Comparative Effectiveness Review
Number 186

Interventions Targeting Sensory Challenges in Children With Autism Spectrum Disorder—An Update

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Comparative Effectiveness Review

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This report is based on research conducted by the Vanderbilt Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-2015-00003-I). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

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

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

This report may periodically be assessed for the currency of conclusions. If an assessment is done, the resulting surveillance report describing the methodology and findings will be found on the Effective Health Care Program Web site at www.effectivehealthcare.ahrq.gov. Search on the title of the 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.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews can help clarify whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about AHRQ EPC systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

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If you have comments on this systematic review, they may be sent by mail to the Task Order Officers named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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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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Technical Expert Panel

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.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

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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.

Peer Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential nonfinancial conflicts may be retained. The TOO

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Interventions Targeting Sensory Challenges in Children With Autism Spectrum Disorder—An Update

Structured Abstract

Objectives. To evaluate the effectiveness and safety of interventions targeting sensory challenges in children with autism spectrum disorder (ASD).

Data sources. We searched MEDLINE®, Embase®, the Cumulative Index of Nursing and Allied Health Literature®, and PsycINFO® from January 2010 to September 2016.

Review methods. We included studies comparing interventions incorporating sensory-focused modalities with alternative treatments or no treatment. Studies had to include at least 10 children with ASD ages 2–12 years. Two investigators independently screened studies and rated risk of bias. We extracted and summarized data qualitatively because of the significant heterogeneity. We also assessed strength of the evidence (SOE).

Results. We identified 24 unique comparative studies (17 newly published studies and 7 studies addressed in our 2011 review of therapies for children with ASD). Studies included 20 randomized controlled trials (RCTs), 1 nonrandomized trial, and 3 retrospective cohort studies (3 low, 10 moderate, and 11 high risk of bias [ROB]). Populations, intervention approaches, and outcomes assessed varied across studies. Relative to usual care or other interventions, sensory integration–based approaches improved measures related to sensory and motor skills in the short term (3 RCTs with high, moderate, and low ROB and 1 high ROB retrospective cohort study). Environmental enrichment improved nonverbal cognitive skills in treated children compared with standard care in two small RCTs (low and moderate ROB). Four small RCTs (2 moderate and 2 high ROB) of auditory integration–based approaches reported mixed results. Studies of music therapy (4 RCTs—1 low, 2 moderate, and 1 high ROB—and 1 high ROB nonrandomized trial) used different protocols and addressed different outcomes, precluding synthesis. Massage improved ASD symptom severity and sensory challenges versus a waitlist control condition (7 studies, 5 with likely overlapping participants, 3 moderate and 4 high ROB). Additional RCTs (moderate and high ROB) of interventions with sensory-related components (tactile stimulation exercises, weighted blankets) reported few significant differences between treatment groups.

Conclusions. Some interventions targeting sensory challenges may produce modest short-term (<6 months) improvements, primarily in sensory-related outcomes and outcomes related to ASD symptom severity; however, the evidence base for any category of intervention is small, and durability of effects beyond the immediate intervention period is unclear. Sensory integration–based approaches improved outcomes related to sensory challenges (low SOE) and motor skills (low SOE), and massage improved sensory responses (low SOE) and ASD symptoms (low SOE). Environmental enrichment improved nonverbal cognitive skills (low SOE). Auditory integration–based approaches did not improve language outcomes (low SOE). Some positive effects were associated with other approaches studied (music therapy, weighted blankets), but findings in these small studies were not consistent (insufficient SOE). Data on longer term results are lacking, as are data on characteristics that modify outcomes, effectiveness of interventions across environments or contexts, and components of interventions that may drive

effects. In sum, while some therapies may hold promise and warrant further study, substantial needs exist for continuing improvements in methodologic rigor in the field.

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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.[1] 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 a core symptom, many children with ASD may also have significant cognitive impairment.

Children with ASD may experience impairments in processing sensory stimuli, including intense interests in or aversion to certain types of sensory input; while somewhat challenging to operationalize, quantify, and measure clinically, estimates of impairments related to sensory processing have ranged from 42 percent to 88 percent of people with ASD and include both hyper- and hypo-responsiveness.[2-4] Though sensory challenges are common and impairing features of ASD for many individuals, the exact nature of sensory integration in the development and lifespan trajectory is less understood. The field has historically lacked accepted frameworks for diagnosing sensory challenges (e.g., not part of DSM diagnostic criteria until DSM-5) and developing responsive interventions.[2, 3, 5, 6]

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[7-10] 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.[11] Treatment frequently is complicated by symptoms or comorbidities that may warrant targeted intervention. There is no cure for ASD and no global consensus on which intervention is most effective.[12, 13] 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.

Interventions Targeting Sensory Challenges

Increasingly, as reflected in their inclusion in the new DSM-5 diagnostic criteria, the sensory challenges associated with ASD have also become a target for specialized assessment and treatment. Sensory symptoms can involve both strong interests as well as strong aversions, with

interventions commonly targeting aversions/challenges, meeting needs for sensory input within adaptive frameworks, or perceived processing deficits with the goal of improving people's abilities to interact with their environments. For example, a child with ASD may have difficulty tolerating bright lights, clothing or food textures, specific noises (such as a baby crying), tasks of daily living (such as brushing hair or teeth), touch, or more idiosyncratic stimuli such as certain colors. These sensitivities can significantly interfere with children's ability to care for themselves, leave the home, participate in school or other interventions, and be involved in social situations. Children may also display a hyperfocus on play or activities that involves a sensory component, sometimes referred to as "sensory-seeking" or "stimming" behaviors.

Sensory-focused interventions take a variety of forms and can be implemented by a variety of licensed professionals (such as occupational therapists), teachers, parents, and other providers. Such interventions are not consistently defined but typically involve the incorporation of sensory experiences (e.g., weighted clothing or materials, interventions that provide auditory sensations) to affect a variety of outcomes including adaptive behavior and language.

Scope and Key Questions

Scope of Review

This review updates findings reported in the 2011 Agency for Healthcare Research and Quality (AHRQ) review Therapies for Children with ASD[14] with a focus on studies of interventions targeting sensory challenges. We defined interventions targeting sensory challenges in line with the DSM-5 definition and definitions used in other reviews of sensory-focused interventions.[2, 3] DSM-5 classifies sensory challenges as a manifestation of the core symptom of restricted and repetitive patterns of behavior, interests, or activities. The DSM describes sensory challenges as "hyper- or hyporeactivity to sensory input, manifested through extreme responses to specific sounds or textures, excessive smelling or touching of objects, fascination with lights or spinning objects, and sometimes apparent indifference to pain, heat, or cold."[1] Interventions targeting sensory challenges are typically described as designed to provide controlled sensory experiences in order to encourage the modulation and integration of information from the environment, thus promoting adaptive responses to sensory inputs.

Though the field lacks broad consensus on a definition of sensory-focused approaches, interventions typically use sensory modalities to target behaviors that may be associated with sensory-related impairments.[3, 15] We do not include studies of other approaches (e.g., educational interventions) that may address a sensory-related outcome in the current review. A companion review updating findings related to medical interventions 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 interventions targeting sensory challenges?

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 (≥6 months) on core symptoms (e.g., social deficits, communication deficits, and repetitive behaviors)?
d. What are the longer term effects (≥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 interventions targeting sensory challenges?

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 interventions targeting sensory challenges?

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

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

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

Categorization of Interventions

Interventions targeting sensory challenges may be broadly categorized by their core focus (e.g., environmental modification/adaptation, compensatory strategies, sensory processing, auditory integration). However, frequently these categories of sensory-related approaches include overlapping targets and intervention strategies, as well as unique and differing aspects of the same constructs. As such it is extremely challenging to identify definitively the category into which many offered interventions should be placed. With input from our clinical experts, we categorized approaches based on the core strategies used in each intervention. In some cases this approach grouped together interventions that may have used specific, manualized techniques with others that used only a subset of those techniques (e.g., Ayres-based sensory integration and sensory integration models that may have used some Ayres strategies). We note that no alternative approaches (e.g., considering Ayres-based approaches and other sensory integration approaches as separate categories) would have substantially changed our overall findings in terms of strength of evidence.

