2, p&lt;0.003</p> <p>DPBC-Unusual and Bizarre Behavior G1: 2.6 ± 1.7 G2: 4.8 ± 2.6 G1 vs G2, p&lt;0.007</p> <p>DPBC-Autistic Behavior G1: 5.6 ± 2.4 G2: 11.2 ± 5 G1 vs G2, p&lt;0.001</p>
<p>Elder et al., 2006<sup>56, 57</sup> RCT</p> <p>G1: Gluten and Casein free diet/Regular Diet, 15 G2: Regular Diet/Gluten and Casein free diet, 15</p> <p>12 weeks/EOT</p> <p>Moderate ROB</p>	<p>Age 7.32 ± 4.1 (2-16)</p> <p>IQ NR</p>	<p>CARS-Total Score ND</p> <p>Ecological Communication Orientation Language Sampling Summary ND</p> <p>Behavioral Response Frequencies-Child Initiating ND</p> <p>Behavioral Response Frequencies-Child Responding ND</p> <p>Behavioral Response Frequencies-Intelligible Words ND</p> <p>Verbal Social Exchanges-Verbal Responses G1: 16 ± 27 G2: 16 ± 27</p> <p>Verbal Social Exchanges-Verbal</p>	<p><b>6 Weeks</b> CARS-Total Score G1: 33.6 ± 8.6 G2: 31.2 ± 8.7 G1 vs G2, p=ns</p> <p>Ecological Communication Orientation Language Sampling Summary G1: 175.8 ± 86.4 G2: 174.4 ± 86 G1 vs G2, p=ns</p> <p>Behavioral Response Frequencies-Child Initiating G1: 9.5 ± 9.6 G2: 7.5 ± 6.1 G1 vs G2, p=ns</p> <p>Behavioral Response Frequencies-Child Responding G1: 27.7 ± 21.8 G2: 14.3 ± 6.5 G1 vs G2, p=ns</p> <p>Behavioral Response Frequencies-Intelligible Words G1: 26.8 ± 35.1</p>

<p>Author, Year Study Design</p> <p>Groups (dose), N enrollment / N final</p> <p>Treatment duration/Follow-up timepoint post-treatment</p> <p>Risk of Bias</p>	<p>Mean age, years <math>\pm</math> SD</p> <p>Mean IQ <math>\pm</math>SD</p>	<p>Outcome measure/Baseline scores, mean <math>\pm</math>SD</p>	<p>Outcome measure/Post- treatment scores, mean <math>\pm</math> SD</p>
		<p>Imitation G1: 3.85 <math>\pm</math> 6.9 G2: 3.85 <math>\pm</math> 6.9</p> <p>Lexical Productions G1: 35 <math>\pm</math> 37 G2: 35 <math>\pm</math> 37</p>	<p>G2: 24 <math>\pm</math> 43.5 G1 vs G2, p=ns</p> <p>Verbal Social Exchanges-Verbal Responses G1: 11 <math>\pm</math> 12 G2: 11 <math>\pm</math> 12 G1 vs G2, p=ns</p> <p>Verbal Social Exchanges-Verbal Imitation G1: 1.85 <math>\pm</math> 2.23 G2: 1.85 <math>\pm</math> 2.23 G1 vs G2, p=ns</p> <p>Lexical Productions G1: 32 <math>\pm</math> 33 G2: 32 <math>\pm</math> 33 G1 vs G2, p=ns</p> <p><b>12 Weeks</b> CARS-Total Score G1: 37.5 <math>\pm</math> 6.6 G2: 33.5 <math>\pm</math> 8.4 G1 vs G2, p=ns Change score G1: 1.2 <math>\pm</math> 6 G2: 2 <math>\pm</math> 7.7</p> <p>Ecological Communication Orientation Language Sampling Summary G1: 111.6 <math>\pm</math> 46.6 G2: 162.9 <math>\pm</math> 108.8 G1 vs G2, p=ns Change score G1: -42.2 <math>\pm</math> 38.1 G2: -4.1 <math>\pm</math> 68</p> <p>Behavioral Response Frequencies-Child Initiating G1: 5.2 <math>\pm</math> 3.2 G2: 10.8 <math>\pm</math> 8.4 G1 vs G2, p=ns Change score G1: -0.6 <math>\pm</math> 4.5 G2: 3.3 <math>\pm</math> 8.4</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
			<p>Behavioral Response Frequencies-Child Responding G1: 15 ± 15 G2: 11.9 ± 4.5 G1 vs G2, p=ns Change score G1: -8.4 ± 7 G2: -2.4 ± 7.7</p> <p>Behavioral Response Frequencies-Intelligible Words G1: 12.4 ± 14.2 G2: 30.9 ± 36 G1 vs G2, p=ns Change score G1: -2.6 ± 12.4 G2: 6.9 ± 17</p> <p>Verbal Social Exchanges-Verbal Responses G1: 15 ± 18 G2: 15 ± 18 G1 vs G2, p=ns</p> <p>Verbal Social Exchanges-Verbal Imitation G1: 3.54 ± 7.84 G2: 3.54 ± 7.84 G1 vs G2, p=ns</p> <p>Lexical Productions G1: 37 ± 34 G2: 37 ± 34 G1 vs G2, p=ns</p>
<p>Ghalichi et al., 2016<sup>58</sup> RCT</p> <p>G1: Gluten free diet, 38/38 G2: Regular diet, 38/38</p> <p>6 weeks/EOT</p> <p>High ROB</p>	<p>Age G1: 7.84 ± 3.55 G2: 8 ± 3.22</p> <p>IQ NR</p>	<p>GARS-Steretyped Behaviors G1: 17.61 ± 6.74 G2: 18.92 ± 5.89</p> <p>GARS-Communication G1: 33.87 ± 8.31 G2: 32.53 ± 9.48</p> <p>GARS-Social Interaction</p>	<p>GARS-Stereotyped Behaviors G1: 14.5 ± 7.92 G2: 19.32 ± 6.27 G1 vs G2, p&lt;0.001</p> <p>GARS-Communication G1: 32.97 ± 9.28 G2: 32.58 ± 9.4 G1 vs G2, p=0.005</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
		<p>G1: 19 ± 50 G2: 14 ± 36.8</p> <p>GARS-Total Score G1: 18.14 ± 19.36 G2: 18.99 ± 21.5</p> <p>Rome-III-Stomachache G1: 11 (28.9) G2: 10 (26.3)</p> <p>Rome-III-Bloating G1: 21 (55.3) G2: 18 (47.4)</p> <p>Rome-III-Constipation G1: 19 (50) G2: 14 (36.8)</p> <p>Rome-III-Diarrhea G1: 1 (2.6) G2: 3 (7.9)</p>	<p>GARS-Social Interaction G1: 2 ± 5.3 G2: 18 ± 47.4 G1 vs G2, p=0.66</p> <p>GARS-Total Score G1: 14.91 ± 16.94 G2: 20.72 ± 22.72 G1 vs G2, p=NR</p> <p>Rome-III-Stomachache G1: 7 (18.4) G2: 12 (31.6) G1 vs G2, p=NR</p> <p>Rome-III-Bloating G1: 13 (34.2) G2: 19 (50) G1 vs G2, p=NR</p> <p>Rome-III-Constipation G1: 2 (5.3) G2: 18 (47.4) G1 vs G2, p=NR</p> <p>Rome-III-Diarrhea G1: 1 (2.6) G2: 5 (13.2) G1 vs G2, p=NR</p>
<p>Johnson et al., 2011<sup>59</sup> RCT</p> <p>G1: Gluten free and Casein free diet, 8/8 G2: Healthy, low sugar diet, 14/14</p> <p>3 months/EOT</p> <p>Moderate ROB</p>	<p>Age (months) G1: 40.13 ± 9.26 G2: 39.5 ± 8.72</p> <p>IQ NR</p>	<p>Mullen Scales of Early Learning-Visual Reception G1: 30.6 ± 11.5 G2: 26.1 ± 10.9</p> <p>Mullen Scales of Early Learning-Fine Motor G1: 28.3 12.8 G2: 27.9 10.8</p> <p>Mullen Scales of Early Learning-Receptive Language G1: 26.1 ± 13.6 G2: 23.5 ± 13.6</p> <p>Mullen Scales of Early Learning-Expressive Language G1: 21 ± 10.2</p>	<p>Mullen Scales of Early Learning-Visual Reception G1: 28.9 ± 11.9 G2: 30.1 ± 10.6 G1 vs G2, p=0.005</p> <p>Mullen Scales of Early Learning-Fine Motor G1: 28 ± 12.1 G2: 30.1 ± 10.3 G1 vs G2, p=ns</p> <p>Mullen Scales of Early Learning-Receptive Language G1: 26.9 ± 11.6 G2: 25 ± 13.5 G1 vs G2, p=NS</p> <p>Mullen Scales of Early</p>

<b>Author, Year Study Design</b>  <b>Groups (dose), N enrollment / N final</b>  <b>Treatment duration/Follow-up timepoint post-treatment</b>  <b>Risk of Bias</b>	<b>Mean age, years ± SD</b>  <b>Mean IQ ±SD</b>	<b>Outcome measure/Baseline scores, mean ±SD</b>	<b>Outcome measure/Post- treatment scores, mean ± SD</b>
		G2: 21.5 ± 11.6  CBCL-Total Score G1: 64.3 ± 8.35 G2: 60.2 ± 11  Direct Behavior Observation Measure- Verbal G1: 19 ± 6.37 G2: 16 ± 9.79  Direct Behavior Observation Measure- Attend G1: 28.1 ± 5.46 G2: 24.2 ± 6.68  Direct Behavior Observation Measure- Initiate G1: 2.38 ± 1.92 G2: 3.46 ± 3.28	Learning-Expressive Language G1: 25 ± 10.5 G2: 22.9 ± 12.9 G1 vs G2, p=ns  CBCL-Total Score G1: 62.1 ± 4.8 G2: 60.3 ± 9.38 G1 vs G2, p=ns  Direct Behavior Observation Measure- Verbal G1: 15.5 ± 8.93 G2: 14.9 ± 9.77 G1 vs G2, p=ns  Direct Behavior Observation Measure- Attend G1: 23.4 ± 10.3 G2: 23.3 ± 7.84 G1 vs G2, p=ns  Direct Behavior Observation Measure- Initiate G1: 3.5 ± 3.67 G2: 3.58 ± 4.52 G1 vs G2, p=ns

ABC-Aberrant Behavior Checklist; VABS-Vineland Adaptive Behavior Scale; EOT-End of Treatment; AWPC-Approach Withdrawal Problems Composite; ADOS-Autism Diagnostic Observation Schedule; GARS-Gilliam Autism Rating Scale

**Table F-5. Key findings in studies of risperidone adjuncts**

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
<p>Ghaleiha et al., 2015<sup>60</sup> RCT</p> <p>G1: Risperidone + pioglitazone (up to 2 mg/day + 30 mg/day), 22/20 G2: Risperidone + placebo (NA), 22/20</p> <p>10 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 6.95 ± 2.40 G2: 6.20 ± 1.32</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 18.25 ± 4.38 G2: 19.00 ± 5.70</p> <p>ABC-Lethargy G1: 15.05 ± 7.56 G2: 13.66 ± 7.26</p> <p>ABC-Stereotypic behavior G1: 7.70 ± 4.61 G2: 9.40 ± 5.28</p> <p>ABC-Hyperactivity G1: 25.00 ± 10.05 G2: 27.86 ± 9.85</p> <p>ABC-Inappropriate speech G1: 5.70 ± 3.60 G2: 4.70 ± 3.78</p>	<p><b>Change scores from baseline</b></p> <p>ABC-Irritability G1: 10.20 ± 5.87 G2: 5.90 ± 5.04 G1 vs G2: p=0.03</p> <p>ABC-Lethargy G1: 3.75 ± 4.69 G2: 1.05 ± 2.96 G1 vs G2: p=0.04</p> <p>ABC-Stereotypic behavior G1: 2.10 ± 2.90 G2: 1.40 ± 1.98 G1 vs G2: p=ns</p> <p>ABC-Hyperactivity G1: 10.15 ± 6.42 G2: 5.30 ± 7.76 G1 vs G2: p=0.04</p> <p>ABC-Inappropriate speech G1: 1.40 ± 3.20 G2: 0.70 ± 1.45 G1 vs G2: p=ns</p> <p>Treatment responses: n (%) Partial response (≥ 25% reduction in irritability score): G1: 9 (45) G2: 3 (15) G1 vs. G2: p=0.04</p> <p>Complete response (≥ 50% reduction in irritability score): G1: 9 (45) G2: 7 (35) G1 vs. G2: p=ns</p>



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<p>Ghanizadeh et al., 2015<sup>61</sup> RCT</p> <p>G1: Risperidone + buspirone (up to 3 mg/day + up to 20 mg/kg), 20/16 G2: Risperidone + placebo (NA), 20/18</p> <p>8 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 7.05 ± 2.3 G2: 7.5 ± 2.6</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 25.7 ± 5.7 G2: 24.7 ± 7.6</p>	<p><b>EOT</b> ABC-Irritability G1: 16.6 ± 7.6 G2: 18.2 ± 7.7</p> <p>Treatment response, n (%) &gt;25% reduction in irritability score: n (%): G1: 13 (81.2) G2: 8 (44.4) G1 vs. G2: p&lt;0.02, RR=1.82</p> <p>≥ 30% reduction in irritability score: G1: 13 (81.2) G2: 7 (38.9) G1 vs. G2: p&lt;0.01, RR=2.1</p>
<p>Nikoo et al., 2015<sup>62</sup> RCT</p> <p>G1: Risperidone + N-acetylcysteine (1-2.0 mg/day + 600-900 mg/day), 25/20 G2: Risperidone + placebo (NA), 25/20</p> <p>10 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 7.50 ± 2.63 G2: 7.60 ± 2.60</p> <p>IQ G1: NR G2: NR</p>	<p>ABC-Irritability G1: 21.20 ± 5.16 G2: 19.70 ± 7.61</p> <p>ABC-Lethargy G1: 21.10 ± 6.39 G2: 20.65 ± 9.62</p> <p>ABC-Stereotypic behavior G1: 10.55 ± 4.22 G2: 10.05 ± 5.35</p> <p>ABC-Hyperactivity G1: 27.65 ± 6.16 G2: 25.10 ± 9.44</p> <p>ABC-Inappropriate speech G1: 5.70 ± 2.92 G2: 4.75 ± 3.72</p>	<p><b>EOT</b> ABC-Irritability G1: 11.95 ± 4.87 G2: 14.35 ± 6.27 G1 vs G2: p&lt;0.05</p> <p>ABC-Lethargy G1: 17.15 ± 5.46 G2: 17.95 ± 8.40 G1 vs G2: p=ns</p> <p>ABC-Stereotypic behavior G1: 7.75 ± 4.90 G2: 8.70 ± 5.44 G1 vs G2: p=ns</p> <p>ABC-Hyperactivity G1: 21.45 ± 8.47 G2: 23.05 ± 9.03 G1 vs G2: p&lt;0.05</p> <p>ABC-Inappropriate speech G1: 4.95 ± 2.85 G2: 4.80 ± 3.47 G1 vs G2: p=ns</p>