Based on the literature meeting criteria for this review, we categorized interventions as:

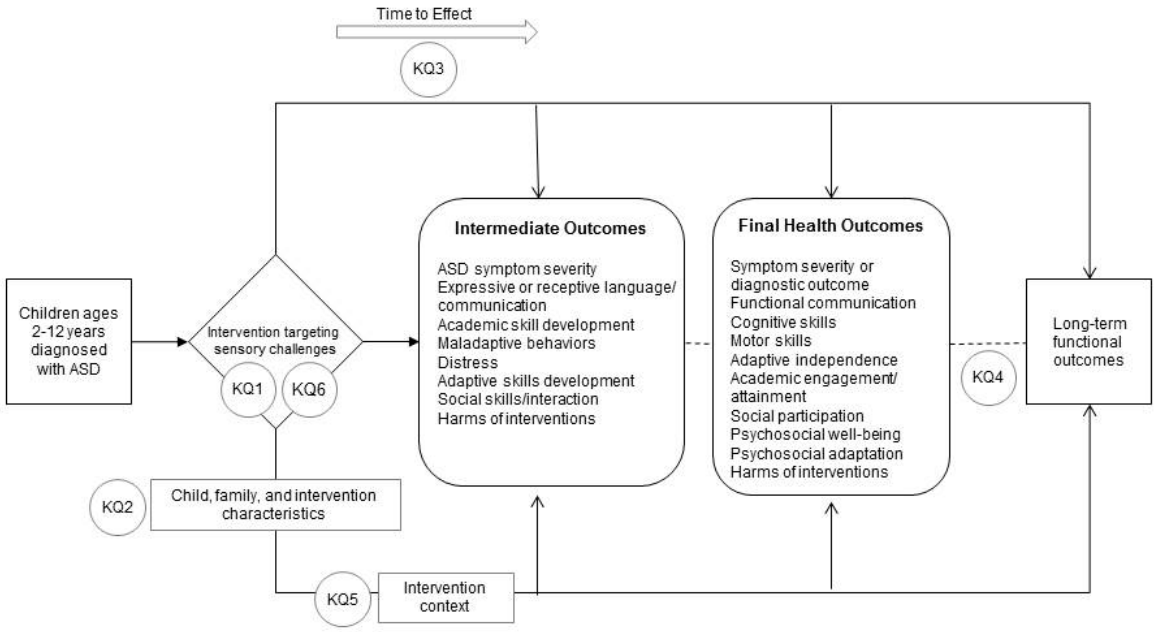
- Sensory integration-based (interventions using combinations of sensory and kinetic components such as materials with different textures, touch/massage, swinging and trampoline exercises, and balance and muscle resistance exercises to ameliorate sensory challenges)
- Environmental enrichment-based (interventions incorporating targeted exposure to sensory stimuli to promote tolerance of stimuli in other contexts)
- Auditory integration-based (interventions incorporating auditory components such as filtered sound to ameliorate sensory processing challenges via theorized re-training of aural pathways)
- Music therapy-based (interventions incorporating playing or singing music, or movement to music, to improve challenging behaviors and sensory difficulties)
- Touch/Massage-based (interventions incorporating touch-based approaches by a therapist or caregiver)
- Other (included interventions [tactile-based tasks, weighted blankets] not cleanly fitting into one of the broader categories).

We recognize that other approaches to categorizing interventions targeting sensory challenges could be used.

Analytic Framework

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

Figure 1. Analytic framework for review



ASD=autism spectrum disorder; KQ=Key Question

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 interventions targeting sensory challenges, and it provides an assessment of the risk of bias of studies that aim to determine outcomes of sensory-related 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 related to interventions targeting sensory challenges in ASD and of areas for future research.

Methods

In this chapter, we briefly outline the procedures that we used to produce a Comparative Effectiveness Review (CER) update addressing interventions targeting sensory challenges for children with autism spectrum disorder (ASD). Appendix A includes a more detailed discussion of our methods. 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*.[16]

Topic Surveillance and Review Protocol

The topic for the original report[14] 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.[17] 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 approaches to address sensory challenges and medical approaches (reported in a separate update). These areas reflect both areas of clinical relevance and sufficient newly published literature for a review update. Given the different major emphases of these interventions (i.e., sensory processing/integration abilities and challenging behaviors) and subsequent differences in study populations, we report findings in two separate reviews.

Based also on the surveillance process and discussions with stakeholders, we revised the KQ addressed in the 2011 report 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 therapies for children with ASD, we used four key databases: the MEDLINE® medical literature database via the PubMed® interface; EMBASE (Excerpta Medica Database), an international biomedical and pharmacological literature database via the Ovid® interface; the Cumulative Index of Nursing and Allied Health Literature (CINAHL), and PsycINFO®. Search strategies for KQs applied a combination of controlled vocabulary (Medical Subject Headings [MeSH] and Emtree headings) to focus specifically on interventions targeting sensory challenges in children with ASD and harms of interventions (Appendix B). We restricted literature searches for KQs to studies published from 2010 to September 2016 to reflect literature available since the publication of the 2011 review.

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 have obtained available publications of results from completed trials.

Inclusion and Exclusion Criteria

Table 1 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 recognize that these study design criteria excluded single-subject or single-case experimental designs that have been used to study interventions targeting sensory challenges. These studies are challenging to incorporate in a meaningful way in comparative effectiveness reviews, which attempt to evaluate the effectiveness of interventions at the population level. To mitigate the exclusion of such studies; however, we include summaries of recent reviews that have included such studies and discuss our findings in light of those in other reviews (see Findings in Relation to What Is Already Known).

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. 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. Studies also included only children with a diagnosis of ASD (or data reported separately for children with ASD).

Table 1. Inclusion criteria

Category	Criteria
Study Population	Children ages 2-12 with ASD (mean age plus standard deviation is ≤ 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 ≥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 -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 separately evaluated the abstracts of studies identified in our searches for KQs for inclusion or exclusion, using an Abstract Review Form (Appendix C). 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 C) that included questions stemming from our inclusion and exclusion criteria. A senior reviewer resolved disagreements between reviewers. Appendix D 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://srdr.ahrq.gov/).

Data Extraction

We designed extraction 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. 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.

Data Synthesis

Studies were too heterogeneous to allow for meta-analyses. We summarized data for Key Questions qualitatively using summary tables.

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*.[16] We developed this tool 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. Appendix C includes our risk of bias assessment form, and Appendix E includes the risk of bias ratings for each study. Appendix A includes additional details about our risk of bias approach.

Determining Overall Risk of Bias Ratings

We used the thresholds we established 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 described above individually and considered the individual ratings to determine an overall quality assessment of low, moderate, or high risk of bias. Appendix A includes additional details.

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 F.

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 (see Appendix A for full details). The degree of confidence that the observed effect of an intervention is unlikely to change is presented as strength of evidence. Methods for applying strength of evidence assessments are established in the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*[16] and are based on consideration 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[14] and studies reported in the current review). The possible strength of evidence 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.

Peer Review and Public Commentary

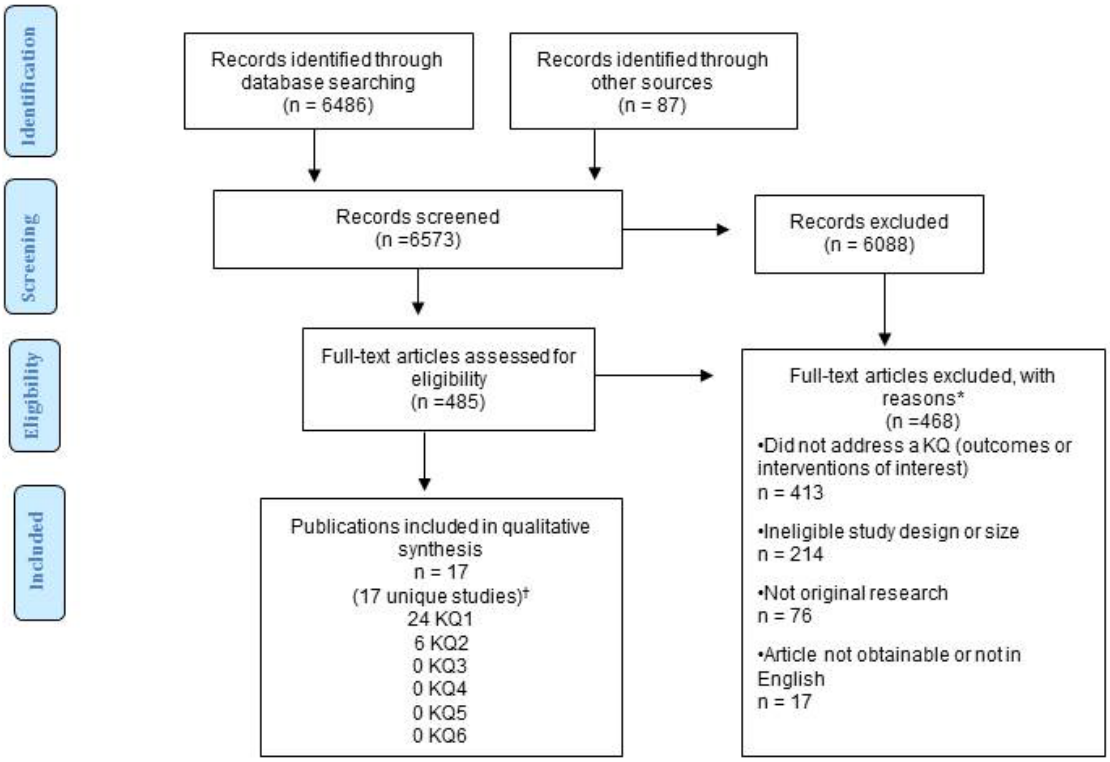
Researchers and clinicians with expertise in treating children with ASD and individuals representing stakeholder and user communities provided external peer review of this report. The draft report was posted on the AHRQ Web site for 4 weeks to elicit public comment. We addressed all reviewer comments, 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 6573 nonduplicative titles or abstracts with potential relevance, with 485 proceeding to full text review (Figure 2). We excluded 468 studies at full text review. We included 17 unique studies (17 publications; one publication reports two separate studies[18] and one study was reported in two papers[19, 20]) in the review. These 17 studies included 13 randomized controlled trials (RCTs), one nonrandomized trial, and three retrospective cohort studies. In addition to these 17 studies published since the completion of our original review of therapies for children with autism spectrum disorder (ASD) in 2011,[14] we include seven comparative studies addressed in the 2011 review in order to present a comprehensive assessment of the literature addressing interventions targeting sensory challenges.

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.
*Numbers do not tally as studies could be excluded for multiple reasons.
†One paper reports two separate trials. We also include analysis of 7 comparative studies reported in our 2011 review of therapies for children with ASD; thus, we describe a total of 24 studies.
Abbreviations: KQ = Key Question; n = number.

Description of Included Studies

The 24 studies addressing interventions targeting sensory challenges included 20 RCTs (including one paper that reported two separate studies[18-37] one nonrandomized trial, [38] and three retrospective cohort studies[39-41] (Table 2). Three studies had low risk of bias,[22, 24, 37] 10 had moderate,[19-21, 23, 25, 27, 28, 33-36] and 11 had high risk.[18, 26, 29-32, 38-41] Fourteen studies were conducted in the United States,[18-26, 29, 33, 34, 36, 40] two in the UK,[28, 35] two in Korea,[30, 41] and one each in Japan,[39] Iran,[38] Turkey,[31] Brazil,[37] Thailand,[32] and Australia.[27]

In total, studies included approximately 1010 children (median 34 total children/study) ranging in age from 2 to 16 years. Overlap of participants in a series of massage-focused studies by one investigative team is unclear. While studies likely included some of the same children, the extent of overlap is not clear.[25, 26, 33, 36, 40]

Severity of ASD and sensory dysfunction varied across studies. Only two studies reported any followup of participants after the completion of treatment,[26, 38] and one had more than 6 months of treatment[39] while another planned for 5 months of treatment but required 7 months to complete the intervention.[37] Because few studies addressed sub-questions under Key Questions (KQ) 1 and 2, we present results in the aggregate under each of these KQ. Appendix G includes detailed summary tables summarizing key outcomes.

Table 2. Overview of studies addressing interventions targeting sensory challenges

Characteristic	RCTs (n=20)	Nonrandomized Trials (n=1)	Retrospective Cohort Studies (n=3)	Total Literature
Intervention Category				
Sensory integration-based approaches	3	0	1	4
Environmental enrichment-based approaches	2	0	0	2
Auditory integration-based approaches	4	0	0	4
Music therapy-based approaches	4	1	0	5
Massage-based approaches	5	0	2	7
Additional approaches	2	0	0	2
Treatment Duration				
<1-4 weeks	5	1	0	6
5-8 weeks	2	0	0	2
9-12 weeks	4	0	0	4
13-20 weeks	6	0	2	8
≥21 weeks	3	0	1	4
Region of Study Conduct				
Asia	3	1	2	6
Australia	1	0	0	1
Europe	2	0	0	2
North America	13	0	1	14
South America	1	0	0	1
Risk of Bias				
Low	3	0	0	3
Moderate	10	0	0	10
High	7	1	3	11
Total N Participants	**790**	**27**	**193**	**1010**

N = Number; RCT = Randomized Controlled Trial

Table 3 outlines outcome areas targeted in studies meeting our review criteria. Most studies addressed sensory challenges and symptom severity.

Table 3. Overview of key outcome areas targeted

Intervention/ Outcomes Targeted	ASD Symptom Severity	Sensory Challenges	Language/ Communication	Social Engagement	Nonverbal Cognitive Skills	Challenging Behaviors	Adaptive Behavior	Sleep	Harms of Intervention
Sensory Integration-based Approaches[21, 22, 31, 39]	X	X		X	X		X		
Environmental enrichment-based Approaches[23, 24]	X		X		X				
Auditory Integration-based Approaches[18, 34, 35]	X	X	X			X			
Music Therapy[19, 20, 27, 30, 37, 38]	X	X	X	X					
Massage-based Approaches[25, 26, 32, 33, 36, 40, 41]	X	X		X		X	X	X	
Tactile-based Task[29]			X		X				
Weighted Blanket[28]	X	X						X	X

ASD= autism spectrum disorder
Note: X=Outcome area addressed by a study in the intervention category noted

Gray Literature

Our searches of ClinicalTrials.gov and other trial registries did not yield additional eligible studies for the review. We used information from organization Web sites searched to provide additional context for the discussion section of the report.

Key Question 1. Benefits and Harms of Interventions Targeting Sensory Challenges

Studies of Sensory Integration-Based Approaches

Key Points

- Four studies addressing sensory integration (SI)-based approaches were small and short-term (typically <6 months), with no followup beyond the immediate treatment period. No study reported harms of intervention.
- Sensory-related outcomes improved in children receiving an SI-based intervention compared with those receiving usual care or other treatment (statistically significant improvements in three of four studies addressing the outcome). We have low confidence in this conclusion (low strength of evidence).
- Motor skills outcomes were improved in children receiving SI-based treatment compared with those receiving usual care or other treatment (statistically significant improvements in three of three studies addressing the outcome). We have low confidence in this conclusion (low strength of evidence).