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<p>Ghanizadeh, et al., 2013<sup>65</sup> RCT</p> <p>G1: Risperidone + N-acetylcysteine (up to 3 mg/day + 1200 mg/day), 20/17 G2: Risperidone + placebo (NA), 20/14</p> <p>8 weeks/EOT</p> <p>Low RoB</p>	<p>Age: G1: 8.8 ± 3.1 G2: 7.9 ± 2.4</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 13.2 ± 5.3 G2: 16.7 ± 7.8</p> <p>ABC-Hyperactivity G1: 29.3 ± 6.4 G2: 31.9 ± 8.9</p> <p>ABC-Lethargy G1: 11.9 ± 6.5 G2: 12.2 ± 8.3</p> <p>ABC-Stereotypic behavior G1: 6.6 ± 4.5 G2: 8.5 ± 6.3</p> <p>ABC-Inappropriate speech G1: 3.9 ± 3.7 G2: 5.7 ± 3.8</p>	<p><b>EOT</b></p> <p>ABC-Irritability G1: 9.7 ± 4.1 G2: 15.1 ± 7.8 G1 vs G2: p&lt;0.035</p> <p>ABC-Hyperactivity G1: 18.3 ± 6.9 G2: 24.3 ± 12.1 G1 vs G2: p=ns</p> <p>ABC-Lethargy G1: 8.5 ± 6.5 G2: 10.9 ± 7.6 G1 vs G2: p=ns</p> <p>ABC-Stereotypic behavior G1: 3.9 ± 2.7 G2: 7.8 ± 6.6 G1 vs G2: p=ns</p> <p>ABC-Inappropriate speech G1: 3.2 ± 3.4 G2: 5.2 ± 4.0 G1 vs G2: p=ns</p>
<p>Asadabadi, et al., 2013<sup>64</sup> RCT</p> <p>G1: Risperidone + celecoxib (up to 3 mg/day + up to 300 mg/day), 20/20 G2: Risperidone + placebo (NA), 20/20</p> <p>10 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 7.6 ± 1.7 G2: 7.5 ± 1.5</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 17.3 ± 1.6 G2: 17.6 ± 2.4</p> <p>ABC-Lethargy G1: 17.0 ± 3.0 G2: 17.1 ± 3.2</p> <p>ABC-Stereotypic behavior G1: 9.1 ± 2.2 G2: 9.2 ± 2.3</p> <p>ABC-Hyperactivity G1: 22.0 ± 2.9 G2: 22.6 ± 3.0</p> <p>ABC-Inappropriate speech G1: 5.4 ± 1.4 G2: 5.5 ± 0.9</p>	<p><b>EOT</b></p> <p>ABC-Irritability G1: 8.7 ± 1.6 G2: 12.4 ± 3.0 G1 vs G2: p&lt;0.001</p> <p>ABC-Lethargy G1: 9.9 ± 3.1 G2: 14.3 ± 2.1 G1 vs G2: p&lt;0.001</p> <p>ABC-Stereotypic behavior G1: 4.0 ± 1.2 G2: 6.9 ± 2.3 G1 vs G2: p&lt;0.001</p> <p>ABC-Hyperactivity G1: 11.2 ± 2.1 G2: 12.9 ± 2.6 G1 vs G2: p=ns</p> <p>ABC-Inappropriate speech</p>

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			<p>G1: 4.1 ± 2.0 G2: 4.3 ± 1.2 G1 vs G2: p=ns</p>
<p>Ghaleiha, et al., 2013<sup>65</sup> RCT</p> <p>G1: Risperidone + memantine (up to 3 mg/day + up to 20 mg/day), 20/20 G2: Risperidone + placebo (NA), 20/20</p> <p>10 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 7.42 ± 1.48 G2: 7.97 ± 1.68</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 18.25 ± 1.55 G2: 17.65 ± 3.74</p> <p>ABC-Lethargy G1: 16.55 ± 4.26 G2: 16.85 ± 3.48</p> <p>ABC-Stereotypic behavior G1: 8.83 ± 3.08 G2: 8.26 ± 2.67</p> <p>ABC-Hyperactivity G1: 23.00 ± 4.69 G2: 22.45 ± 7.91</p> <p>ABC-Inappropriate speech G1: 6.00 ± 1.36 G2: 5.85 ± 1.46</p>	<p><b>EOT</b></p> <p>ABC-Irritability G1: 8.90 ± 1.55 G2: 12.75 ± 3.05 G1 vs G2: p&lt;0.01</p> <p>ABC-Lethargy G1: 11.65 ± 3.39 G2: 13.85 ± 2.10 G1 vs G2: p=ns</p> <p>ABC-Stereotypic behavior G1: 3.30 ± 1.30 G2: 6.99 ± 1.97 G1 vs G2: p&lt;0.01</p> <p>ABC-Hyperactivity G1: 8.25 ± 2.19 G2: 13.85 ± 3.28 G1 vs G2: p=&lt;0.01</p> <p>ABC-Inappropriate speech G1: 4.50 ± 1.75 G2: 4.69 ± 1.60 G1 vs G2: p=ns</p>
<p>Ghaleiha, et al., 2013<sup>66</sup> RCT</p> <p>G1: Risperidone + riluzole (up to 3 mg/day + up to 100 mg/day), 25/20 G2: Risperidone + placebo (NA), 24/20</p> <p>10 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 8.4 ± 2.3 G2: 7.6 ± 1.7</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 21.40 ± 4.18 G2: 22.10 ± 9.98</p> <p>ABC-Lethargy G1: 23.95 ± 8.04 G2: 24.30 ± 10.98</p> <p>ABC-Stereotypic behavior G1: 7.80 ± 3.43 G2: 8.25 ± 4.93</p>	<p><b>EOT</b></p> <p>ABC-Irritability G1: 11.85 ± 5.57 G2: 16.25 ± 7.86 G1 vs G2: p=0.03</p> <p>Treatment responses: n (%) Partial response (≥ 25% reduction in irritability score): G1: 17 (85)</p>

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		<p>ABC-Hyperactivity G1: 26.35 ± 7.67 G2: 27.95 ± 10.68</p> <p>ABC-Inappropriate speech G1: 5.85 ± 3.38 G2: 5.80 ± 3.10</p>	<p>G2: 8 (40) G1 vs. G2: p=0.003</p> <p>Complete response (≥ 50% reduction in irritability score): G1: 7 (35) G2: 3 (15) G1 vs. G2: p=ns</p> <p>ABC-Lethargy G1: 17.10 ± 5.98 G2: 21.45 ± 9.43 G1 vs G2: p=0.02</p> <p>ABC-Stereotypic behavior G1: 4.90 ± 3.49 G2: 7.75 ± 5.10 G1 vs G2: p=0.03</p> <p>ABC-Hyperactivity G1: 20.35 ± 9.15 G2: 26.65 ± 9.97 G1 vs G2: p=0.005</p> <p>ABC-Inappropriate speech G1: 4.95 ± 3.20 G2: 5.70 ± 2.51 G1 vs G2: p=ns</p> <p>CGI – Very Much Improved G1: 3 (15) G2: 1 (5)</p> <p>CGI – Much Improved G1: 8 (40) G2: 4 (20)</p> <p>CGI-responders: G1:11 (55) G2: 5 (25) G1 Vs. G2, p=0.05</p>

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<p>Ghaleiha 2013<sup>67</sup> RCT</p> <p>G1: Galantamine + Risperidone (2-24 mg/day + 0.5-2 mg/day), 23/20 G2: Risperidone + Placebo (0.5-2mg/day), 23/20</p> <p>10 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 6.85 <math>\pm</math> 1.98 G2: 5.90 <math>\pm</math> 1.38</p> <p>IQ NR</p>	<p>ABC-C-Irritability G1: 15.59 <math>\pm</math> 5.83 G2: 14.95 <math>\pm</math> 4.38</p> <p>ABC-C-Lethargy/Social withdrawal G1: 11.10 <math>\pm</math> 5.34 G2: 10.40 <math>\pm</math> 5.27</p> <p>ABC-C-Stereotypical behavior G1: 6.10 <math>\pm</math> 5.93 G2: 5.80 <math>\pm</math> 5.08</p> <p>ABC-C-Hyperactivity/noncompliance G1: 20.85 <math>\pm</math> 11.69 G2: 22.30 <math>\pm</math> 9.83</p> <p>ABC-C-Inappropriate Speech G1: 3.50 <math>\pm</math> 3.95 G2: 3.25 <math>\pm</math> 4.43</p>	<p><b>EOT</b></p> <p>ABC-C-Irritability G1: 5.30 <math>\pm</math> 4.25 G2: 8.80 <math>\pm</math> 5.03 G1 vs G2: p=0.017</p> <p>ABC-C-Lethargy/Social Withdrawal G1: 5.60 <math>\pm</math> 4.43 G2: 8.35 <math>\pm</math> 5.59 G1 vs G2: p=0.003</p> <p>ABC-C-Stereotypical Behavior G1: 3.95 <math>\pm</math> 5.06 G2: 4.50 <math>\pm</math> 4.34 G1 vs G2: p=ns</p> <p>ABC-C-Hyperactivity/noncompliance G1: 10.85 <math>\pm</math> 9.49 G2: 16.05 <math>\pm</math> 7.52 G1 vs G2: p=ns</p> <p>ABC-C-Inappropriate Speech G1: 2.15 <math>\pm</math> 2.68 G2: 2.80 <math>\pm</math> 3.63 G1 vs G2: p=ns</p>
<p>Mohammadi, et al., 2013<sup>68</sup> RCT</p> <p>G1: Risperidone + amantadine (up to 2 mg/day + up to 150 mg/day), 20/20 G2: Risperidone + placebo (NA), 20/19</p> <p>10 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 6.4 <math>\pm</math> 2.3 G2: 7.1 <math>\pm</math> 2.4</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 20.00 <math>\pm</math> 5.30 G2: 20.90 <math>\pm</math> 6.61</p> <p>ABC-Lethargy G1: 18.55 <math>\pm</math> 7.13 G2: 18.15 <math>\pm</math> 4.80</p> <p>ABC-Stereotypic behavior G1: 10.90 <math>\pm</math> 4.03 G2: 11.30 <math>\pm</math> 5.42</p> <p>ABC-Hyperactivity G1: 28.15 <math>\pm</math> 6.88 G2: 28.55 <math>\pm</math> 8.67</p> <p>ABC-Inappropriate speech G1: 5.70 <math>\pm</math> 3.11 G2: 4.55 <math>\pm</math> 3.48</p>	<p><b>Change (reduction from baseline)</b></p> <p>ABC-Irritability G1: 8.60 <math>\pm</math> 4.65 G2: 5.35 <math>\pm</math> 3.95 p=0.02</p> <p>ABC-Lethargy G1: 1.35 <math>\pm</math> 3.18 G2: 1.30 <math>\pm</math> 3.33 p=ns</p> <p>ABC-Stereotypic behavior G1: 1.20 <math>\pm</math> 2.33 G2: 1.20 <math>\pm</math> 2.09 p=ns</p> <p>ABC-Hyperactivity G1: 6.15 <math>\pm</math> 5.11 G2: 2.50 <math>\pm</math> 5.00</p>

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			<p>P=0.03</p> <p>ABC-Inappropriate speech G1: 0.40 ± 0.99 G2: 0.05 ± 0.22 p=ns</p> <p>CGI Very much improved, n: G1: 2 G2: 1</p> <p>Much improved, n: G1: 8 G2: 3</p> <p>Improvement, n (%): G1: 10 (50) G2: 4 (20) G1 vs. G2: p=0.047</p>
<p>Hasanzadeh, et al., 2012<sup>69</sup> RCT</p> <p>G1: Risperidone + Ginko T.D (up to 3 mg/day + up to 120 mg/day), 23/23 G2: Risperidone + placebo (NA), 24/ 24</p> <p>10 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 6.04 ± 1.61 G2: 6.76 ± 2.60</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 14.95 ± 7.86 G2: 14.08 ± 7.55</p> <p>ABC-Lethargy G1: 11.63 ± 7.90 G2: 12.32 ± 9.38</p> <p>ABC-Stereotypic behavior G1: 6.77 ± 4.42 G2: 6.32 ± 4.11</p> <p>ABC-Hyperactivity G1: 22.68 ± 9.88 G2: 21.36 ± 6.96</p> <p>ABC-Inappropriate speech G1: 3.36 ± 1.96 G2: 3.92 ± 2.11</p>	<p><b>EOT</b></p> <p>ABC-Irritability G1: 10.54 ± 5.75 G2: 9.88 ± 7.35 G1 vs G2: p=ns</p> <p>ABC-Lethargy G1: 6.86 ± 6.08 G2: 7.36 ± 6.14 G1 vs G2: p=ns</p> <p>ABC-Stereotypic behavior G1: 4.7 ± 23.28 G2: 5.00 ± 3.80 G1 vs G2: p=ns</p> <p>ABC-Hyperactivity G1: 16.54 ± 8.51 G2: 14.84 ± 6.25 G1 vs G2: p=ns</p> <p>ABC-Inappropriate speech G1: 2.09 ± 1.63 G2: 2.44 ± 1.58 G1 vs G2: p=ns</p>

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<p>Akhondzadeh, et al., 2010<sup>70</sup> RCT</p> <p>G1: Risperidone + pentoxifylline (up to 3 mg/day + up to 600 mg/day), 20/20 G2: Risperidone + placebo (NA), 20/20</p> <p>10 weeks/EOT</p> <p>Moderate RoB</p>	<p>Age: G1: 8.05 ± 2.01 G2: 7.37 ± 2.41</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 16.67 ± 2.71 G2: 16.06 ± 3.00</p> <p>ABC-Lethargy G1: 18.27 ± 2.97 G2: 17.29 ± 3.23</p> <p>ABC-Stereotypic behavior G1: 8.01 ± 1.30 G2: 7.72 ± 1.44</p> <p>ABC-Hyperactivity G1: 16.03 ± 2.60 G2: 15.44 ± 2.88</p> <p>ABC-Inappropriate speech G1: 5.13 ± 0.83 G2: 4.94 ± 0.92</p>	<p><b>EOT</b></p> <p>ABC-Irritability G1: 7.14 ± 3.23 G2: 11.65 ± 1.72 Group X time: p≤0.0001</p> <p>ABC-Lethargy G1: 8.03 ± 3.64 G2: 13.05 ± 1.93 Group X time: p≤0.0001</p> <p>ABC-Stereotypic behavior G1: 3.57 ± 1.61 G2: 5.59 ± 0.82 Group X time: p≤0.0001</p> <p>ABC-Hyperactivity G1: 8.92 ± 4.05 G2: 12.59 ± 1.86 Group X time: p≤0.0001</p> <p>ABC-Inappropriate speech G1: 2.08 ± 0.94 G2: 3.73 ± 0.55 Group X time: p≤0.0001</p>
<p>Ghaleiha et al., 2016<sup>71</sup> RCT</p> <p>G1: Risperidone + Minocycline ( up to 2mg/day + 50 mg 2/day), 25/23 G2: Risperidone + Placebo ( up to 2 mg/day + 1 capsule 2/day), 25/23</p> <p>10 weeks/EOT</p> <p>Low ROB</p>	<p>Age G1: 7.39 ± 2.48 G2: 7.78 ± 2.59</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 21.26 ± 4.82 G2: 19.91 ± 7.2</p> <p>ABC-Social Withdrawal/Lethargy G1: 21.39 ± 6.05 G2: 20.3 ± 9.12</p> <p>ABC-Stereotypic Behavior G1: 10.96 ± 4.09 G2: 11.09 ± 5.77</p> <p>ABC-Hyperactivity G1: 28.22 ± 5.97 G2: 25.04 ± 9.04</p> <p>ABC-Inappropriate</p>	<p>ABC-Irritability G1: 12.09 ± 4.55 G2: 14.04 ± 5.98 G1 vs G2, p=0.003; d=0.91; MD (95% CI) = 3.30 (1.15–5.46)</p> <p>ABC-Social Withdrawal/Lethargy G1: 17.87 ± 5.69 G2: 17.7 ± 8.18 G1 vs G2, p=ns; d=0.22; MD (95% CI) = 0.91 (-1.57 to 4.00)</p> <p>ABC-Stereotypic Behavior G1: 8.22 ± 4.81</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
		<p>Speech G1: 6.17 ± 3.01 G2: 5.04 ± 3.56</p>	<p>G2: 9.43 ± 5.69 G1 vs G2, p=ns; d=0.36; MD (95% CI) = 1.08 (-0.68 to 2.86)</p> <p>ABC-Hyperactivity G1: 21.3 ± 7.9 G2: 22.91 ± 8.98 G1 vs G2, p=0.002; d=0.95; MD (95% CI) = 4.78 (1.80– 7.70)</p> <p>ABC-Inappropriate Speech G1: 5.35 ± 2.9 G2: 4.78 ± 3.45 G1 vs G2, p=ns; d=0.34; MD (95% CI) = 0.56 (-0.40 to 1.53)</p>
<p>Rezaei, et al., 2010<sup>72</sup> RCT</p> <p>G1: Risperidone + topiramate (up to 3 mg/day + up to 200 mg/day), 20/20 G2: Risperidone + placebo (NA), 20/20</p> <p>8 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 8.17 ± 1.85 G2: 7.85 ± 1.82</p> <p>IQ NR</p>	<p>ABC-Irritability G1: 17.25 ± 3.12 G2: 16.80 ± 4.22</p> <p>ABC-Lethargy G1: 17.65 ± 6.02 G2: 17.55 ± 4.28</p> <p>ABC-Stereotypic behavior G1: 8.83 ± 3.89 G2: 8.71 ± 3.21</p> <p>ABC-Hyperactivity G1: 22.75 ± 4.85 G2: 22.00 ± 9.17</p> <p>ABC-Inappropriate speech G1: 5.25 ± 2.01 G2: 5.10 ± 1.80</p>	<p><b>EOT</b> ABC-Irritability G1: 8.20 ± 2.44 G2: 15.30 ± 4.64 G1 vs G2: p=0.04</p> <p>ABC-Lethargy G1: 14.15 ± 6.67 G2: 15.60 ± 4.28 G1 vs G2: p=ns</p> <p>ABC-Stereotypic behavior G1: 3.40 ± 1.04 G2: 8.09 ± 3.04 G1 vs G2: p=0.04</p> <p>ABC-Hyperactivity G1: 7.60 ± 2.37 G2: 19.25 ± 8.30 G1 vs G2: p=0.04</p> <p>ABC-Inappropriate speech G1: 3.93 ± 2.17 G2: 4.24 ± 1.59 G1 vs G2: p=ns</p>