- We could not assess the effects of SI-based treatment on adaptive behavior given differences in outcomes measures (insufficient strength of evidence).

Overview of the Literature

We identified three RCTs (one low,[22] one moderate,[21] and one high[31] risk of bias) and one retrospective cohort study (high risk of bias[39]) addressing SI-based approaches. These studies included one RCT with high risk of bias addressed in our 2011 review.[31] All four studies included either explicitly noted that they were based on Ayres sensory integration principles[21, 22] or noted using a coordinated program of specific sensory-based activities selected based on a given child's needs and incorporated into the child's daily routine.[31, 39] Studies were conducted in the United States,[21, 22] Japan,[39] and Turkey[31] and included a total of 119 children between the ages of 2 to 12 years. Treatment duration ranged from 6 weeks to 10 months, and no study reported long-term followup after the end of treatment.

Detailed Analysis

In these small, short-term studies, outcomes on sensory-related measures and motor skills measures were improved in children receiving a SI-based intervention compared with another intervention in three of four studies, but effects on other outcomes were typically not statistically significantly different between groups (Appendix G). Several outcomes were also parent-reported, and parents were often aware of intervention status.

In one low risk of bias RCT, children with autism or Pervasive Development Disorder-Not Otherwise Specified (PDD-NOS) and a diagnosed sensory processing disorder received SI-based treatment or treatment focused on building fine motor skills.[22] Intervention for both groups consisted of 18 45-minute sessions over a 6-week span. Both groups improved significantly on blinded parent and teacher ratings of goal attainment (Goal Attainment Scale [GAS]) related to sensory processing, motor skills, and social functioning, with children receiving SI improving significantly more than those receiving motor skills intervention (p values $\leq$0.05). Children in the SI group had significantly fewer parent-rated autistic mannerisms post-treatment than the fine motor group ($p \leq 0.05$), but other measures of sensory processing, ASD symptoms, or neurological functioning did not differ between groups.

Another RCT with moderate risk of bias compared manualized occupational therapy with sensory integration (OT/SI) to care-as-usual.[21] OT/SI treatment consisted of three weekly sessions over the course of 10 weeks, which were monitored for treatment fidelity. Outcome measurements included parent-generated GAS. After treatment, children receiving OT/SI showed significantly more goals attained and significantly greater improvements in social skills and self-care measures compared with children receiving usual care ($p=0.003$). Scores on the Vineland Adaptive Behavior Scales (VABS) or other measures related to functional skills did not differ between groups. Children receiving OT/SI had greater improvements in need for caregiver assistance with self-care and social skills (p values $\leq$0.05).

In a retrospective cohort study (high risk of bias) using previously collected data to compare SI-based therapy in children with high functioning ASD (IQs > 70), both groups received active treatment that included either SI therapy or eclectic group therapy.[39] Treatment lasted for 8 to 10 months. Participants in the SI group improved significantly more than those in the control group in measures of motor abilities, memory and visualization, and combined sensory motor and cognitive skills conducted by an unblinded investigator (p values<0.05) but not for measures of spatial positioning and sense of touch or verbal ability. Finally, in a high risk of bias RCT

evaluating the effects of an SI protocol on low-functioning children with ASD, children receiving SI intervention had significantly fewer sensory problems at followup than children in the usual care control group using a parent-rated scale.[31]

Studies of Environmental Enrichment-Based Approaches

Key Points

- Two small RCTs addressing environmental enrichment were short term (<6 months). Neither study reported harms of intervention.
- Environmental enrichment approaches improved nonverbal cognitive skills. We have low confidence in this conclusion (low strength of evidence).
- These approaches do not affect expressive language. We have low confidence in this conclusion (low strength of evidence)
- We could not make conclusions about effects on atypical sensory responses or receptive language as these outcomes were only addressed in one RCT (insufficient strength of evidence).

Overview of the Literature

Two RCTs (low and moderate risk of bias), both conducted by the same investigators in the United States, examined environmental enrichment.[23, 24] The 78 children included in studies range in age from 3 to 12 years and received treatment for 6 months, with followup immediately post-treatment in both studies. Children in the studies had specific diagnoses of autism (vs. ASD).

Detailed Analysis

Two small RCTs of environmental enrichment examined the same protocol and reported improvements in ASD symptoms, receptive language, and nonverbal cognitive skills after 6 months of treatment (Appendix G). In one RCT (moderate risk of bias) comparing male children who received standard care plus sensorimotor enrichment to those who received standard care alone, the treatment group received olfactory/tactile stimulation as well as four to seven other parent-led, sensory-stimulating exercises twice a day over the course of 6 months.[23] Levels of concurrent interventions (e.g., speech, behavioral, physical therapies) were similar across groups and held as stable as possible. Compared with usual care, children receiving environmental enrichment had a more significant decrease in clinician-rated ASD symptoms (p=0.03) at the end of treatment, with nearly five times as many participants in the treatment group showing clinically significant drops of five points or more (42% vs. 7%, p=0.03). The treatment group also had a 9-point increase in nonverbal cognitive skills as measured by the Leiter-R compared with a decrease of approximately 3 points in the usual care group (p=0.008). Both groups improved on expressive language skills, with no significant differences.

A second RCT (low risk of bias) built upon the preliminary work by examining use of the same sensorimotor enrichment regimen over 6 months.[24] Investigators randomized participants to three groups: full treatment, as described in the initial study above; partial treatment, which entailed an abbreviated treatment regimen, and standard care. However, because no differences were found between intervention outcomes across the two treatment groups, the study collapsed findings into a combined treatment group. The treatment groups experienced significant attrition (> 50% across both) that may affect the generalizability of the results. After 6 months, the

treatment group showed more improvement than did the control group in receptive language skills, but both groups improved comparably for expressive language. The treatment group had significantly more improvement on mean nonverbal IQ scores as well as parent-rated sensory reactivity. Although more children in the treatment group compared with the control group shifted their diagnostic classification on the Autism Diagnostic Observation Schedule-2 (ADOS-2) from "autism" to "autism spectrum," all children across both groups continued to meet the cut-offs for ASD, making it difficult to interpret the clinical significance of the findings.

Studies of Auditory Integration-Based Approaches

Key Points

- All four RCTs addressing auditory integration-based approaches were small and short term (<6 months). No study reported harms of intervention.
- Auditory integration-based approaches do not improve language outcomes. We have low confidence in this conclusion (low strength of evidence).

Overview of the Literature

Four RCTs with moderate[34, 35] and high[18] risk of bias evaluated auditory integration-based approaches. One paper reports two RCTs,[18] and two studies were included in our 2011 review.[34, 35] Studies included a total of 173 children between the ages of 3 and 13 years, and treatment duration ranged from 1 week to 18 weeks, with followup immediately post-treatment.

Detailed Analysis

Two small, short term RCTs of auditory integration-based approaches reported no significant differences between groups in language outcomes assessed on parent, teacher, and clinician observation measures,[34, 35] while two studies reported significant parent-rated improvements in hearing sensitivity and behavior (Appendix G).[18]

One crossover RCT evaluated the effects of Tomatis Sound Therapy on language skills in children with autistic disorder who had not previously had auditory stimulation treatments.[34] In the treatment condition, children listened to music passed through an electronic ear for attenuation and modulation for two hours per day in accordance with the Tomatis Method protocol. In the placebo condition, children listened to commercially produced music. The study reported no significant group effects. Another RCT of auditory integration therapy including children with significant language delays reported no significant benefits of auditory integration.[35]

Two high risk of bias RCTs (reported in a single publication[18]) examined the use of auditory integration strategies theorized to reduce auditory hypersensitivity by "exercising" the neural regulation abilities of the middle ear muscles. Across both trials, two different sets of participants completed five 45-minute sessions on consecutive days. In Trial 1, participants wore headphones and either listened to filtered music or no sound. In Trial 2, participants either listened to filtered music or unfiltered music. Participants either had at least five words of functional speech or were able to follow one-step instructions. It should be noted that although the ADI-R was used to confirm diagnosis, a subset of participants did not meet full diagnostic cut-offs on this instrument. One week after intervention, parents reported more improvement in the areas of hearing sensitivity, spontaneous speech, listening, and behavioral organization after filtered music compared with children in the control condition (p values <0.01). Children who received

filtered music in Trial 2 also had significantly better parent-rated scores on hearing sensitivity and emotional control compared with control children (p values <0.05). Groups in either trial did not differ in the other behavioral domains rated.