<b>Author, Year Study Design</b>  <b>Groups (dose), N enrollment / N final</b>  <b>Treatment duration/Follow-up timepoint post-treatment</b>  <b>Risk of Bias</b>	<b>Mean age, years ± SD</b>  <b>Mean IQ ±SD</b>	<b>Outcome measure/Baseline scores, mean ±SD</b>	<b>Outcome measure/Post- treatment scores, mean ± SD</b>
Akhondzadeh et al., 2008 <sup>73</sup> RCT  G1: Risperidone + Piracetam (+ 3 mg/day + 800 mg/day), 20/20 G2: Risperidone + Placebo (NA), 20/20  10 weeks/EOT  Moderate RoB	Age G1: 6.90 ± 1.86 G2: 6.75 ± 1.80  IQ NR	ABC-Community Total Score G1: 23.15 ± 5.8 G2: 24 ± 8.25	<b>Mean change score from baseline</b> ABC-Community Total Score G1: -11.9 ± 3.79 G2: -5.15 ± 3.04 G1 vs G2, p<0.0001

EOT-End of Treatment; ABC-Aberrant Behavior Checklist; CGI-Clinical Global Impression

**Table F-6. Key findings in studies of other medical interventions**

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
<b>Donepezil</b>			
<p>Handen et al., 2005<sup>74</sup> RCT</p> <p>G1: Donepezil (2.5-10 mg/day), 18/15 G2: Placebo (NA), 16/16</p> <p>10 weeks/EOT</p> <p>Moderate RoB</p>	<p>Age, mean (range) G1: 11 yrs 6 mos (8 yrs 7 mos – 16 yrs 8 mos) G2: 11 yrs 8 mos (8 yrs 1 mo – 16 yrs 6 mos)</p> <p>IQ G1: 96.8 (73- 142) G2: 96.7 (82- 146)</p>	<p>Trail Making Test G1: 123.6 56.5 G2: 154.9 77.8</p> <p>Verbal Fluency-total number of verbal fluency switches G1: 6.83 3.17 G2: 8.31 2.73</p> <p>Design Fluency- number of design fluency test switches G1: 3.44 2.5 G2: 4.75 2.79</p> <p>Color-Word Interference- inhibition/switch time G1: 93.3 38.3 G2: 90.5 25.4</p> <p>Sorting Test (STCC and STFS)-number of confirmed correct sorts G1: 6.72 2.97 G2: 7.19 1.87</p> <p>Sorting Test (STCC and STFS)-total number of free sorts G1: 25.2 11.1 G2: 26.6 7.6</p> <p>Twenty Questions Test-total number of questions asked G1: 24.7 13.7 G2: 18.9 8.9</p> <p>Tower of California test-total number of moves G1: 12.1 4.1 G2: 12.3 4.9</p> <p>Word Context Test- total number of points</p>	<p><b>EOT</b></p> <p>Trail Making Test G1: 118.3 79.1 G2: 104.7 53.4 G1 Vs G2, p= 0.72</p> <p>Verbal Fluency-total number of verbal fluency switches G1: 6.17 5.12 G2: 6.94 4.97 G1 Vs G2, p=0.372</p> <p>Design Fluency- number of design fluency test switches G1: 5.22 2.69 G2: 4.31 4.25 G1 Vs G2, p=0.57</p> <p>Color-Word Interference- inhibition/switch time G1: 81.3 28.9 G2: 79.7 34.2 G1 Vs G2, p=0.74</p> <p>Sorting Test (STCC and STFS)-number of confirmed correct sorts G1: 5.89 3.1 G2: 5.69 4.36 G1 Vs G2, p=0.89</p> <p>Sorting Test (STCC and STFS)-total number of free sorts G1: 19.4 11.6 G2: 21.7 10.9 G1 Vs G2, p=0.57</p> <p>Twenty Questions Test-total number of questions asked G1: 22.2 10.8 G2: 15.1 8.5 G1 Vs G2, p=0.06</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
		<p>earned G1: 4.9 4.9 G2: 6.1 3.3</p> <p>EOWPVT-Expressive Language Scaled Score G1: 104.6 22.4 G2: 108.7 17</p> <p>Memory Test-Percent Correct G1: 40.7 14.1 G2: 47.1 10.3</p>	<p>Tower of California test-total number of moves G1: 15.2 4.7 G2: 14.9 7.7 G1 Vs G2, p=0.94</p> <p>Word Context Test- total number of points earned G1: 3 3.2 G2: 3.8 4.9 G1 Vs G2, p=0.43</p> <p>EOWPVT-Expressive Language Scaled Score G1: 3.8 4.9 G2: 109.7 21 G1 Vs G2, p=0.5</p> <p>Memory Test-Percent Correct G1: 114.5 16.1 G2: 50.2 11 G1 Vs G2, p=0.28</p>
<b>Anti-epileptics</b>			
<p>Hollander et al., 2010<sup>75</sup> RCT</p> <p>G1: Divalproex sodium (125mg qhs - 500mg bid), 16/16 G2: Placebo (NA), 11/11</p> <p>12 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 9.66 ± 2.64 G2: 8.97 ± 2.8</p> <p>IQ G1: 52.92 ± 18.5 G2: 76.1 ± 26.45</p>	<p>ABC – Irritability G1: 22 ± 7.81 G2: 20.30 ± 7.36</p> <p>CGI – Irritability G1: 5.13 ± 0.72 G2: 4.73 ± 0.47</p> <p>The Overt Aggression Scale-Modified (OAS- M) G1: 6.43 ± 1.41 G2: 5.36 ± 2.2</p> <p>CYBOCS G1: NR G2: NR</p> <p>VABS G1: 37.13 ± 15.9 G2: 42.4 ± 17.21</p>	<p><b>EOT</b> ABC – Irritability G1: 14.5 ± 6.67 G2: 17.70 ± 7.94 G1 vs G2: p= NR</p> <p>CGI – Irritability Response, n (%) G1: 10 (62,5) G2: 1 (9.1) G1 vs G2, p=0.008</p> <p>The Overt Aggression Scale-Modified (OAS- M) G1: 5.42 ± 2.17 G2: 6.25 ± 1.28 G1 vs G2: p=ns</p> <p>CYBOCS G1: NR G2: NR G1 vs G2:p=ns</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
			<p>VABS G1: NR G2: NR G1 vs G2: p=ns</p>
<b>Bumetanide</b>			
<p>Du et al., 2012<sup>76</sup> RCT</p> <p>G1: Bumetanide + ABA (0.5mg/bid), 32/29 G2: ABA only (30-40mins/day), 28/26</p> <p>3 months/EOT</p> <p>High RoB</p> <p>(Note: Discussed in section on combined treatments in main report)</p>	<p>Age G1: 4.60 ± 1.90 G2: 4.50 ± 1.67</p> <p>IQ NR</p>	<p>Autism Behavior Checklist G2: 74.68 ± 4.47 G1: 75.61 ± 11.38 G1 vs G2, p=0.700</p> <p>CARS G2: 37.28 ± 3.53 G1: 36.39 ± 3.85 G1 vs G2, p=0.362</p> <p>Clinical Global Impressions (CGI) - Improvement and severity G2: 4.48 ± 0.82 G1: 4.47 ± 1.05 G1 vs G2, p=0.975</p>	<p><b>EOT</b> Autism Behavior Checklist G2: 62.88 ± 4.96 G1: 57.47 ± 7.19 G1 vs G2, p&lt; 0.01</p> <p>CARS G2: 31.64 ± 1.72 G1: 30.79 ± 2.45 G1 vs G2, p=ns</p> <p>Clinical Global Impressions (CGI) - Improvement and severity G1: G1: 3.17 ± 0.38 G2: 3.40 ± 0.50 G1 vs G2, p&lt; 0.05</p>
<p>Lemonnier et al., 2012<sup>77</sup> RCT</p> <p>G1: Bumetanide (0.5mg/bid), 30/27 G2: Placebo (NA), 30/27</p> <p>3 months/EOT</p> <p>Moderate RoB</p>	<p>Age, months G1: 82.5 ± 23.2 G2: 85.3 ± 21.3 mos</p> <p>IQ NR</p>	<p>CARS G1: 41.6 ± 3.6 G2: 41.1 ± 4.1</p> <p>CGI NR</p> <p>ADOS-G NR</p>	<p><b>CARS (day 90)</b> G1: 36 ± 5.7 G2: 39.3 ± 4.9 G1 vs G2: p= 0.004</p> <p><b>CARS (day 120)</b> G1: 38.8 ± 4.7 G2: 40.5 ± 3.8</p> <p><b>EOT</b> CGI G1: 2.04 ± 0.87 G2: 1.56 ± 0.85 G1 vs G2: p=0.017</p> <p>Significant amelioration G1: 14 (51.8%) G2: 6 (22.2)</p> <p>Small amelioration G1: 7 (25.9) G2: 3 (11.1)</p>

<p><b>Author, Year Study Design</b></p> <p><b>Groups (dose), N enrollment / N final</b></p> <p><b>Treatment duration/Follow-up timepoint post-treatment</b></p> <p><b>Risk of Bias</b></p>	<p><b>Mean age, years ± SD</b></p> <p><b>Mean IQ ±SD</b></p>	<p><b>Outcome measure/Baseline scores, mean ±SD</b></p>	<p><b>Outcome measure/Post- treatment scores, mean ± SD</b></p>
			<p>No amelioration G1: 6 (22.2) G2: 18 (66.6)</p> <p>ADOS-G, mean change scores G1: +7.8 ± 7.4 G2: +5.3 ± 6.6 G1 vs G2: p=ns</p>
<b>HBOT</b>			
<p>Sampanthavivat et al., 2012<sup>78</sup> RCT</p> <p>G1: HBOT (20, 1 hr sessions/day at 153kPa), 29/29 G2: Sham air (20, 1 hr sessions/day at 116kPa), 29/29</p> <p>20 days/EOT</p> <p>Moderate RoB</p>	<p>Age G1: 6.10 ± 1.17 G2: 5.67 ± 1.01</p> <p>IQ NR</p>	<p>A TEC-Parent G1: 68.07 ± 25.43 G2: 64.86 ± 22.80</p> <p>A TEC-Clinician G1: 60.21 ± 19.92 G2: 60.55 ± 21.36</p> <p>CGIS-Parent G1: 4.03 ± 1.05 G2: 3.79 ± 0.98</p> <p>CGIS-Clinician G1: 3.62 ± 0.78 G2: 3.83 ± 0.93</p>	<p><b>EOT</b></p> <p>A TEC-Parent G1: 58.31 ± 21.94 G2: 55.86 ± 24.93 G1 vs G2: p=ns</p> <p>A TEC-Clinician G1: 52.38 ± 19.11 G2: 52.93 ± 18.93 G1 vs G2: p=ns</p> <p>CGIS-Parent G1: 3.69 ± 0.93 G2: 3.66 ± 0.86 G1, p=0.005 G2, p=NS</p> <p>CGIS-Clinician G1: 3.48 ± 0.78 G2: 3.76 ± 0.83 G1 vs G2: p=ns</p> <p>Change scores CGIC-Parent G1: 2.34 ± 0.61 G2: 2.55 ± 0.83 G1 vs. G2:p=ns</p> <p>CGIC-Clinician G1: 2.31 ± 0.6 G2: 2.72 ± 0.8 G1 vs G2:, p=0.03</p>
<p>Granpeesheh et al., 2010<sup>79</sup> RCT</p> <p>G1: HBOT (24% oxygen at 1.3 atm pressure), 18/17 G2: Placebo (NA), 16/16</p> <p>15 weeks/EOT</p>	<p>Age G1: 6.11 G2: 6.25</p> <p>IQ NR</p>	<p>SRS NR</p> <p>ADOS NR</p>	<p><b>Mean change score:</b></p> <p>SRS- Social Awareness G1: -3.14 ± 14.21 G2: -1.33 ± 16.62 G1 vs G2: p=ns</p> <p>SRS-Social Cognition</p>

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<p>Low RoB</p>			<p>G1: 1.79 ± 8.82 G2: -5.33 ± 16.01 G1 vs G2: p=ns</p> <p>SRS-Social Communication G1: -1.00 ± 13.06 G2: 3.13 ± 12.02 G1 vs G2:p=ns</p> <p>SRS-Social Motivation G1: -5.50 ± 12.45 G2: -6.33 ± 13.12 G1 vs G2:p=ns</p> <p>SRS-Autistic Mannerisms G1: 1.64 ± 14.58 G2: -3.33 ± 12.49 G1 vs G2, p=0.33</p> <p>Number (%) improving ADOS-Total G1: 5/18 (27.8) G2: 4/16 (25) G1 vs G2: p=ns</p> <p>ADOS-Communication G1: 3/18 (16.7) G2: 2/16 (12.5) G1 vs G2: p=ns</p> <p>ADOS-Socialization G1: 3/18 (16.7) G2: 2/16 (12.5) G1 vs G2: p=ns</p>
<p>Rossignol 2009<sup>80</sup> RCT</p> <p>G1: HBOT (1.3 atm and 24% oxygen), 33/30 G2: Room air (1.03 atm and 21% oxygen), 29/26</p> <p>4 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 4.97 ± 1.29 G2: 4.86 ± 1.13</p> <p>IQ NR</p>	<p>ABC – Irritability G1: 13.2 ± 9.5 G2: 12.2 ± 7.9</p> <p>ABC – Social Withdrawal/Lethargy G1: 10.5 ± 6.9 G2: 11.2 ± 6.9</p> <p>ABC – Stereotypic Behavior G1: 7.5 ± 4.9 G2: 6.2 ± 4.7</p>	<p>ABC – Irritability G1: 10.5 ± 7.4 G2: 11.3 ± 6.4 G1 vs G2: p=0.0976</p> <p>ABC – Social Withdrawal/Lethargy G1: 9.3 ± 6.7 G2: 8.9 ± 5.6 G1 vs G2: p=ns</p> <p>ABC – Stereotypic Behavior</p>

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		<p>ABC – Hyperactivity G1: 20.7 ± 9.9 G2: 20.1 ± 8.2</p> <p>ABC – Inappropriate Speech G1: 3.4 ± 3.1 G2: 3.6 ± 3.6</p> <p>ATEC – Total Score G1: 75.3 ± 19.5 G2: 75.6 ± 21</p>	<p>G1: 6.2 ± 5.1 G2: 5.4 ± 4 G1 vs G2: p=ns</p> <p>ABC – Hyperactivity G1: 17.8 ± 9.2 G2: 16.8 ± 7.7 G1 vs G2: p=ns</p> <p>ABC – Inappropriate Speech G1: 2.6 ± 2.5 G2: 3.3 ± 3.2</p> <p>ATEC – Total Score G1: 65.9 ± 16.4 G2: 70.1 ± 21.9 G1 vs G2: p=ns</p> <p>CGI – Improvement (Much or very much improved) G1: 9 (30) G2: 2 (7.7) G1 vs G2: p=0.0471</p>
<b>Melatonin</b>			
<p>Cortesi et al., 2012<sup>81</sup> RCT</p> <p>G1: Controlled-release melatonin + CBT (3mg/day), 40/35 G2: Controlled-release melatonin (3mg/day), 40/34 G3: CBT (4 sessions/week), 40/33 G4: Placebo (NA), 40/32</p> <p>12 weeks/EOT</p> <p>Low</p> <p>(Note: Discussed in section on combined treatments in main report)</p>	<p>Age G1: 6.4 ± 1.1 G2: 6.8 ± 0.9 G3: 7.1 ± 0.7 G4: 6.3 ± 1.2</p> <p>IQ NR</p>	<p>CSHQ CSHQ-Total score G1: 66.11 ± 5.47 G2: 66.67 ± 8.55 G3: 64.48 ± 5.48 G4: 64.20 ± 4.85</p> <p>Bed resistance G1: 14.53 ± 1.82 G2: 13.85 ± 2.23 G3: 13.44 ± 2.08 G4: 13.63 ± 1.82</p> <p>SOD G1: 2.88 ± 0.32 G2: 2.85 ± 0.35 G3: 2.89 ± 0.30 G4: 2.90 ± 0.31</p> <p>Sleep anxiety G1: 7.95 ± 1.83 G2: 8.35 ± 2.19</p>	<p><b>EOT</b> CSHQ CSHQ-Total score G1: 47.84 ± 2.94 G2: 54.78 ± 6.22 G3: 60.06 ± 4.71 G4: 64.80 ± 4.52 Time x group p&lt;0.001</p> <p>Bed resistance G1: 8.46 ± 1.39 G2: 10.50 ± 2.20 G3: 11.62 ± 2.22 G4: 14.10 ± 1.93 Time x group p&lt;0.001</p> <p>SOD G1: 1.69 ± 0.73 G2: 2.10 ± 0.68 G3: 2.51 ± 0.57 G4: 2.93 ± 0.25 Time x group p&lt;0.001</p>

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		<p>G3: 8.62 ± 1.98 G4: 7.66 ± 1.73</p> <p>Night-wakings G1: 7.61 ± 0.89 G2: 7.67 ± 0.94 G3: 7.62 ± 0.94 G4: 7.76 ± 0.93</p> <p>Sleep duration G1: 7.34 ± 1.35 G2: 7.17 ± 1.51 G3: 7.01 ± 1.48 G4: 6.46 ± 1.25</p> <p>Parasomnias G1: 9.15 ± 1.68 G2: 9.10 ± 2.42 G3: 9.75 ± 2.11 G4: 8.96 ± 1.80</p> <p>SDB G1: 3.18 ± 0.40 G2: 3.20 ± 0.44 G3: 3.10 ± 0.30 G4: 3.15 ± 0.40</p> <p>DS G1: 13.92 ± 2.86 G2: 13.35 ± 3.84 G3: 13.31 ± 2.67 G4: 13.13 ± 3.11</p> <p>Sleep Diary TST G1: 414.03 ± 45.34 G2: 410.28 ± 45.07 G3: 408.08 ± 49.03 G4: 413.00 ± 45.13</p> <p>SOL G1: 85.84 ± 20.02 G2: 81.21 ± 32.35 G3: 76.34 ± 31.70 G4: 78.20 ± 33.83</p> <p>WASO G1: 69.50 ± 23.35 G2: 73.71 ± 45.00 G3: 68.72 ± 31.77 G4: 69.75 ± 45.21</p>	<p>Sleep anxiety G1: 5.23 ± 0.95 G2: 7.21 ± 1.87 G3: 7.17 ± 1.48 G4: 7.93 ± 1.99 Time x group p&lt;0.001</p> <p>Night-wakings G1: 4.42 ± 0.90 G2: 5.03 ± 1.10 G3: 7.06 ± 1.06 G4: 7.86 ± 0.81 Time x group p&lt;0.001</p> <p>Sleep duration G1: 4.38 ± 1.02 G2: 4.82 ± 0.94 G3: 6.68 ± 1.16 G4: 6.40 ± 1.29 Time x group p&lt;0.001</p> <p>Parasomnias G1: 8.92 ± 1.38 G2: 9.35 ± 1.78 G3: 9.82 ± 2.25 G4: 9.16 ± 1.53 Time x group p=ns</p> <p>SDB G1: 3.22 ± 0.35 G2: 3.15 ± 0.48 G3: 3.20 ± 0.41 G4: 3.20 ± 0.44 Time x group p=ns</p> <p>DS G1: 10.84 ± 1.68 G2: 11.39 ± 2.34 G3: 11.96 ± 1.97 G4: 12.96 ± 1.97 Time x group p&lt;0.001</p> <p>Sleep Diary TST G1: 505.01 ± 31.18 G2: 481.10 ± 33.15 G3: 445.13 ± 48.37 G4: 416.23 ± 43.60 Time x group p&lt;0.001</p>



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		<p><b>NAPTIME</b> G1: 28.26 ± 49.13 G2: 33.57 ± 56.63 G3: 35.31 ± 60.17 G4: 37.33 ± 56.19</p> <p><b>SE</b> G1: 70.26 ± 4.83 G2: 71.10 ± 4.91 G3: 71.37 ± 4.77 G4: 71.13 ± 4.99</p> <p><b>BEDTIME</b> G1: 23.33 ± 1.35 G2: 23.45 ± 1.15 G3: 23.39 ± 1.03 G4: 23.41 ± 1.19</p>	<p><b>SOL</b> G1: 33.69 ± 14.40 G2: 45.21 ± 23.21 G3: 59.13 ± 27.60 G4: 79.60 ± 31.85 Time x group p&lt;0.001</p> <p><b>WASO</b> G1: 29.69 ± 12.97 G2: 42.21 ± 22.35 G3: 61.17 ± 28.93 G4: 70.15 ± 42.76 Time x group p&lt;0.001</p> <p><b>NAPTIME</b> G1: 9.20 ± 22.48 G2: 17.00 ± 33.11 G3: 12.29 ± 24.24 G4: 36.10 ± 33.28 Time x group p=ns</p> <p><b>SE</b> G1: 84.46 ± 4.23 G2: 82.71 ± 4.00 G3: 79.58 ± 2.82 G4: 71.93 ± 4.62 Time x group p&lt;0.001</p> <p><b>BEDTIME</b> G1: 22.06 ± 1.05 G2: 22.30 ± 1.10 G3: 22.55 ± 1.01 G4: 23.51 ± 1.12 Time x group p&lt;0.001</p>
<p>Wright et al., 2011<sup>82</sup> RCT</p> <p>G1: Melatonin (2-10mg/day), 9/6 G2: Placebo (NA), 11/10 Crossover</p> <p>9 months/EOT</p> <p>Moderate RoB</p>	<p>Age G1: 8.9 ± 3.0 G2: 8.5 ± 2.3</p> <p>IQ NR</p>	<p>Dysomnias, n=12 G1+G2: 34.0 ± 9.4</p> <p>Parasomnias, n=14 G1+G2: 18.7 ± 7.7</p> <p>Sleep apneas, n=13 G1+G2: 13.0 ± 9.4</p> <p>Other sleep disorders, n=10 G1+G2: 25.1 ± 5.6</p> <p>DBC-Total, n=17 G1+G2: 90.1 ± 18.7</p>	<p><b>EOT</b> Dysomnias, n=12 G1: 22.2 ± 6.6 G2: 27.8 ± 6.3 p=0.04</p> <p>Parasomnias, n=14 G1: 17.3 ± 4.5 G2: 20.1 ± 8.1 p=ns</p> <p>Sleep apneas, n=13 G1: 11.4 ± 4.2 G2: 12.7 ± 3.4 p=ns</p>

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		<p>DBC-Disruptive, n=17 G1+G2: 26.2 ± 13.0</p> <p>DBC- Self-absorption, n=17 G1+G2: 33.0 ± 11.0</p> <p>DBC-Communication, n=17 G1+G2: 11.4 ± 3.6</p> <p>DBC-Anxiety, n=17 G1+G2: 8.8 ± 2.8</p> <p>DBC-Social relating, n=17 G1+G2: 9.4 ± 3.1</p> <p>GHQ total n=17 G1+G2: 3.7 ± 7.1</p> <p>No. of awakenings n=17 G1+G2: 0.5 ± 0.5</p> <p>Total sleep minutes, n=17 G1+G2: 499.9 ± 66.4</p> <p>Sleep latency, n=17 G1+G2: 135.0 ± 63.0</p>	<p>Other sleep disorders, n=10 G1: 23.8 ± 3.4 G2: 25.9 ± 6.2 p=ns</p> <p>DBC-Total G1: 75.12 ± 23.29 G2: 82.25 ± 25.79 p=0.05</p> <p>DBC-Disruptive G1: 21.82 ± 11.97 G2: 23.88 ± 11.12 p=ns</p> <p>DBC- Self-absorption G1: 28.94 ± 13.41 G2: 30.06 ± 14.05 p=ns</p> <p>DBC-Communication G1: 8.24 ± 3.29 G2: 9.75 ± 5.04 p=0.045</p> <p>DBC-Anxiety G1: 7.53 ± 3.39 G2: 7.56 ± 3.86 p=ns</p> <p>DBC-Social relating G1: 7.82 ± 3.11 G2: 9.06 ± 4.27 p=ns</p> <p>GHQ total G1: 1.4 ± 2.7 G2: 3.2 ± 4.6 p=ns</p> <p>No. of awakenings G1: 0.43 ± 0.64 G2: 0.58 ± 0.74 p=ns</p> <p>Total sleep minutes G1: 556.11 ± 53.59 G2: 507.66 ± 70.67 p=0.002</p>

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			<p>Sleep latency G1: 82.84 ± 50.61 G2: 124.79 ± NR p=0.004</p>
<b>Other</b>			
<p>Amatachaya et al., 2014<sup>83, 84</sup> RCT</p> <p>G1: Transcranial direct current stimulation (1mA), 10/10 G2: Sham (NA), 10/10</p> <p>8 weeks/EOT</p> <p>Moderate RoB</p>	<p>Age G1 + G2: 5-8</p> <p>IQ NR</p>	<p>CARS G1: 34.95 ± 4.73 G2: 34.6 ± 4.41</p> <p>ATEC-Total G1: 67.25 ± 9.88 G2: 69.15 ± 8.98</p> <p>ATEC-Language G1: 10.6 ± 5.59 G2: 10.75 ± 4.72</p> <p>ATEC- Social G1: 16.4 ± 4.5 G2: 17.45 ± 2.67</p> <p>ATEC-Sensory and cognitive awareness G1: 20.1 ± 3.91 G2: 20.5 ± 3.4</p> <p>ATEC-Health and behavioral problem G1: 20.15 ± 8.34 G2: 20.45 ± 7.21</p> <p>CGAS G1: 54.35 ± 11.07 G2: 53.35 ± 10.31</p> <p>CGI-Severity G1: 4.05 ± 0.94 G2: 4.15 ± 0.99</p>	<p><b>EOT</b></p> <p>CARS G1: 32.2 ± 3.98 G2: 35 ± 4.3 p &lt; 0.05</p> <p>ATEC-Total G1: 58 ± 5.28 G2: 69.65 ± 9.13 p ≤ 0.001</p> <p>ATEC-Language G1: 10.5 ± 5.39 G2: 10.55 ± 5.2</p> <p>ATEC- Social G1: 14.45 ± 4.85 G2: 17.7 ± 2.98 p &lt; 0.05</p> <p>ATEC-Sensory and cognitive awareness G1: 18.35 ± 5.35 G2: 22.3 ± 4.47 p &lt; 0.05</p> <p>ATEC-Health and behavioral problem G1: 14.7 ± 6.21 G2: 19.1 ± 6.47 p &lt; 0.05</p> <p>CGAS G1: 60 ± 10.57 G2: 53.1 ± 10.14 p &lt; 0.05</p> <p>CGI-Improvement, n (%) Very much improved G1: 0 G2: 0 p=ns</p>

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			<p>Much improved G1: 9 (45) G2: 3 (15) p ≤ 0.05</p> <p>Minimally improved G1: 8 (40) p=ns</p> <p>No change G1: 1 (5) G2: 6 (30) p=ns</p> <p>Minimally worse G1: 2 (10) G2: 2 (10) p=ns</p> <p>Much worse G1: 0 G2: 5 (25) p &lt; 0.05</p> <p>Very much worse G1: 0 G2: 0 p=ns</p>
<p>Dadds et al., 2014<sup>85</sup> RCT</p> <p>G1: Intranasal oxytocin (12 or 24 IU), 19/19 G2: Placebo (NA), 19/189</p> <p>4 days/EOT</p> <p>Moderate RoB</p>	<p>Age G1: 11.79 ± 2.82 G2: 10.74 ± 2.38</p> <p>IQ G1: 90.47 ± 11.70 G2: 88.64 ± 7.98</p>	<p>SRS G1: 17.13 ± 5.57 G2: 20.56 ± 6.70</p> <p>Video Observation Repetitive Behaviors G1: 0.24 ± 0.26 G2: 0.20 ± 0.25</p> <p>Video Observation Social Interaction Skills G1: 1.63 ± 0.50 G2: 1.69 ± 0.38</p> <p>Facial Emotion Recognition G1: 0.79 ± 0.11 G2: 0.77 ± 0.14</p> <p>OSU G1: 3.76 ± 0.70 G2: 4.17 ± 0.79</p>	<p><b>3 mos follow-up</b></p> <p>SRS G1: 16.47 ± 5.94 G2: 15.78 ± 7.85 G1 vs G2: p=ns</p> <p>Video Observation Repetitive Behaviors G1: 0.27 ± 0.24 G2: 0.25 ± 0.24 G1 vs G2: p=ns</p> <p>Video Observation Social Interaction Skills G1: 1.92 ± 0.51 G2: 1.96 ± 0.49 G1 vs G2: p=ns</p> <p>Facial Emotion Recognition G1: 0.87 ± 0.08 G2: 0.86 ± 0.07 G1 vs G2: p=ns</p>