Studies of Music Therapy-Based Approaches

Key Points

- All studies addressing music therapy-based approaches were small and short term (<6 months), and none reported harms of intervention.
- We could not make conclusions about effects of music therapy approaches on any outcome given that studies had multiple comparators and addressed different outcomes (insufficient strength of evidence).

Overview of the Literature

Four RCTs and one nonrandomized trial (one conducted in Australia,[27] one in Iran,[38] one in Brazil,[37] one in the United States, [19, 20] and one in Korea[30]) examined music therapy-based approaches. One study compared a rhythm-based intervention with a non-human (robot) control and with human-delivered control intervention.[19, 20] One nonrandomized trial comparing music therapy and toy play was included in our 2011 review.[30]

Studies included a total of 115 children ranging in age from 3 to 12 years, and treatment duration ranged from 45 days to 20 weeks. Followup occurred immediately at the end of treatment in all but one of the studies, which followed up at 2 months post-treatment.[38] Two studies had low risk of bias,[19, 20, 37] one had moderate risk of bias,[27] and two studies had high risk.[30, 38]

Detailed Analysis

The five small studies addressing music therapy reported some significant effects on measures of behavior (social engagement, behavioral organization), verbal and nonverbal communication, and joint attention (directing and sharing attention to objects or events) with music-based intervention compared with control interventions (Appendix G). Studies used different protocols and addressed different outcomes; thus, drawing conclusions across studies is challenging. In some studies children also received other interventions in addition to music-based approaches.

One RCT (low risk of bias) compared Relational Music Therapy to treatment-as-usual in 24 male children with Autistic disorder, PDD-NOS, or Asperger Syndrome.[37] Relational Music Therapy is not a standardized protocol but rather a participant-driven, non-directive approach that incorporates musical instruments to promote interaction. Intervention consisted of 16 30-minute sessions that took approximately 7 months to complete. Groups did not differ significantly on outcomes measured using the Childhood Autism Rating Scale (CARS) at followup.

Another low risk of bias RCT compared three intervention conditions (four 45-minute sessions/week for 8 weeks) targeting pre- and post-test measures of communication, attention, and motor skills: a trainer-led rhythm and movement-based group, a robot group focused on imitation, and a control group engaging in tabletop activities.[19, 20] The rhythm and control groups improved from baseline on an overall measure of joint attention, while the robot group did not; between-group differences were not statistically significant. Both rhythm and robot treatment

groups demonstrated greater post-test attention to trainers than to objects than did the control group (p values <0.001), with greater attention in the rhythm group than the robot group (p<0.001). The rhythm group also demonstrated the greatest duration of spontaneous social attention, followed by the robot group and the control group (p<0.001). Children in the robot group also had greater self-directed vocalization compared with the other groups (p values <0.002), while children in the rhythm and control groups had greater spontaneous social verbalization to trainers than did children in the robot group (p values <0.03).

One RCT (moderate risk of bias) compared family-centered music therapy plus early intervention to early intervention only.[27] Participants had little to no functional verbal communication and received 2 to 3 hours of community-based intervention per week while participating. Intervention consisted of one hour per week of semi-structured sessions within the home for 16 weeks. Therapists worked with parents and participants to improve selected core social engagement skills through music-based activities. Children who received music therapy had more improvement than controls in parent-rated social engagement (p< 0.001) but remained significantly impaired relative to typically developing peers. Groups did not differ on parent-reported autism symptoms, speech and language, or quality of the parent-child relationship.

In a high risk of bias nonrandomized trial comparing 12 1-hour Orff-Schulwerk music therapy sessions over the course of 45 days to no treatment, social skills improved significantly in the treatment group between baseline to post-treatment but not from post-treatment to follow-up.[38] The control group did not improve at any time point, and differences between the treatment and control groups were not significant at the final followup.

In a final crossover RCT with high risk of bias comparing music therapy and toy play, groups did not differ on the Pervasive Development Disorder Behavior Inventory (PDDBI), though both groups improved with time.[30] Results from the Early Social Communication Scales, reflecting growth in joint attention skills, suggested that music therapy was significantly more effective than play sessions. Change scores pre- to post- music therapy were significantly greater than change scores pre- to post- play sessions. In coding for emotional and motivational responsiveness (i.e., joy, emotional synchronicity, initiation of engagement), investigators observed more joy, emotional synchronicity, and initiation of engagement during music therapy than in play sessions. In addition, children had significantly more compliant behavior and significantly fewer episodes of no response behaviors in the music therapy condition.

Studies of Touch/Massage

Key Points

- One group of investigators conducted five short-term (<6 months treatment duration) studies comparing massage with no massage treatment, and participant overlap is unclear. No study reported harms of intervention.
- Additional studies assessed massage therapy plus attachment therapy compared with attachment therapy alone or massage plus SI-based treatment vs. SI-based treatment alone.
- Massage improved sensory challenges and ASD symptom severity vs. no massage. Our confidence in this conclusion is low (low strength of evidence).
- Massage did not improve maladaptive behavior. Our confidence in this conclusion is low (low strength of evidence).

- We could not make conclusions about the effects of massage on language/communication outcomes given inconsistent findings and use of different outcome measures (insufficient strength of evidence).
- We could not make conclusions about longer-term outcomes (≥6 months) as only one study reported longer-term followup (insufficient strength of evidence). We could not make conclusions about effects on measures of daily living skills, also assessed in only one study (insufficient strength of evidence). Only one study compared massage plus SI-based treatment to SI-based treatment alone or attachment therapy plus massage with attachment therapy alone so we could not make conclusions about these studies (insufficient strength of evidence).

Overview of the Literature

Seven studies (6 RCTs and one retrospective cohort study) addressed touch-based therapy. Five studies (four RCTs and one cohort) compared Qigong or traditional massage to no massage treatment (waitlist condition). [25, 26, 33, 36, 40] One RCT compared massage plus SI-based treatment with SI-based treatment alone,[32] and one retrospective cohort compared attachment therapy plus massage with attachment therapy alone.[41] Studies were conducted in the United States,[25, 26, 33, 36, 40] Korea,[41]and Thailand[32] and had moderate[25, 33, 36] and high risk of bias.[26, 32, 40, 41] Three RCTs were also reported in our 2011 review.[26, 32, 33]

One team of investigators has published most of the literature in this area, and the extent of overlap among participants in these studies is unclear.[25, 26, 33, 40, 42] Studies included approximately 439 children receiving treatment for 2 to 5 months. One study reported followup of participants 5 months after the end of treatment.[26]

Detailed Analysis

Massage Versus No Massage. Almost all of studies are from one group of investigators, and the participant overlap is unclear (Appendix F). Some used only parent-and teacher-rated outcomes, but others used standardized measures of autism symptoms, language, and adaptive functioning (e.g., CARS, Preschool Language Scale [PLS], Vineland Adaptive Behavior Scales [VABS]). Studies generally reported improvements related to sensory processing, autism symptoms, and parent stress in both treatment and control groups over the course of 5 months of either parent or parent + therapist-delivered intervention, with treatment groups improving significantly more than controls. Some studies also examined the moderating influence of baseline variables, such as parent stress or autism severity, which are important confounds to explore. The difficulty differentiating populations in these studies limits the strength of evidence for their findings, although results seem promising regarding a sensory-focused intervention that can be delivered within the home environment with minimal risk of harms.