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		<p>CARS G1: 32.26 ± 3.25 G2: 33.84 ± 3.70</p>	<p>OSU G1: 3.60 ± 0.63 G2: 3.78 ± 0.94 G1 vs G2: p=ns</p> <p>CARS G1: 30.07 ± 2.78 G2: 31.06 ± 5.20 G1 vs G2: p=ns</p>
<p>Klaiman et al., 2013<sup>86</sup> RCT</p> <p>G1: Tetrahydrobiopterin (20mg/kg/day), 23/23 G2: Placebo (NA), 23/23</p> <p>16 weeks/EOT</p> <p>Low RoB</p>	<p>Age, months G1: 60.1 ± 12.0 G2: 60.2 ± 12.6</p> <p>IQ NR</p>	<p>CGI-Severity [N (%)] Frequency of markedly, severely, or extremely ill G1: 10 (48) G2: 15 (68)</p> <p>ABC-Irritability G1: 11.1 ± 7.7 G2: 11.9 ± 7.8</p> <p>ABC-Social withdrawal/lethargy G1: 9.5 ± 7.5 G2: 16.2 ± 10.0</p> <p>ABC-Stereotypy G1: 6.1 ± 3.9 G2: 6.1 ± 3.6</p> <p>ABC-Hyperactivity G1: 21.5 ± 10.3 G2: 22.9 ± 11.6</p> <p>ABC-Inappropriate speech G1: 3.7 ± 2.4 G2: 3.4 ± 4.1</p> <p>SRS G1: 81.4 ± 10.3 G2: 83.6 ± 9.2</p> <p>PLS G1: 77.8 ± 29.2 G2: 57.1 ± 25.7</p> <p>Vineland G1: 320.5 ± 47.9 G2: 274.4 ± 51.4</p>	<p><b>16 wks follow-up</b> CGI-Severity, N (%) Frequency of markedly, severely, or extremely ill G1: 7 (35) G2: 14 (64) G1 vs G2: p=ns</p> <p>Improvement, frequency of very much or much improved G1: 5 (25) G2: 3 (14) G1 vs G2: p=ns</p> <p>ABC-Irritability G1: 10.0 ± 7.8 G2: 10.8 ± 7.8 G1 vs G2: p=ns</p> <p>ABC-Social withdrawal/lethargy G1: 5.2 ± 4.4 G2: 13.6 ± 7.5 G1 vs G2: p&lt;0.01</p> <p>ABC-Stereotypy G1: 5.4 ± 3.8 G2: 6.7 ± 4.5 G1 vs G2: p=ns</p> <p>ABC-Hyperactivity G1: 18.2 ± 8.5 G2: 22.8 ± 10.3 G1 vs G2: p=ns</p> <p>ABC-Inappropriate speech G1: 2.6 ± 1.9</p>

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			<p>G2: 3.9 ± 3.6 G1 vs G2: p=ns</p> <p>SRS G1: 76.7 ± 10.9 G2: 83.2 ± 10.4 G1 vs G2: p=ns</p> <p>PLS G1: 84.0 ± 28.8 G2: 60.4 ± 25.4 G1 vs G2: p=0.01</p> <p>Vineland G1: 344.76 ± 50.0 G2: 294.9 ± 70.1 G1 vs G2: p=0.02</p>
<p>Lv et al., 2013<sup>87</sup> NRCT</p> <p>G1: Human cord blood mononuclear cells (CBMNCs) (2 × 10<sup>6</sup>/kg) + rehabilitation therapy, 14/14 G2: CBMNCs + umbilical cord-derived mesenchymal stem cells (UCMSCs) (2 × 10<sup>6</sup>/kg and 1 × 10<sup>6</sup>/kg) + rehabilitation, 9/9 G3: Rehabilitation therapy, 14/13</p> <p>5-7 days (4 transplants)/EOT</p> <p>High RoB</p>	<p>Age G1: 7.41 ± 2.63 G2: 6.20 ± 2.12 G3: 5.60 ± 2.01</p> <p>IQ G1: NR G2: NR G3: NR</p>	<p>CARS G1: 46.43 ± 8.65 G2: 45.11 ± 4.31 G3: 43.15 ± 4.38</p> <p>CGI NR</p> <p>ABC-Total G1: 94.07 ± 21.98 G2: 91.78 ± 25.92 G3: 75.46 ± 12.05</p> <p>ABC-Irritability G1: 16.36 ± 9.61 G2: 15.00 ± 7.81 G3: 9.15 ± 5.58</p> <p>ABC-Lethargy/Social withdrawal G1: 30.71 ± 6.08 G2: 31.00 ± 6.98 G3: 35.08 ± 4.96</p> <p>ABC-Stereotypic behavior G1: 29.43 ± 9.77 G2: 28.33 ± 8.47 G3: 22.77 ± 6.86</p> <p>ABC-Hyperactivity G1: 11.86 ± 4.55 G2: 11.89 ± 6.88 G3: 6.08 ± 3.15</p>	<p><b>EOT</b></p> <p>CARS G1: 37.14 ± 10.15 G2: 28.00 ± 6.18 G3: 37.23 ± 3.42</p> <p>CGI-GI [N (%)] Very much improved G1: 1 (7.14) G2: 3 (33.33) G3: 0 (0)</p> <p>Much improved G1: 6 (42.86) G2: 5 (55.56) G3: 1 (7.69)</p> <p>Minimally improved G1: 2 (14.29) G2: 1 (11.11) G3: 11 (84.62)</p> <p>No change G1: 5 (35.71) G2: 0 (0.00) G3: 1 (7.69)</p> <p>Minimally worse G1: 0 (0.00) G2: 0 (0.00) G3: 0 (0.00)</p> <p>Much worse G1: 0 (0.00)</p>

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		<p>ABC-Inappropriate speech G1: 5.71 ± 4.30 G2: 5.56 ± 2.83 G3: 2.38 ± 2.10</p>	<p>G2: 0 (0.00) G3: 0 (0.00)</p> <p>Very much worse G1: 0 (0.00) G2: 0 (0.00) G3: 0 (0.00)</p> <p>CGI-EI [N (%)] Unchanged or worse G1: 5 (35.71) G2: 0 (0.00) G3: 1 (7.69)</p> <p>Minimal G1: 2 (14.29) G2: 1 (11.11) G3: 11 (84.62)</p> <p>Moderate G1: 7 (50.00) G2: 6 (66.67) G3: 1 (7.69)</p> <p>Marked G1: 0 (0.00) G2: 2 (22.22) G3: 0 (0.00)</p> <p>ABC-Total G1: 58.36 ± 31.73 G2: 36.78 ± 16.95 G3: 62.31 ± 11.3 G1 vs G3+ p&lt;0.05 G2 vs G3: p&lt; 0.05</p> <p>ABC-Irritability G1: 8.14 ± 8.37 G2: 4.22 ± 3.19 G3: 6.92 ± 4.96 p=ns</p> <p>ABC-Lethargy/Social withdrawal G1: 24.14 ± 9.65 G2: 16.00 ± 7.92 G3: 30.54 ± 5.03 G1 vs G3: p&lt;0.05 G2 vs G3: p&lt;0.05</p> <p>ABC-Stereotypic</p>

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			<p>behavior G1: 17.07 ± 9.93 G2: 9.33 ± 5.81 G3: 17.31 ± 4.05 G2 vs G3: p,0.05</p> <p>ABC-Hyperactivity G1: 6.86 ± 5.26 G2: 4.67 ± 3.74 G3: 5.08 ± 2.40 p=ns</p> <p>ABC-Inappropriate speech G1: 2.14 ± 2.32 G2: 2.56 ± 2.19 G3: 2.46 ± 2.63 p=ns</p>
<p>Arnold et al., 2012<sup>88</sup> RCT</p> <p>G1: Mecamylamine (0.5-5 mg/kg/day), 12/10 G2: Placebo (NA), 8/8</p> <p>14 weeks/EOT</p> <p>Low RoB</p>	<p>Age G1: 6.76 ± 2.24 G2: 8.36 ± 2.83</p> <p>IQ G1: 77.58 ± 21.12 G2: 62.62 ± 32.53</p>	<p>OACIS-S G1: 5.25 ± 0.75 G2: 5.63 ± 0.74</p> <p>OARS G1: 1.83 ± 0.42 G2: 2.06 ± 0.45</p> <p>ABC-Irritability G1: 12.75 ± 9.42 G2: 12.88 ± 9.60</p> <p>ABC-Lethargy G1: 10.42 ± 6.61 G2: 17.00 ± 9.37</p> <p>ABC-Stereotype G1: 4.17 ± 3.54 G2: 9.75 ± 6.25</p> <p>ABC-Hyperactivity G1: 21.08 ± 11.74 G2: 19.13 ± 13.02</p> <p>ABC-Inappropriate Speech G1: 4.50 ± 3.73 G2: 4.38 ± 3.16</p> <p>RBS-Stereotypy G1: 4.58 ± 2.87 G2: 7.38 ± 3.16</p>	<p><b>Mean change score</b> OACIS-S G1: -0.58 ± 0.79 G2: -0.63 ± 0.74</p> <p>OARS G1: -0.30 ± 0.33 G2: -0.32 ± 0.34</p> <p>ABC-Irritability G1: -3.17 ± 8.76 G2: -5.00 ± 10.78</p> <p>ABC-Lethargy G1: -4.25 ± 6.97 G2: -7.50 ± 9.56</p> <p>ABC-Stereotype G1: -1.42 ± 2.64 G2: -1.63 ± 7.11</p> <p>ABC-Hyperactivity G1: -6.92 ± 11.25 G2: -5.50 ± 12.06</p> <p>ABC-Inappropriate speech G1: -1.50 ± 3.90 G2: -1.75 ± 2.38</p> <p>RBS-Stereotypy G1: -1.92 ± 2.94 G2: -0.63 ± 6.21</p>



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		<p>RBS-Self Injury G1: 1.75 ± 2.01 G2: 4.50 ± 3.82</p> <p>RBS-Compulsive G1: 5.50 ± 3.90 G2: 7.25 ± 4.53</p> <p>RBS-Ritualistic G1: 6.00 ± 4.63 G2: 5.88 ± 4.91</p> <p>RBS-Sameness G1: 8.08 ± 5.62 G2: 9.38 ± 6.14</p> <p>RBS-Restricted G1: 3.92 ± 3.23 G2: 4.13 ± 2.75</p> <p>SRS-Receptive G1: 11.92 ± 2.64 G2: 16.38 ± 2.62</p> <p>SRS-Cognitive G1: 19.50 ± 2.88 G2: 22.75 ± 6.04</p> <p>SRS-Expressive G1: 34.33 ± 8.14 G2: 39.88 ± 11.68</p> <p>SRS-Motivation G1: 13.00 ± 4.69 G2: 19.13 ± 4.26</p> <p>SRS-Preoccupations G1: 16.33 ± 6.88 G2: 22.50 ± 7.67</p> <p>EVT G1: 74.0 ± 16.34 G2: 47.5 ± 24.74</p>	<p>RBS-Self injury G1: -0.83 ± 1.53 G2: -2.88 ± 4.39</p> <p>RBS-Compulsive G1: -2.42 ± 3.55 G2: -3.50 ± 3.38</p> <p>RBS-Ritualistic G1: -1.75 ± 4.58 G2: -2.00 ± 3.02</p> <p>RBS-Sameness G1: -4.67 ± 6.05 G2: -2.50 ± 3.21</p> <p>RBS-Restricted G1: -1.58 ± 2.50 G2: -1.13 ± 2.64</p> <p>SRS-Receptive G1: 0.33 ± 1.78 G2: -2.25 ± 3.06</p> <p>SRS-Cognitive G1: -2.50 ± 5.39 G2: -2.13 ± 5.74</p> <p>SRS-Expressive G1: -4.17 ± 7.31 G2: -7.25 ± 8.55</p> <p>SRS-Motivation G1: -3.83 ± 4.55 G2: -5.75 ± 4.89</p> <p>SRS-Preoccupations G1: -3.33 ± 7.43 G2: -5.75 ± 4.89</p> <p>EVT G1: -2.14 ± 10.12 G2: 0 ± 6.42</p>
<p>Hardan et al., 2012<sup>89</sup> RCT</p> <p>G1: N-acetylcysteine (NAC) (900 mg up to 3 times/day), 15/134 G2: Placebo, 18/15</p>	<p>Age G1: 7.0 ± 2.1 G2: 7.2 ± 2.2</p> <p>IQ NR</p>	<p>ABC Irritability G1: 16.9±7.9 G2: 14.8±9.6</p> <p>ABC Lethargy G1: 15.2±9.5 G2: 12.1±7.8</p>	<p><b>EOT</b> ABC Irritability G1: 7.2±5.7 G2: 13.1±9.9 p&lt;.001</p> <p>ABC Lethargy</p>

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<p>12 weeks/EOT</p> <p>Low RoB</p>		<p>ABC Stereotypy G1: 9.1±5.5 G2: 8.9±6.5</p> <p>ABC Hyperactivity G1: 23.4±9.0 G2: 23.8±9.3</p> <p>ABC Inappropriate Speech G1: 4.9±3.2 G2: 4.1±3.7</p> <p>RBS-R Stereotypies G1: 6.7±3.8 G2: 8.1±5.3</p> <p>RBS Self-Injurious Behavior G1: 3.9±4.4 G2: 3.4±3.8</p> <p>RBS Compulsions G1: 4.7±3.7 G2: 5.8±4.8</p> <p>RBS Rituals G1: 5.3±3.7 G2: 6.6±4.5</p> <p>RBS Sameness G1: 7.8±7.2 G2: 9.2±8.1</p> <p>RBS Restricted G1: 4.7±3.4 G2: 5.2±3.7</p> <p>SRS Total G1: 111.9±28.3 G2: 104.7±28.1</p> <p>SRS Social Awareness G1: 12.7±3.4 G2: 13.5±3.7</p> <p>SRS Social Cognition G1: 21.9±6.3 G2: 21.2±5.8</p>	<p>G1: 11±9.4 G2: 8.3±7.7 p=.ns</p> <p>ABC Stereotypy G1: 5.6±5.7 G2: 8.0±7.0 p=ns</p> <p>ABC Hyperactivity G1: 12.4±11.4 G2: 21.0±11.5 p=ns</p> <p>ABC Inappropriate Speech G1: 2.5±2.6 G2: 3.6±3.6 p=ns</p> <p>RBS Stereotypies G1: 4.6±3.4 G2: 6.9±5.2 p= .014</p> <p>RBS Self Injurious Behavior G1: 2.2±2.3 G2: 3.0±3.6 p=ns</p> <p>RBS Compulsions G1: 2.5±2.1 G2: 5.2±5.0 p=ns</p> <p>RBS Rituals G1: 4.3±3.4 G2: 5.6±4.9 p=ns</p> <p>RBS Sameness G1: 5.3±4.7 G2: 7.9±6.2 p=ns</p> <p>RBS Restricted G1: 3.5±2.3 G2: 4.8±3.6 p=ns</p>

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		<p>SRS Social Communication G1: 39.6±11.3 G2: 39.3±8.6</p> <p>SRS Social Motivation G1: 16.6±6.3 G2: 16.9±6.5</p> <p>SRS Autism Mannerisms G1: 21.7±5.6 G2: 21.4±7.3</p> <p>CGI Severity G1: 5.1±0.7 G2: 5.3±0.8</p>	<p>SRS Total G1: 93.8±26.7 G2: 98.5±37.8 p=ns</p> <p>SRS Social Awareness G1: 11.5±3.3 G2: 13.4±4.7 p=ns</p> <p>SRS social Cognition G1: 18.8±7.0 G2: 18.9±5.6 p=.037</p> <p>SRS Social Communication G1: 33.3±10.9 G2: 34.5±14.5 p=.ns</p> <p>SRS Social Motivation G1: 13.0±4.7 G2: 14.5±7.0 p=ns</p> <p>SRS Autism Mannerisms G1: 16.0±6.1 G2: 20.3±6.9 p=.045</p> <p>CGI Severity G1: 4.5±0.8 G2: 4.9±0.9 p=ns</p> <p>CGI Improvement G1: 2.9±1.1 G2: 3.2±.09 p=ns</p>
<p>Chez et al., 2003<sup>90</sup> RCT</p> <p>G1: Donepezil hydrochloride only, / G2: Placebo/ Donepezil hydrochloride, /</p> <p>12 wks/EOT</p> <p>Moderate RoB</p>	<p>Age G1: 6.8 (2.1-9.9) G2: 6.9 (4.1-10.3)</p> <p>IQ NR</p>	<p>CARS G1: 34.7 ± 7.7 G2: 35.1 ± 7.9</p> <p>Expressive One-Word Picture Vocabulary Test (speech age in months) G1: 35.7 ± 27.8 G2: 31.9 ± 31.1</p>	<p><b>End of 6 wks</b></p> <p>CARS G1: 33.3 ± 8 G2: 32.9 ± 7.7</p> <p>Expressive One-Word Picture Vocabulary Test (speech age in months) G1: 43.3 ± 27.2</p>

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		<p>Receptive One-Word Picture Vocabulary Test (speech age in months) G1: 38.8 ± 23.5 G2: 33.5 ± 27.9</p>	<p>G2: 33.8 ± 32.9</p> <p>Receptive One-Word Picture Vocabulary Test (speech age in months) G1: 50.3 ± 27 G2: 39.83 ± 27</p> <p><b>EOT</b> CARS G1: 30.8 ± 7.9 G2: 30.9 ± 9.1 G1 vs G2, p&lt;0.05</p> <p>Expressive One-Word Picture Vocabulary Test (speech age in months) G1: 42.5 ± 28.5 G2: 40.9 ± 38.8 G1 vs G2, p&lt;0.05</p> <p>Receptive One-Word Picture Vocabulary Test (speech age in months) G1: 49.7 ± 34.2 G2: 87.37 ± 14.2 G1 vs G2, p&lt;0.05</p>
<p>King et al., 2001<sup>91</sup> RCT</p> <p>G1: Amantadine, 19/17 G2: Placebo, 20/17</p> <p>4 wks/EOT</p> <p>Moderate RoB</p>	<p>Age 5-19</p> <p>IQ &gt;35</p>	<p>ABC – Irritability G1: 19.1 (3-38) G2: 18.7 (3-33)</p> <p>ABC – Hyperactivity G1: 29.4 (16-42) G2: 32.7 (17-46)</p> <p>CGI – Severity (Mild) G1: 0 (0) G2: 1 (5)</p> <p>CGI – Severity (Moderate) G1: 11 (57.8) G2: 11 (55)</p> <p>CGI – Severity (Severe) G1: 8 (42.1) G2: 7 (35)</p>	<p><b>EOT</b> ABC – Response rate (Reduction of at least 25% for irritability and/or hyperactivity) G1: 7 (37) G2: 9 (47) G1 vs G2, p=ns</p> <p>CGI – Improvement (Marked Improvement) G1: 5 (26) G2: 1 (5)</p>

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<p>Duffy et al., 2014<sup>92</sup> Retrospective Cohort</p> <p>G1: Steroid (2 mg/kg/day), 20/20 G2: Control (non- steroid treated) (NA), 24/24</p> <p>4-14 months/EOT</p> <p>High RoB</p>	<p>Age G1: 3.909 ± 1.248 G2: 4.522 ± 1.800</p> <p>IQ G1: NR G2: NR</p>	<p>EEG NR</p> <p>FMAER NR</p>	<p><b>Mean change score</b> EEG change, n Improved G1: 3 G2: 8</p> <p>No change G1: 10 G2: 12</p> <p>Worse G1: 7 G2: 4 G1 vs G2: p=ns</p> <p>CLSQ mean change in scores Receptive G1: 4.80 G2: 0.167</p> <p>Expressive G1: 4.10 G2: 0.542</p> <p>Change in language scores, n Receptive Better G1: 17 G2: 6</p> <p>No difference G1: 3 G2: 16</p> <p>Worse G1: 0 G2: 2 G1 vs G2: p≤0.0002</p> <p>Expressive Better G1: 17 G2: 10</p> <p>No difference G1: 2 G2: 13</p> <p>Worse</p>

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			<p>G1: 1 G2: 1 G1 vs G2: p≤0.0031</p>
<p>Wasserman et al., 2006<sup>93</sup> RCT</p> <p>G1: Levetiracetam (862.50 ± 279.19 mg/day), 10/9 G2: Placebo (ND), 10/8</p> <p>10 weeks/EOT</p> <p>Low ROB</p>	<p>Age G1: 7.62 ± 1.69 G2: 9.82 ± 3.95</p> <p>IQ-Leiter-R G1: 38 ± 28.7 G2: 60.43 ± 26.4</p> <p>IQ-WISC G1: 91.33 ± 14.6 G2: 29 ± 0</p>	<p>CGI-Autistic Disorder Severity G1: 4.2 ± 0.79 G2: 4.3 ± 1.16</p> <p>CYBOCS-Compulsion G1: 14.3 ± 2.62 G2: 14.8 ± 3.8</p>	<p>G1 vs G2, p=0.013</p> <p><b>Parent</b> ABC-Irritability G1 vs G2, p=ns</p> <p>ABC-Social Withdrawal/Lethargy G1 vs G2, p=ns, z=-1.786, SE=0.133</p> <p>ABC-Stereotypic Behavior G1 vs G2, p=ns, z=-0.042, SE=0.102</p> <p>ABC-Hyperactivity G1 vs G2, p=ns, z=-0.462, SE=0.091</p> <p>ABC-Inappropriate Speech G1 vs G2, p=ns, z=0.099, SE=0.099</p> <p><b>Teacher</b> ABC-Irritability G1 vs G2, p=0.003, z=-2.955, SE=0.109</p> <p>ABC-Social Withdrawal/Lethargy G1 vs G2, p=ns, z=-0.623, SE=0.166</p> <p>ABC-Stereotypic Behavior G1 vs G2, p=ns, z=0.401, SE=0.127</p> <p>ABC-Hyperactivity G1 vs G2, p=ns, z=-0.653, SE=0.094</p> <p>ABC-Inappropriate Speech G1 vs G2, p=ns, z=-</p>

Author, Year Study Design	Mean age, years $\pm$ SD	Outcome measure/Baseline scores, mean $\pm$ SD	Outcome measure/Post- treatment scores, mean $\pm$ SD
Groups (dose), N enrollment / N final	Mean IQ $\pm$ SD		
Treatment duration/Follow-up timepoint post-treatment			
Risk of Bias			
			0.268, SE=0.105
Danfors et al., 2005 <sup>94</sup> RCT  G1: Tetrahydrobiopterin/Placebo (3mg/kg),12 G2: Placebo/ Tetrahydrobiopterin (ND), 12  12 months/EOT  Moderate ROB	Age 4-7  IQ NR	CARS-Total Score G1: 35.4 $\pm$ 2.6 G2: 37.4 $\pm$ 7.1  Social Interaction G1: 9 $\pm$ 0.6 G2: 10.8 $\pm$ 1.6	Points Decreased CARS-Total Score G1: 2.1 $\pm$ 2.1 G2: 2.1 $\pm$ 4.3 G1 vs G2, p=ns  Social Interaction G1: 1.6 $\pm$ 1.1 G2: 0.3 $\pm$ 1.4 G1 vs G2, p=0.04
Dean et al., 2016 <sup>95</sup> RCT  G1: N-acetyl cysteine (500 mg/day), 48/34 G2: Placebo (ND),50 /37  6 months/EOT  Moderate ROB	Age G1: 78.4 $\pm$ 21.7 G2: 74.9 $\pm$ 23.8  IQ G1: 74.3 $\pm$ 15.6 G2: 71.7 $\pm$ 13.8	SRS-Total Score G1: 102.9 $\pm$ 26.4 G2: 99.7 $\pm$ 24.8  CCC-General Communication G1: 33.6 $\pm$ 13.1 G2: 34.7 $\pm$ 14.6  CCC-Social Interaction Deviance G1: 3.1 $\pm$ 8.5 G2: 3.3 $\pm$ 6.7  Repetitive Behavior Scale-Total Score G1: 28.5 $\pm$ 19.4 G2: 24.8 $\pm$ 14.1  CGI-Severity G1: 4.1 $\pm$ 1 G2: 4.2 $\pm$ 1  Developmental Behavior Checklist- Total Score G1: 57 $\pm$ 23.2 G2: 59 $\pm$ 27.6	SRS-Total Score G1: 92.1 $\pm$ 29.3 G2: 88.7 $\pm$ 27.7 G1 vs G2, p=ns  CCC-General Communication G1: 34.7 $\pm$ 11.9 G2: 41.5 $\pm$ 16.5 G1 vs G2, p=ns  CCC-Social Interaction Deviance Change Score G1: 0.05 $\pm$ 8.4 G2: -2.2 $\pm$ 8.2 G1 vs G2, p=ns  Repetitive Behavior Scale-Total Score G1: 24.3 $\pm$ 24.3 G2: 20.8 $\pm$ 16.3 G1 vs G2, p=ns  CGI-Severity G1: 3.9 $\pm$ 1 G2: 3.6 $\pm$ 1 G1 vs G2, p=ns  Developmental Behavior Checklist- Total Score G1: 43.9 $\pm$ 25.2 G2: 48.2 $\pm$ 18 G1 vs G2, p=ns
Nikvarz et al., 2016 <sup>96</sup> RCT	Age G1: 6.83 $\pm$ 2.98	ABC-Irritability G1: 22.4 $\pm$ 11.16	ABC-Irritability G1: 13.5 $\pm$ 10.63

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<p>G1: Memantine (up to 20 mg/day), 16/15 G2: Risperidone (up to 3 mg/day), 18/15</p> <p>8 weeks/EOT</p> <p>Moderate ROB</p>	<p>G2: 6.56 ± 3.51</p> <p>IQ NR</p>	<p>G2: 21.26 ± 6.85</p> <p>ABC-Social Withdrawal/Lethargy G1: 22.13 ± 7.17 G2: 17.53 ± 9.66</p> <p>ABC-Stereotypic Behavior G1: 5.66 ± 5.7 G2: 5.66 ± 5.97</p> <p>ABC-Inappropriate Speech G1: 6.27 ± 4.4 G2: 6 ± 2.97</p> <p>ABC-Hyperactivity G1: 30.4 ± 9.47 G2: 27.53 ± 12.03</p> <p>CARS-Total Score G1: 42.56 ± 6 G2: 40.16 ± 5.52</p> <p>CGI-Severity-Mildly III G1: 1 (6.7) G2: 0 (0)</p> <p>CGI-Severity- Moderately III G1: 1 (6.7) G2: 3 (20)</p> <p>CGI-Severity-Markedly III G1: 8 (53.33) G2: 6 (40)</p> <p>CGI-Severity-Severely III G1: 5 (33.3) G2: 6 (40)</p>	<p>G2: 9.36 ± 6.29 G1 vs G2, p=ns; ES=0.63</p> <p>ABC-Social Withdrawal/Lethargy G1: 14.7 ± 8.4 G2: 10.96 ± 6.9 G1 vs G2, p=ns;ES=0.1</p> <p>ABC-Stereotypic Behavior G1: 4.6 ± 5.06 G2: 3.4 ± 3.86 G1 vs G2, p=ns;ES=0.13</p> <p>ABC-Inappropriate Speech G1: 4.09 ± 3.44 G2: 3.73 ± 3.07 G1 vs G2, p=ns;ES=0.07</p> <p>ABC-Hyperactivity G1: 20.3 ± 10.04 G2: 14.53 ± 8.3 G1 vs G2, p=ns;ES=0.37</p> <p>CARS-Total Score G1: 14.53 ± 8.3 G2: 34.9 ± 5.64 G1 vs G2, p=NS; ES=0.001</p> <p>CGI-Improvement- Very Much Improved G1: 1 (6.7) G2: 4 (26.7)</p> <p>CGI-Improvement- Much Improved G1: 7 (46.7) G2: 7 (46.7)</p> <p>CGI-Improvement- Minimally Improved G1: 3 (20) G2: 3 (20)</p>



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			<p>CGI-Improvement-No Change G1: 4 (26.7) G2: 1 (6.6)</p> <p>CGI change G1 vs G2, p=ns</p>
<p>Aman et al., 2016<sup>97</sup> RCT</p> <p>G1: Mementine (3-15 mg/day), 60/52 G2: Placebo (ND), 61/50</p> <p>12 weeks/OLE 42 weeks</p> <p>Low ROB</p>	<p>Age G1: 9 ± 2.2 G2: 8.9 ± 2.2</p> <p>IQ G1: 77.9 ± 23.1 G2: 75.7 ± 19.4</p>	<p>SRS-Total Raw Score</p> <p>G1: 101.3 ± 25.2 G2: 100.2 ± 21.4</p>	<p><b>12 Weeks</b> SRS-Total Raw Score -7.2 ± 6.6</p> <p><b>42 weeks (OLE)</b> NR</p>
<p>Arnold et al., 2006<sup>98</sup> RCT</p> <p>G1: Atomoxetine/Placebo (1.4 mg/kg), 16 G2: Placebo/Atomoxetine (1.4 mg/kg), 16</p> <p>6 weeks/EOT</p> <p>Moderate ROB</p>	<p>Age 9.26 ± 2.93</p> <p>IQ NR</p>	<p>ABC-Hyperactivity G1: 24.69 ± 13.08 G2: 22.5 ± 12.87</p> <p>ABC-Irritability G1: 16 ± 9.28 G2: 14.18 ± 9.87</p> <p>ABC-Social Withdrawal/Lethargy G1: 8.69 ± 9.24 G2: 6.62 ± 8.36</p> <p>ABC-Stereotypic Behavior G1: 7.37 ± 6.2 G2: 6.19 ± 5.86</p> <p>ABC-Inappropriate Speech G1: 5.75 ± 3.38 G2: 4.68 ± 2.41</p> <p>CGI-Severity G1: 4.69 ± 0.6 G2: 4.69 ± 0.6</p> <p>Repetitive Behavior Scale – Total Score G1: 53.12 ± 22.2 G2: 49.06 ± 21.54</p>	<p>ABC-Hyperactivity G1: 19.31 ± 13.42 G2: 22.37 ± 12.89 G1 vs G2, p=0.04; ES=0.9</p> <p>ABC-Irritability G1: 13.06 ± 9.28 G2: 14.13 ± 9.89 G1 vs G2, p=ns</p> <p>ABC-Social Withdrawal/Lethargy G1: 6.5 ± 8 G2: 7.43 ± 9.64 G1 vs G2, p=0.01; ES=1.18</p> <p>ABC-Stereotypic Behavior G1: 4.69 ± 5.84 G2: 6.63 ± 5.8 G1 vs G2, p=ns</p> <p>ABC-Inappropriate Speech G1: 4.87 ± 2.85 G2: 5.43 ± 3.16 G1 vs G2, p=ns</p> <p>Repetitive Behavior Scale – Total Score</p>