As noted, four RCTs (three with moderate risk of bias[25, 33,36] and one with a high risk of bias[26]) and one retrospective cohort study[40] (high risk of bias) had unclear participant overlap and compared children who received Qigong Sensory Training (QST) to wait-listed controls or usual care. In one study comparing children who received QST to children receiving treatment as usual,[25] parents participated in seven sessions instructing them in the basics of Qigong. Most children concurrently attended early intervention preschools for 5-10 hours a week, and participants included an unknown number of sibling pairs. Children receiving QST significantly improved from baseline on teacher and parent ratings of autism symptoms as well as parent

ratings of sensory challenges, self-regulation skills, communication skills, and maladaptive behaviors (p values ≤0.05). When compared with the waitlist control group, improvements were significantly larger for autism symptoms (PDDBI), parent stress, and sensory/self-regulation challenges (Sensory and Self-Regulation Checklist), with medium to large effect sizes. Changes in teacher-rated ASD symptoms (Autism Behavior Checklist [ABC]) were not significantly different between treatment and control groups. Some children (N not clear) received parent + therapist-delivered massage (dual group) while others received only parent-delivered massage. While both groups improved on all measures from baseline, children in the dual group had greater improvements than those in the parent-only group (p values=ns).

Participants in a second RCT included five sibling pairs.[26] Children in the treatment group also had more severe challenging behaviors and sensory impairments at baseline. Children who received QST significantly improved on parent- and teacher-reported measures of autism symptoms, maladaptive behavior, communication skills, and sensory functioning from baseline, whereas children in the control group improved only on teacher measures of maladaptive behaviors (p values≤0.05). Children in the treatment group improved significantly more on teacher-rated measures of behavior and language (PDDBI, ABC) but not in maladaptive behavior compared with the control group. Children who received QST also improved more on all parent-rated measures of behavior and sensory processing (PDDBI, SSC) than did children in the control group.[26] Parent-rated data on 19 treatment group participants still available for data collection showed that gains were maintained 5-months after the end of treatment.

A third RCT from the same group compared waitlisted controls to children who received five months of a QST Dual Program (parent + therapist-delivered massage).[36] Baseline variables and attrition rates were similar across groups. Children in both groups showed improvement over time in most domains, although control group improvements were generally of smaller magnitude than the treatment group. Post-hoc analyses revealed specific treatment effects on parent-reported but not clinician-rated measures: autism symptoms, receptive (but not expressive) language, sensory processing, and parent stress improved more in the treatment group compared with control (p values <0.01). Group differences in social and living skills were not significant.

A final study from this group, with high risk of bias and unclear participant overlap with prior studies, retrospectively compared outcomes for children who either received QST for 5-months or were waitlisted controls.[40] Participants in the treatment groups received two varying levels of intervention (Home Program—parent only massage; Dual Program—parent + therapist-delivered massage), and outcome measures were reported by both parents and therapists using different reporting strategies (questionnaire versus observation). Participants in the treatment groups showed significant improvements in tactile defensiveness, self-regulation skills, and parent stress levels compared with controls.

Massage + SI-Based Treatment Versus SI-Based Treatment Alone. One RCT with high risk of bias (included in the 2011 review) investigated 8 weeks of SI-based therapy compared with SI-based therapy plus traditional Thai massage.[32] Children in the intervention group (but not the control group) had significantly improved parent ratings of anxiety and conduct both relative to baseline and relative to controls (p≤0.03). Children in both conditions had improved sleep as well as teacher ratings of conduct, attention, and activity level, and these ratings did not significantly differ across treatment groups. Participants in the treatment group had fewer symptoms of hyperactivity and sleep problems at baseline.[32]

Massage + Attachment Therapy Versus Attachment Therapy Alone. One retrospective cohort study (high risk of bias) investigated the impact of massage therapy with and without attachment therapy on social maturity, ASD symptoms, and mother-child attachment.[41] The attachment program involved two hours per day of play activities to promote mother-child interactions, five days per week, for four months. Participants in the experimental group also received one hour of massage therapy per week from trained nurses. The nurses encouraged mothers to talk and sing to children and also demonstrated massage techniques. Social maturity on the observer-rated Vineland Social Maturity Scale improved in the massage group compared with the attachment only group (p=0.005), but CARS scores did not differ significantly between groups.

Additional Studies

Key Points

- One study addressed tactile stimulation exercises and one addressed weighted blankets. These studies provided insufficient data to draw conclusions (insufficient strength of evidence).

Overview of the Literature

One RCT of a tactile input task conducted in the United States had high risk of bias and included 34 children between 4 and 14 years old.[29] Treatment duration was 24 to 48 hours. Another RCT with low risk of bias conducted in the United Kingdom included 54 children between 5 and 16 years of age.[28] Treatment duration was 2 weeks. Both studies had followup immediately post-treatment.

Detailed Analysis

Other interventions with sensory-related components reported few significant differences between treatment groups (Appendix G).

Tactile Input. One RCT (high risk of bias) examined the impact of a tactile-based task on the ability of 34 children with autism to learn a novel task.[29] Participants included children who could not complete standardized cognitive or language evaluations. Children either participated in a tactual-kinesthetic experience (a "hands on" learning activity) or observed someone else performing the activity. Stimuli were presented across two sessions, 24-48 hours apart. Children in the hands-on participation group scored significantly better on ratings of perceived ease of implementing the learning task than children in the control condition (p values ≤ 0.05).

Weighted Blankets. One crossover RCT with moderate risk of bias examined the impact of a weighted blanket on sleep disturbance in children with severe problems with sleep onset or maintenance.[28] Children used a control or weighted blanket for 12-16 days and then switched. No significant differences emerged on any of the variables of interest related to sleep onset/quality, child behavior, or family functioning. Regardless of baseline factors such as sensory sensitivities, autism severity, and sleep problems, parents were more likely to rate their children as calmer and sleeping better when using the weighted blanket, despite a lack of physiological evidence to support this. Additionally, both children and parents reported

preferring the weighted blanket. Investigators reported that one child developed a rash that may have been due to the blanket (resolved in 2 days).

Key Question 2. Modifiers of Treatment Outcomes

Few studies were likely adequately powered to assess modifiers of effects, and few studies reported potential modifiers. While we sought characteristics of interventions, providers, parents, or children that may modify treatment effects, studies reported only child and family characteristics. We present findings as reported in each study below as potential indicators of characteristics that may affect outcomes.

Child Characteristics. One study of an environmental enrichment-based approach reported that while more children in the treatment group compared with the control group shifted their diagnostic classification on the ADOS-2 from "autism" to "autism spectrum," all children across both groups continued to meet the cut-offs for ASD, making it difficult to interpret the clinical significance of the findings. Baseline language and cognitive skills scores contributed to the majority of the variance when predicting which children in the treatment group would shift diagnostic cut-offs on the ADOS.[24] In another RCT comparing filtered and unfiltered music, participants whose parents rated them as having improved hearing sensitivity were more likely to show an increase in their sharing behaviors during a semi-structured play evaluation.[18] An RCT comparing home-based Qigong massage therapy to waitlisted controls found that children with fewer sensory symptoms and fewer difficulties with self-regulation benefited more from the treatment program.[26] In other studies of massage, treatment effects on child behaviors and language were not moderated by baseline ASD severity as measured on the CARS,[36] and interactions between self-regulation skills and tactile sensitivity or tactile sensitivity and parenting stress were not significant.[40]

In a music therapy RCT, analyses based on diagnostic subtype indicated that participants with diagnoses of autism had significant improvement in the CARS domain of nonverbal communication ($p = .008$) compared with children in the control group with diagnoses of autism.[37] The study reported no other significant differences based upon either participant subtype or treatment received. Finally, one study comparing weighted blankets and regular blankets reported that no baseline factors related to autism severity, sleep problems, or sensory sensitivities modified parents' ratings of children's sleep quality.[28]

Family Characteristics. Although many studies collected parent report of child functioning, only one asked parents about their own functioning. One study of massage assessed parental stress levels and found that children in the treatment group had greater improvements in autism symptoms and overall behavior if their parents were less stressed at intake.[25] This would be an important avenue of future research, given that parental and family variables may influence how parents perceive children's functioning and subsequently complete questionnaires. Another study evaluated the quality of parent-child relationships as a potential modifier but did not find any treatment effects.[27]

Key Question 3. Time to Effect of Interventions

No study examined the time to effect for sensory related interventions.