Author, Year Study Design	Mean age, years ± SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post- treatment scores, mean ± SD
Groups (dose), N enrollment / N final	Mean IQ ±SD		
Treatment duration/Follow-up timepoint post-treatment			
Risk of Bias			
			G1: 43.5 ± 23.94 G2: 45 ± 5.99 G1 vs G2, p=ns  CGI-Improvement G1: 9 (56) G2: 4 (25) G1 vs G2, p=NR
<b>Buspirone</b>			
Chugani et al., 2016 <sup>99</sup> RCT  G1: Buspirone (2.5 mg), 54/46 G2: Buspirone (5.0 mg), 55/49 G3: Placebo (ND), 57/47  24 weeks/EOT  RoB	Age - 2 to < 4 years G1: 25 (46.3) G2: 23 (41.8) G3: 25 (43.9)  Age - 4 to < 6 years years G1: 29 (53.7) G2: 32 (58.2) G3: 32 (56.1)  IQ NR	ADOS-Composite Total Score G1: 18.3 ± 0.7 G2: 18.4 ± 0.6 G3: 19.6 ± 0.6  ADOS-Social Affect Score G1: 13.9 ± 0.5 G2: 14.2 ± 0.5 G3: 15 ± 0.5  ADOS-Restricted and Repetitive G1: 4.4 ± 0.3 G2: 4.1 ± 0.3 G3: 4.7 ± 0.3  VABS-Social Skills G1: 68.7 ± 1.5 G2: 71 ± 1.5 G3: 70.4 ± 1.5  VABS-Communication G1: 65.5 ± 2.2 G2: 70.6 ± 2.2 G3: 68.5 ± 2.2  ABC-Language Deviance G1: 4.4 ± 0.5 G2: 3.7 ± 0.5 G3: 3.8 ± 0.5  ABC-Anxiety Composite G1: 0.536 ± 0.1 G2: -0.014 ± 0.1 G3: 58.6 ± 3.8  ABC-Social Deviance	ADOS-Composite Total Score G1: 16.2 ± 0.7 G2: 17.9 ± 0.7 G3: 18.6 ± 0.7  ADOS-Social Affect Score G1: 13.3 ± 0.6 G2: 13.4 ± 0.6 G3: 14.1 ± 0.6  ADOS-Restricted and Repetitive G1: 3.5 ± 0.03 G2: 4.6 ± 0.3 G3: 4.4 ± 0.3  VABS-Social Skills G1: 70.4 ± 1.7 G2: 72.3 ± 1.7 G3: 72.4 ± 1.7  VABS-Communication G1: 68.2 ± 2.3 G2: 72.7 ± 2.2 G3: 69.7 ± 2.2  ABC-Language Deviance G1: 4.4 ± 0.5 G2: 3.7 ± 0.5 G3: 3.8 ± 0.5  ABC-Anxiety Composite G1: 0.118 ± 0.1 G2: -0.12 ± 0.1 G3: -0.242 ± 0.1  ABC-Social Deviance

Author, Year Study Design	Mean age, years ± SD	Outcome measure/Baseline scores, mean ±SD	Outcome measure/Post- treatment scores, mean ± SD
Groups (dose), N enrollment / N final	Mean IQ ±SD		
Treatment duration/Follow-up timepoint post-treatment			
Risk of Bias			
		G1: 15.3 ± 1.2 G2: 11.8 ± 1.2 G3: 14.2 ± 1.2	G1: 12.1 ± 1.1 G2: 10.6 ± 1.1 G3: 11 ± 1.1
		Repetitive Behavior Scale-Total Score G1: 46.9 ± 3.5 G2: 31.5 ± 3.5 G3: 36.7 ± 3.5	Repetitive Behavior Scale-Total Score G1: 38 ± 3.3 G2: 29.9 ± 3.3 G3: 34.2 ± 3.2
		CYBOCS-Total Score G1: 12.1 ± 0.6 G2: 11.5 ± 0.6 G3: 11.9 ± 0.6	CYBOCS-Total Score G1: 11.1 ± 0.6 G2: 10.7 ± 0.6 G3: 11.2 ± 0.6
		Sensory Processing Measure-Total Score G1: 58.6 ± 3.8 G2: 67.2 ± 3.7 G3: 65.4 ± 3.7	Sensory Processing Measure-Total Score G1: 59.6 ± 3.6 G2: 68.1 ± 3.5 G3: 66.7 ± 3.6

ABC-Aberrant Behavior Checklist; CGI-Clinical Global Impression; VABS-Vineland Adaptive Behavior Scale; CYBOCS-Children's Yale-Brown Obsessive Compulsive Scale; EOT-End of Treatment; SRS-Social Responsiveness Scale ; SDB-sleep-disordered breathing ; PLS-Preschool Language Scale ; EOWPVT-Expressive One Word Vocabulary Test ; CSHQ- ; DS-duration of sleep ; TST-Total Sleep Time ; CARS-Childhood Autism Rating Scale ; ADOS-Autism Diagnostic Observation Schedule ; ATEC-Autism Treatment Evaluation Checklist ; CGIS-Clinical Global Impression-Severity ; SOD-sleep onset delay; CGAS- Children's Global Assessment Scale; SOL-sleep onset latency ; WASO-wake after sleep onset ; SE-sleep efficiency; DBC-Developmental Behavior Checklist ; GHQ-General Health Questionnaire ; OSU- ; OACIS- ; OARS- ; RBS- ; EVT- ; EEG-electroencephalogram ; FMAER- frequency modulated auditory evoked response

## Harms

**Table F-7. Harms/adverse effects in studies of risperidone adjuncts**

Harm/Adverse Event	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
<b>Risperidone + piracetam</b>		
Appetite increase <sup>73</sup>	1 (7/20)	35%
Dry mouth <sup>73</sup>	1 (4/20)	20%
EPS/impaired movement <sup>73</sup>	1 (6/20)	30%
Gastrointestinal problems <sup>73</sup>	1 (4/20)	20%
Somnolence <sup>73</sup>	1 (23/20)	%
<b>Risperidone + amantadine</b>		
Appetite increase <sup>68</sup>	1(6/20)	30%
<b>Risperidone + buspirone</b>		
Appetite Increase <sup>61</sup>	1 (10/16)	61.1%
Somnolence <sup>61</sup>	1 (3/16)	18.75%
<b>Risperidone + celecoxib</b>		
Appetite Increase <sup>64</sup>	1 (3/20)	15%
Dizziness <sup>64</sup>	1 (2/20)	10%
GI <sup>64</sup>	1 (5/20)	25%

Harm/Adverse Event	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Insomnia <sup>64</sup>	1 (2/20)	10%
Somnolence <sup>64</sup>	1 (3/20)	15%
EPS/impaired movement <sup>64</sup>	1 (10/20)	50%
<b>Risperidone + Galantamine</b>		
Agitation/nervousness/restlessness <sup>67</sup>	1 (4/20)	20%
Appetite Increase <sup>67</sup>	1 (8/20)	40%
Somnolence <sup>67</sup>	1 (2/20)	10%
<b>Risperidone + Ginkgo biloba</b>		
Agitation/nervousness/restlessness <sup>69</sup>	1 (8/23)	
Appetite decrease <sup>69</sup>	1 (3/23)	13%
Appetite Increase <sup>69</sup>	1 (6/23)	26.1%
EPS/impaired movement <sup>69</sup>	1 (5/23)	21.7%
GI symptoms <sup>69</sup>	1 (8/23)	34.8%
Somnolence <sup>69</sup>	1 (13/23)	56.5%
<b>Risperidone + memantine</b>		
Appetite increase <sup>65</sup>	1 (2/20)	10%
Dizziness <sup>65</sup>	1 (3/20)	15%
GI <sup>65</sup>	1 (5/20)	25%
Skin Changes <sup>65</sup>	1 (2/20)	10%
Somnolence <sup>65</sup>	1 (4/20)	20%
EPS/impaired movement <sup>65</sup>	1 (6/20)	30%
<b>Risperidone + N-acetylcysteine</b>		
Agitation/nervousness/restlessness <sup>63</sup>	1 (6/17)	35.3%
Appetite decrease <sup>63</sup>	1 (3/17)	17.6%
Appetite Increase <sup>63</sup>	1 (5/17)	29.4%
Dry mouth <sup>62</sup>	1 (2/20)	10%
EPS/impaired movement <sup>63</sup>	1 (7/20)	35%
Gastrointestinal problems <sup>62, 63</sup>	2 (23/37)	5.9%-30%
Headache <sup>62</sup>	1 (4/20)	20%
Somnolence <sup>63</sup>	1 (9/20)	45%
<b>Risperidone + Pentoxifylline</b>		
Agitation/nervousness/restlessness <sup>70</sup>	1 (2/20)	10%
Appetite increase <sup>70</sup>	1 (8/20)	40%
Dry mouth <sup>70</sup>	1 (2/20)	10%
Gastrointestinal problems <sup>70</sup>	1 (6/20)	30%
Somnolence <sup>70</sup>	1 (9/20)	45%
Weight gain <sup>70</sup>	1 (8/20)	40%
EPS/impaired movement <sup>70</sup>	1 (7/20)	25%
<b>Risperidone + Pioglitazone</b>		
Dizziness <sup>60</sup>	1 (2/20)	20%
Gastrointestinal problems <sup>60</sup>	1 (10/20)	50%
Headache <sup>60</sup>	1 (3/20)	15%
<b>Risperidone + Minocycline</b>		
Gastrointestinal problems <sup>71</sup>	1 (5/23)	8.6%-13%
Appetite increase <sup>71</sup>	1 (2/23)	8.6%
Dizziness <sup>71</sup>	1 (2/23)	8.6%
Headache <sup>71</sup>	1 (1/23)	4.3%
Insomnia <sup>71</sup>	1 (2/23)	8.6%
Sedation <sup>71</sup>	1 (3/23)	13%
<b>Risperidone + placebo</b>		
Agitation/nervousness/restlessness <sup>63, 66-70, 73</sup>	7 (18/138)	4.2%-20.8%
Appetite decrease <sup>61, 63-65, 67-70, 72, 73</sup>	10 (19/196)	5%-20%
Appetite increase <sup>61, 63-71, 73</sup>	11 (45/219)	8.6%-41.7%
Dizziness <sup>60, 64, 65, 69, 71, 72</sup>	6 (16/127)	5%-20%
Drooling/increased saliva <sup>66, 68, 69</sup>	3 (10/64)	5%-30%

Harm/Adverse Event	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Dry mouth <sup>60-62, 69, 70, 73</sup>	6 (11/122)	4.2%-15%
EPS/impaired movement <sup>64-66, 69, 70, 72, 73</sup>	7 (45/144)	4.2%-45%
Gastrointestinal problems <sup>60, 62-73</sup>	13 (58/241)	4.3%-30%
Headache <sup>60, 62, 71</sup>	3 (6/63)	4.3%-15%
Infection/fever/cold/congestion symptoms <sup>69</sup>	1 (5/24)	20.8%
Insomnia <sup>64, 65, 71, 72</sup>	4 (10/83)	5%-25%
Paresthesia <sup>72</sup>	1 (5/20)	25%
Sedation <sup>71</sup>	1 (4/23)	17.4%
Skin Changes <sup>63, 65</sup>	2 (2/34)	5%-7.1%
Somnolence <sup>63-67, 69, 70, 72, 73</sup>	9 (59/178)	5%-45%
Weight Gain <sup>70</sup>	1 (7/20)	35%
<b>Risperidone + Riluzole</b>		
Agitation/nervousness/restlessness <sup>66</sup>	1 (7/20)	35%
Appetite decrease <sup>66</sup>	1 (2/20)	10%
Appetite Increase <sup>66</sup>	1 (12/20)	60%
Drooling/Increased Saliva <sup>66</sup>	1 (6/20)	60%
EPS/Impaired movement <sup>66</sup>	1 (4/20)	10%
Gastrointestinal problems <sup>66</sup>	1 (10/20)	50%
Somnolence <sup>66</sup>	1 (10/20)	50%
<b>Risperidone + Topiramate</b>		
Appetite decrease <sup>72</sup>	1 (7/20)	35%
Dizziness <sup>72</sup>	1 (4/20)	20%
Gastrointestinal problems <sup>72</sup>	1 (6/20)	30%
Insomnia <sup>72</sup>	1 (5/20)	25%
Paresthesia <sup>72</sup>	1 (5/20)	25%
Somnolence <sup>72</sup>	1 (8/20)	40%
EPS/impaired movement <sup>72</sup>	1 (9/20)	45%

\*Harms reported by more than one participant. EPS=extrapyramidal symptoms; GI=gastrointestinal

**Table F-8. Harms/adverse effects in studies of citalopram**

Harm/Adverse Event	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
<b>Citalopram hydrobromide</b>		
Agitation/Nervousness/Restlessness <sup>100, 101</sup>	1 (13/73)	17.8%
Anxiety <sup>100, 101</sup>	1 (8/73)	11%
Appetite increase <sup>100, 101</sup>	1 (7/73)	9.6%
Appetite decrease <sup>100, 101</sup>	1 (11/73)	15.1%
Attention <sup>100, 101</sup>	1 (9/73)	12.3%
Challenging behavior <sup>100, 101</sup>	1 (64/73)	87.7%
Energy level changes <sup>100, 101</sup>	1 (28/73)	38.4%
GI symptoms <sup>100, 101</sup>	1 (46/73)	63%
Headache <sup>100, 101</sup>	1 (15/73)	20.5%
Hyperactivity <sup>100, 101</sup>	1 (9/73)	12.3%
Infection/Fever/Cold/Congestion symptoms <sup>100, 101</sup>	1 (56/73)	76.7%
Insomnia <sup>100, 101</sup>	1 (28/73)	38.4%
Nightmares <sup>100, 101</sup>	1 (5/73)	6.8%
Repetitive behavior or language <sup>100, 101</sup>	1 (8/73)	11%
Seizure <sup>100, 101</sup>	1 (2/73)	2.7%
Silliness <sup>100, 101</sup>	1 (9/73)	12.3%
Skin changes <sup>100, 101</sup>	1 (21/73)	28.8%
<b>Placebo</b>		
Agitation/Nervousness/Restlessness <sup>100, 101</sup>	1 (7/76)	9.2%

Harm/Adverse Event	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Anxiety <sup>100, 101</sup>	1 (9/76)	11.8%
Appetite increase <sup>100, 101</sup>	1 (8/76)	10.5%
Appetite decrease <sup>100, 101</sup>	1 (10/76)	13.2%
Attention <sup>100, 101</sup>	1 (2/76)	2.6%
Challenging behavior <sup>100, 101</sup>	1 (44/76)	57.9%
Energy level changes <sup>100, 101</sup>	1 (15/76)	19.7%
GI <sup>100, 101</sup>	1 (24/76)	31.5%
Headache <sup>100, 101</sup>	1 (10/76)	13.2%
Hyperactivity <sup>100, 101</sup>	1 (2/76)	2.6%
Infection/Fever/Cold/Congestion symptoms <sup>100, 101</sup>	1 (42/76)	55.3%
Insomnia <sup>100, 101</sup>	1 (17/76)	22.4%
Silliness <sup>100, 101</sup>	1 (10/76)	13.2%
Skin changes <sup>100, 101</sup>	1 (9/76)	11.8%
Somnolence <sup>100, 101</sup>	1 (10/76)	13.2%

\*Harms reported by more than one participant. GI=gastrointestinal; EPS-extrapyramidal

**Table F-9. Harms/adverse effects in studies of diet and nutritional supplements**

Harm/Adverse Event*	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
<b>Omega 3 fatty acids</b>		
Appetite decrease <sup>39</sup>	1 (7/18)	38.9%
Bruising <sup>39</sup>	1 (4/18)	22.2%
Challenging behaviors <sup>39</sup>	1 (11/18)	61.1%
Epistaxis <sup>41, 45</sup>	2 (2/43)	3.4%-7.1%
Eye/Vision changes <sup>39</sup>	1 (3/18)	16.7%
GI symptoms <sup>39, 41, 45</sup>	3 (28/61)	3.4%-50%
Hyperactivity <sup>39</sup>	1 (3/18)	16.7%
Infection/Fever/Cold/Congestion symptoms <sup>39, 41, 45</sup>	3 (39/61)	3.4%-22.2%
Insomnia <sup>39</sup>	1 (13/18)	72.2%
Lethargy <sup>39</sup>	1 (4/18)	22.2%
Right leg internal rotation <sup>39</sup>	1 (2/18)	11.1%
Self-stimulation <sup>41</sup>	1 (2/29)	6.9%
Skin changes <sup>39, 41, 45</sup>	3 (17/61)	3.4%-55.6%
<b>DHA</b>		
Agitation/Nervousness/Restlessness <sup>42</sup>	1 (2/24)	8.3%
<b>Gluten-Dairy Free Diet</b>		
GI symptoms <sup>51</sup>	1 (3/6)	50%
<b>Gluten-Dairy Containing Diet</b>		
GI <sup>51</sup>	1 (3/6)	50%
<b>Gluten-free, Casein-free Diet</b>		
GI <sup>59</sup>	1 (4/8)	12.5%-25%
Appetite decrease <sup>59</sup>	1 (3/8)	37.5%
<b>Healthy, Low sugar Diet</b>		
GI <sup>59</sup>	1 (2/14)	7.1%
Night wakings <sup>59</sup>	1 (3/14)	7.1%
<b>Methyl B12</b>		
Epistaxis <sup>49</sup>	1 (2/27)	7%
GI <sup>49</sup>	1 (1/27)	4%
Hyperactivity <sup>49</sup>	1 (2/27)	7%
Inattention <sup>49</sup>	1 (1/27)	4%
Increased irritability <sup>49</sup>	1 (1/27)	4%

Harm/Adverse Event*	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Infection/fever/cold/congestion symptoms <sup>49</sup>	1 (6/27)	4%-11%
Insomnia <sup>49</sup>	1 (1/27)	4%
Mouthing <sup>49</sup>	1 (5/27)	19%
Musculoskeletal disorder <sup>49</sup>	1 (1/27)	4%
Skin changes <sup>49</sup>	1 (1/27)	4%
<b>Peptizyde</b>		
Challenging behavior <sup>48</sup>	1 (5/21)	23.8%
<b>Placebo</b>		
Agitation/nervousness/restlessness <sup>93, 94</sup>	2 (4/16)	10%-50%
Appetite decrease <sup>39</sup>	1 (3/19)	15.8%
Bruising <sup>39</sup>	1 (2/19)	10.5%
Challenging behavior <sup>39, 48, 49</sup>	3 (12/64)	4%-21.1%
Epistaxis <sup>39</sup>	1 (3/19)	15.8%
Eye/Vision changes <sup>39, 41</sup>	2 (2/47)	3.6%-5.3%
GI symptoms <sup>39, 49, 95</sup>	2 (27/48)	4%-47.4%
Hyperactivity <sup>45, 49</sup>	2 (10/36)	23.1%-30%
Inattention <sup>49</sup>	1 (1/23)	4%
Infection/Fever/Cold/Congestion symptoms <sup>a 39, 41, 49, 95</sup>	3 (28/76)	3.6%-26.3%
Insomnia <sup>39, 49</sup>	2 (10/51)	5.6%-36.8%
Lethargy <sup>39</sup>	1 (2/19)	10.5%
Mouthing <sup>49</sup>	1 (1/23)	4%
Skin changes <sup>39, 49, 95</sup>	2 (21/48)	4%-47.4%
Urinary changes <sup>39, 93</sup>	3 (5/52)	9%-10.5%

\*Harms reported by more than one participant

<sup>a</sup>One study<sup>39</sup> did not clearly report number of patients in each group that reported upper respiratory infections. This harm was not included in the "Infection/fever/cold/congestive symptoms" count in this table.

GI=gastrointestinal; EPS=extrapyramidal

**Table F-10. Harms/adverse effects in studies of other medical interventions**

Harm/Adverse Event	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
<b>Active tDCS stimulation</b>		
Skin changes <sup>83, 84</sup>	1 (3/10)	30%
<b>Amantadine</b>		
Challenging behavior <sup>91</sup>	1 (2/19)	10%
Insomnia <sup>91</sup>	1 (4/19)	21%
Somnolence <sup>91</sup>	1 (2/19)	10%
<b>Bumetanide</b>		
Hyperactivity <sup>77</sup>	1 (2/27)	7.4%
<b>Buspirone (2.5 mg twice/day)</b>		
Abnormal behavior <sup>99</sup>	1 (5/46)	9%
Affective disorder <sup>99</sup>	1 (8/46)	15%
Agitation/nervousness/restlessness <sup>99</sup>	1 (7/46)	13%
Anxiety <sup>99</sup>	1 (6/46)	11%
Appetite decrease <sup>99</sup>	1 (17/46)	31%
Appetite increase <sup>99</sup>	1 (11/46)	20%
Challenging behavior <sup>99</sup>	1 (33/46)	71.7%
Ear and labyrinth disorders <sup>99</sup>	1 (7/46)	13%
Epistaxis <sup>99</sup>	1 (4/46)	7%
Eye disorders <sup>99</sup>	1 (7/46)	13%
Vomiting <sup>99</sup>	1 (20/46)	37%
Diarrhea <sup>99</sup>	1 (18/46)	33%
Constipation <sup>99</sup>	1 (5/46)	9%
Hyperactivity <sup>99</sup>	1 (15/46)	28%
Immune system disorders <sup>99</sup>	1 (5/46)	9%
Cough <sup>99</sup>	1 (25/46)	46%
Congestion <sup>99</sup>	1 (21/46)	45.6%
Rhinorrhea <sup>99</sup>	1 (15/46)	28%
Pyrexia <sup>99</sup>	1 (31/46)	57%
Ear Infection <sup>99</sup>	1 (11/46)	20%
Upper respiratory tract infection <sup>99</sup>	1 (6/46)	11%
Nasopharyngitis <sup>99</sup>	1 (6/46)	11%
Insomnia <sup>99</sup>	1 (14/46)	30%
Musculoskeletal disorders <sup>99</sup>	1 (5/46)	9%
Skin changes <sup>99</sup>	1 (8/46)	15%
Sleep changes <sup>99</sup>	1 (14/46)	26%
Somnolence <sup>99</sup>	1 (7/46)	13%
Urinary changes <sup>99</sup>	1 (6/46)	11%
<b>Buspirone (5 mg twice/day)</b>		
Abnormal behavior <sup>99</sup>	1 (1/49)	16%
Affective disorder <sup>99</sup>	1 (7/49)	13%
Agitation/nervousness/restlessness <sup>99</sup>	1 (7/49)	13%
Anxiety <sup>99</sup>	1 (3/49)	5%
Appetite decrease <sup>99</sup>	1 (11/49)	20%
Appetite increase <sup>99</sup>	1 (16/49)	29%
Challenging behavior <sup>99</sup>	1 (29/49)	59%
Ear and labyrinth disorders <sup>99</sup>	1 (3/49)	5%
Epistaxis <sup>99</sup>	1 (3/49)	5%
Eye disorders <sup>99</sup>	1 (5/49)	9%
Vomiting <sup>99</sup>	1 (23/49)	42%
Diarrhea <sup>99</sup>	1 (22/49)	40%
Constipation <sup>99</sup>	1 (15/49)	27%
Hyperactivity <sup>99</sup>	1 (12/49)	22%
Immune system disorders <sup>99</sup>	1 (3/49)	5%
Cough <sup>99</sup>	1 (23/49)	42%
Congestion <sup>99</sup>	1 (24/49)	48.9%



Harm/Adverse Event	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
Rhinorrhea <sup>99</sup>	1 (17/49)	31%
Pyrexia <sup>99</sup>	1 (24/49)	44%
Ear Infection <sup>99</sup>	1 (6/49)	11%
Upper respiratory tract infection <sup>99</sup>	1 (3/49)	5%
Nasopharyngitis <sup>99</sup>	1 (4/49)	7%
Insomnia <sup>99</sup>	1 (23/49)	46.9
Musculoskeletal disorders <sup>99</sup>	1 (2/49)	4%
Skin changes <sup>99</sup>	1 (8/49)	15%
Sleep changes <sup>99</sup>	1 (19/49)	35%
Somnolence <sup>99</sup>	1 (6/49)	11%
Urinary changes <sup>99</sup>	1 (7/49)	13%
<b>Divalproex sodium</b>		
Agitation/nervousness/restlessness <sup>75</sup>	1 (2/16)	12.5%
Infection/fever/cold/congestion symptoms <sup>75</sup>	1 (2/16)	12.5%
Insomnia <sup>75</sup>	1 (2/16)	12.5%
Skin changes <sup>75</sup>	1 (2/16)	12.5%
Urinary changes <sup>75</sup>	1 (2/16)	12.5%
<b>Donepezil hydrochloride</b>		
Challenging behavior <sup>90</sup>	1 (5/17)	29.4
<b>Levetiracetam</b>		
Challenging behavior <sup>93</sup>	1 (3/10)	10%-20%
<b>Mecamylamine</b>		
Appetite decrease <sup>88</sup>	1 (4/12)	33.3%
EPS/impaired movement <sup>88</sup>	1 (2/12)	16.7%
GI symptoms <sup>88</sup>	1 (9/12)	75%
Infection/fever/cold/congestion symptoms <sup>88</sup>	1 (9/12)	75%
Mental symptoms <sup>88</sup>	1 (6/12)	50%
Somnolence <sup>88</sup>	1 (5/12)	41.7%
<b>Melatonin</b>		
Appetite decrease <sup>82</sup>	1 (2/6)	35.3%
GI symptoms <sup>82</sup>	1 (4/6)	70.6%
Somnolence <sup>82</sup>	1 (4/6)	70.6%
<b>Memantine</b>		
Affective disorder <sup>97</sup>	1 (2/60)	3.3%
Agitation/nervousness/restlessness <sup>97</sup>	1 (4/60)	6.7%
Challenging behavior <sup>97</sup>	1 (10/60)	8.3%
Enuresis <sup>97</sup>	1 (2/60)	3.3%
GI symptoms <sup>97</sup>	1 (11/60)	1.7%-6.7%
Headache <sup>97</sup>	1 (3/60)	5%
Infection/fever/cold/congestion symptoms <sup>97</sup>	1 (30/60)	1.7%-10%
Insomnia <sup>97</sup>	1 (5/60)	1.7%-6.7%
Self-injurious behavior <sup>97</sup>	1 (2/60)	3.3%
<b>N-acetylcysteine</b>		
Agitation/nervousness/restlessness <sup>89</sup>	1 (3/14)	21.4%
Appetite decrease <sup>89</sup>	1 (2/14)	14.3%
Appetite increase <sup>89</sup>	1 (2/14)	14.3%
Asthma <sup>95</sup>	1 (1/34)	2.9%
Cysts – Unspecified <sup>95</sup>	1 (1/34)	2.9%
EPS/impaired movement <sup>89</sup>	1 (3/14)	21.4%
GI symptoms <sup>89, 95</sup>	2 (23/48)	26.5%100%
Infection/fever/cold/congestion symptoms <sup>89, 95</sup>	2 (20/48)	2.9%-28.6%
Skin changes <sup>95</sup>	1 (2/34)	5.9%

Harm/Adverse Event	N Studies Reporting Harm (# Participants With Harm/Total Participants)	Reported Rates Across Studies
<b>Tetrahydrobiopterin</b>		
Challenging behavior <sup>86</sup>	1 (4/20)	22%
Hyperactivity <sup>86</sup>	1 (2/20)	9%
Insomnia <sup>86</sup>	1 (2/20)	9%
Skin changes <sup>86</sup>	1 (2/20)	9%
Agitation/nervousness/restlessness <sup>94</sup>	1 (3/5)	60%
Sleeping problems <sup>94</sup>	1 (4/5)	80%
<b>Steroid</b>		
Challenging behavior <sup>92</sup>	1 (10/20)	50%
Cushingoid appearance <sup>92</sup>	1 (18/20)	90%
Hypertension <sup>92</sup>	1 (2/20)	10%
Regression <sup>92</sup>	1 (2/20)	10%
Sleep changes <sup>92</sup>	1 (2/20)	10%
Weight gain <sup>92</sup>	1 (19/20)	95%
<b>Hyperbaric oxygen</b>		
Barotrauma <sup>78</sup>	1 (11/29)	37.9%
<b>Placebo</b>		
Abnormal behavior <sup>97, 99</sup>	2 (11/107)	3.3%-16%
Affective disorder <sup>99</sup>	1 (4/47)	7%
Agitation/nervousness/restlessness <sup>75, 89, 93, 94, 97, 99</sup>	6 (56/117)	1.6%-18%
Anxiety <sup>97, 99</sup>	2 (5/107)	2%-6.6%
Appetite decrease <sup>82, 88, 89, 99</sup>	3 (26/80)	20%-62.5%
Appetite increase <sup>99</sup>	1 (11/47)	19%
Barotrauma <sup>78</sup>	1 (3/29)	10.3%
Challenging behavior <sup>86, 91, 93, 97, 102</sup>	5 (51/148)	4.9%-39%
Epistaxis <sup>97, 99</sup>	2 (9/107)	3.3%-12%
EPS/impaired movement <sup>88, 89</sup>	2 (5/23)	6.7%-25%
GI symptoms <sup>80, 82, 86, 88, 89, 92, 97</sup>	7 (45/141)	1.6%-87.5%
Vomiting <sup>99</sup>	1 (22/47)	39%
Diarrhea <sup>99</sup>	1 (20/47)	35%
Constipation <sup>99</sup>	1 (10/47)	18%
Headache <sup>97</sup>	1 (3/60)	4.9%
Hyperactivity <sup>86, 99</sup>	2 (19/69)	4%-32%
Infection/fever/cold/congestion symptoms <sup>75, 88, 89, 97</sup>	4 (50/94)	1.6%-75%
Insomnia <sup>86, 93</sup>	2 (5/32)	10%-17%
Cough <sup>99</sup>	1 (28/47)	49%
Congestion <sup>99</sup>	1 (27/47)	57.4%
Rhinorrhea <sup>99</sup>	1 (15/47)	26%
Pyrexia <sup>99</sup>	1 (29/47)	51%
Ear Infection <sup>99</sup>	1 (8/47)	14%
Upper respiratory tract infection <sup>99</sup>	1 (12/47)	21%
Nasopharyngitis <sup>99</sup>	1 (6/47)	11%
Insomnia <sup>75, 88, 89, 97, 99</sup>	5 (36/159)	1.8%-34%
Mental symptoms <sup>88</sup>	1 (4/8)	50%
Musculoskeletal disorders <sup>99</sup>	1 (5/47)	9%
Psychomotor hyperactivity <sup>97</sup>	1 (4/60)	6.6%
Repetitive behavior or language <sup>86</sup>	1 (2/22)	9%
Seizure <sup>79, 86</sup>	2 (2/37)	4.5%-6.7%
Skin changes <sup>77, 80, 99</sup>	3 (11/100)	3.7%-12%
Sleep changes <sup>94, 99</sup>	2(18/53)	23%-83%
Somnolence <sup>75, 82, 88, 99</sup>	4 (50/76)	25%-81.3%
Urinary changes <sup>93, 99</sup>	2 (8/57)	10%-12%

\*Harms reported by more than one participant. GI=gastrointestinal; EPS=extrapyramidal

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