Key Question 4. Evidence That Effects Measured at the End of Treatment Predict Long-Term Functional Outcomes

Only two studies conducted a followup after treatment ended. Followup occurred at two and five months in each study.[26, 38] Additionally, many of the outcome measures were based upon parent reports rather than using standardized interactive assessments. Therefore, little existing evidence at this time contributes to predicting long-term functional outcomes.

Key Question 5. Effectiveness Across Environments or Contexts

We did not identify studies addressing this outcome directly. Many studies collected parent or teacher report of sensory sensitivities as a way of assessing functioning in multiple environments, but these assessments generally did not evaluate functioning within multiple specific contexts.

Key Question 6. Drivers of Treatment Outcomes

We did not identify any studies addressing this KQ.

Discussion

State of the Literature

We identified a total of 24 studies (20 randomized controlled trials [RCTs], 1 nonrandomized trial, 3 retrospective cohort studies) addressing interventions targeting sensory challenges in children with autism spectrum disorder (ASD). Three studies had low risk of bias,[22, 24, 37] 10 had moderate,[19-21, 23, 25, 27, 28, 33-36] and 11 had high risk (including one paper reporting 2 unique studies).[18, 26, 29-32, 38-41] Most studies were small and used different outcome measures. Treatment length varied from two days to 10 months, with two studies reporting followup after the immediate intervention period.[26, 38] Protocols involved either parents or therapists engaging in one-on-one or group interactions; one RCT used a robot-delivered approach.

Compared with our previous review, more studies were designed in ways that increased their strengths, including random assignment and tracking of attrition; stratification of assignment or matching based upon key baseline variables; blinded ratings; treatment fidelity protocols; tracking or controlling for concurrent interventions; and using standardized outcome measures or measures that incorporated parent-selected outcomes of importance such as goal attainment scaling. We also identified more evidence addressing sensory-integration-based, environmental enrichment, music therapy, and massage modalities in particular. Although more information is available, the lack of consistency in implementation, combined with generally small sample sizes and limited followup, makes it difficult to draw strong conclusions regarding treatment efficacy.

Similarly, many studies continued to rely upon parent report of symptoms, although others used unbiased ratings of behavior (such as actigraphy or standardized measures) as well. It will be important for future work to compare sensory-based interventions not only to treatment as usual, but to other interventions that involve engaged and active time with an adult, as did some studies in the current review.[22, 24, 41] Additional research is needed that controls for environmental or social factors that could cloud our ability to draw conclusions regarding effects.

Summary of Key Findings and Strength of the Evidence

Key Question 1. Benefits and Harms of Interventions Targeting Sensory Challenges

Sensory Integration (SI)-Based Approaches

In four small, short-term studies, sensory-related outcomes improved in children receiving an SI-based intervention compared with those receiving usual care or other treatment (significant improvements in three of four studies addressing the outcome). We have low confidence in this conclusion (low strength of evidence). Motor skills outcomes were significantly improved in children receiving SI-based treatment compared with those receiving usual care or other treatment (significant improvements in three of three studies addressing the outcome). We have low confidence in this conclusion (low strength of evidence). Evidence was insufficient to draw conclusions regarding other comparisons and outcomes. Table 4 outlines these findings.

Table 4. Strength of the evidence for sensory integration-based interventions versus control approaches

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
Sensory Challenges RCT: 1 low,[22] 1 moderate,[21] 1 high[31] (N=99) Retrospective Cohort: 1 high[39] (N=20)	High	In-consistent	Direct	Imprecise	Undetected	**Low SOE for positive effects of sensory integration-based approaches on sensory challenges** Significant improvements in sensory-related behaviors in treatment groups compared with control in 2 RCTs and one cohort study. No group differences in third RCT on parent-reported measure of sensory behaviors but significant improvement in treatment group in sensory-related goals; all studies were small and short-term
Motor Skills RCT: 1 low,[22] 1 moderate[21] (N=69) Retrospective cohort: 1 high[39] (N=20)	High	Consistent	Direct	Imprecise	Undetected	**Low SOE for positive effects of sensory integration on motor skills** Significant improvements in treatment groups vs. control in 3 small studies

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

Environmental Enrichment-Based Approaches

Two small RCTs of environmental enrichment examined the same protocol involving parent-led sensory stimulation exercises and reported improvements in ASD symptoms, receptive language, and nonverbal cognitive skills after 6 months of treatment.[23, 24]

We have low confidence in the conclusion that these approaches improved nonverbal cognitive skills (low strength of evidence). These enrichment approaches do not affect expressive language. We have low confidence in this conclusion (low strength of evidence). We could not make conclusions about effects on atypical sensory responses or receptive language as these outcomes were only addressed in one RCT[24] (insufficient strength of evidence). Table 5 outlines these findings.

Table 5. Strength of the evidence for environmental enrichment interventions versus usual care

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
Nonverbal Cognitive Skills RCT: 1 low,[24] 1 moderate[23] (N=78)	High	Consistent	Direct	Imprecise	Undetected	**Low SOE for positive effects of enrichment on IQ** Significant improvements in IQ (Leiter) in children receiving enrichment compared with those receiving usual care in 2 small RCTs with short-term followup and high limitations given small sample size
Expressive Language RCT: 1 low,[24] 1 moderate[23] (N=78)	High	Consistent	Direct	Imprecise	Undetected	**Low SOE for lack of effect of enrichment on expressive language** No group differences in expressive language in 2 small RCTs with short-term followup and high limitations given small sample size

IQ=intelligence quotient; N=number; RCT=randomized controlled trial; SOE=strength of the evidence

Auditory Integration-Based Approaches

Two small, short-term RCTs of auditory integration-based approaches assessing language outcomes reported no significant differences between groups in receptive language outcomes;[34, 35] one RCT (in a publication reporting 2 unique studies) reported significant parent-rated improvements in spontaneous speech.[18] We have low confidence in the conclusion that these approaches do not improve language outcomes (low strength of evidence) (Table 6).

Table 6. Strength of the evidence for auditory integration-based interventions versus control approaches

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
Language RCT: 2 moderate,[34, 35] 1 high[18] (N=91)	High	In-consistent	Direct	Imprecise	Undetected	**Low SOE for lack of effects of auditory integration approaches on language** No group differences in outcomes in 2 small crossover RCTs with short-term followup; parent-rated improvements in spontaneous speech in treatment group vs. control in a third RCT

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

Music Therapy-Based Approaches

Five small studies addressing music therapy reported some significant effects on measures of behavior (social engagement, behavioral organization), verbal and nonverbal communication, and joint attention with music-based intervention compared with control interventions; however, studies used different protocols and addressed different outcomes

We could not make conclusions about the effects of music therapy approaches on any outcome given that studies had multiple comparators and addressed different outcomes (insufficient strength of evidence).

Massage-Based Approaches

As noted, five of seven massage studies were from one group of investigators, with unclear participant overlap.[25, 26, 32, 33, 36, 40] These studies generally reported improvements related to sensory processing, autism symptoms, and parent stress in both treatment and control groups over the course of 5 months of either parent or parent + therapist-delivered intervention, with treatment groups improving significantly more than controls. The difficulty differentiating between these works limits the strength of evidence for their findings, although results seem promising regarding a sensory-focused intervention that can be delivered within the home environment with minimal risk of harms. Two additional studies assessed massage therapy plus attachment therapy compared with attachment therapy alone or massage plus SI-based treatment vs. SI-based treatment alone.[32, 41]

Massage improved sensory challenges and ASD symptom severity vs. no massage. Our confidence in this conclusion is low (low strength of evidence). Massage did not improve maladaptive behavior. Our confidence in this conclusion is low (low strength of evidence due to unclear extent of overlap among participants and high study limitations [unblinded ratings, diagnostic processes]).

We could not make conclusions about the effects of massage on language/communication outcomes given inconsistent findings and use of different outcome measures (insufficient

strength of evidence). We could not make conclusions about longer-term outcomes (≥6 months) as only one study[26] reported longer-term followup (insufficient strength of evidence). We could not make conclusions about effects on measures of daily living skills, also assessed in only one study[36] (insufficient strength of evidence). Only one study compared massage plus SI-based treatment to SI-based treatment alone[32] or attachment therapy plus massage with attachment therapy alone[41] so we could not make conclusions about these studies (insufficient strength of evidence). Table 7 outlines these findings.

Table 7. Strength of the evidence for massage-based interventions versus waitlist control conditions

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
ASD Symptom Severity RCT: 2 moderate,[25, 36] 1 high[26] (N=191)	High	Consistent	Direct	Imprecise	Undetected	**Low SOE for improvements in ASD symptom severity with massage vs. control in the short-term (<6 months)** Significant group differences in all 3 studies; SOE is low given unclear overlap in participants and high study limitations
Sensory Challenges RCT: 2 moderate,[25, 36] 1 high[26] (N=191) Retrospective Cohort: 1 high[40] (N=129)	High	Consistent	Direct	Imprecise	Undetected	**Low SOE for positive effects on sensory challenges with massage vs. control in the short-term (<6 months)** Significant group differences in all 4 studies; SOE is low given unclear overlap in participants and high study limitations
Maladaptive Behaviors RCT: 1 moderate,[25] (N=42), 1 high[26] (N=46)	High	Consistent	Direct	Imprecise	Undetected	**Low SOE for no effect on maladaptive behaviors with massage vs. control in the short-term (<6 months)** No significant group differences in 2 studies; SOE is low given unclear overlap in participants and high study limitations

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

Additional Interventions

Additional interventions with sensory-related components (tactile stimulation exercises,[29] weighted blankets[28]) reported few significant differences between treatment groups. These studies provided insufficient data to draw conclusions about any outcomes (insufficient strength of evidence).

Other Key Questions

Few studies were likely adequately powered to assess modifiers of effects, and few studies reported potential modifiers. We did not identify studies addressing the time to effect of interventions; evidence that effects measured at the end of treatment predict long-term functional outcomes; effectiveness of treatments across environments or contexts (e.g., clinic, home, school); and drivers of treatment outcomes.

Findings in Relation to What Is Already Known

We identified eleven recent (2010-present) systematic reviews addressing interventions targeting sensory challenges.[6, 10, 43-51] Three reviews were not specific to children with ASD but included studies of individuals with developmental disabilities.[6, 10, 48] As a number of these studies included children with ASD, we retained these reviews.

Reviews addressed comprehensive sensory integration approaches (typically clinic-based interventions using sensory-enhanced modalities to integrate sensory information and potentially ameliorate specific challenges or behaviors); "sensory-based" interventions targeting somatosensory or vestibular symptoms such as therapy balls, massage, and weighted vests; auditory integration; massage; and music therapy. Our findings generally align with these prior reviews of interventions. Reviews noted low to moderate support for sensory integration-based approaches and limited evidence for other approaches. Reviews consistently noted considerable heterogeneity, limited study quality/high risk of bias, limited followup, and lack of treatment fidelity. Reviews differentiating sensory integration approaches and more general "sensory-based" approaches reported better evidence from those studies that evaluated specific, typically manualized sensory integration modalities compared with sensory-based approaches. One review of auditory integration approaches reported no evidence of effectiveness. One review of music therapy reported promising findings related to improvements in social interaction and communication, and one addressing massage reported that limited evidence precluded conclusions. We provide more detailed summaries of these reviews below.

Reviews of Sensory Integration or Sensory-Based Approaches

One review evaluating interventions for sensory processing disorders in children with ASD included 15 single subject design studies, two RCTs, one non-randomized trial, and one case report addressed sensory integration (n=5 studies) or sensory-based interventions (n=14 studies).[3] Six studies had scores of at a least 5 on the 10 point PEDro scale, and four reported higher level evidence on the Center for Evidence-Based Medicine scale. The review reported positive effects on children's individualized goals (effect sizes ranging from 0.72 to 1.17) associated with sensory integration approaches but noted that durability and generalizability of effects was unclear. Evidence for sensory-based approaches was limited, and the review noted that studies suggest no support for weighted vests and little conclusive evidence for therapy balls or other multisensory inputs.

Another review addressing Ayres sensory integration (4 studies) and more general sensory-based interventions (18 studies) in children and adults with ASD reported similar results.[50]The studies addressing sensory integration included 133 children, and reviewers noted significant improvements in individualized goals, symptom severity, and sleep in studies with low risk of bias. Sensory-based studies (including single subject studies and systematic reviews) reported few positive effects and generally lacked measures of treatment fidelity.

In another review including 25 studies addressing sensory integration therapy for children with ASD, investigators noted positive effects in three studies, mixed findings in eight, and no benefits in 14.[49] The review considered "sensory integration" broadly, and did not differentiate manualized sensory integration from approaches such as weighted vests or brushing. Investigators considered 16 studies to report a "suggestive" (vs. conclusive) level of evidence based on methodologic limitations and concluded that the evidence base does not support use of sensory integration to treat children with ASD.

One review assessing sensory-based treatment in children with disabilities (including 236 of 856 children with ASD) included 15 comparative studies (including 13 RCTs) and 15 single subject design studies.[6] Investigators noted methodologic flaws in randomization (for comparative studies) and blinding and fidelity and reported inconsistent results for sensory integration approaches (no group differences in 3 studies, improvements in sensory behaviors and goal attainment in the sensory treatment arm in 4, and greater improvements with behavioral vs. sensory treatment in 2 other studies). Evidence for positive effects of weighted vests was lacking in six studies and mixed results for therapy balls in two studies. Overall the review concluded that inconclusive evidence supports the efficacy of sensory-based approaches and that such approaches are more likely to be ineffective than effective for the majority of children with developmental disabilities.

Another review of single subject studies of individuals with disabilities assessed "sensory integration" broadly and included 17 studies, six including children with ASD.[48] The investigators considered all studies to have high risk of bias and noted a lack of evidence for the efficacy of interventions: few studies reported positive effects, even those studies with better quality.

A third systematic review also focused on sensory approaches for children with behavioral problems (not necessarily ASD) and included 14 studies (11 included children with ASD, n=185).[10] Seven studies were single-subject design and four were RCTs. Investigators rated all studies as excellent or good quality on the PEDro scale and categorized interventions as tactile-, proprioceptive-, or vestibular-based. The review noted some positive effects associated with tactile approaches, particularly massage, on challenging behaviors including inattention. Proprioceptive studies—all single subject—evaluated weighted vests and reported mixed findings related to on-task, self-stimulatory, and stereotypic behaviors (improved findings in one study, mixed in two, and no effects in another). Vestibular-based approaches included therapy balls/cushions and horseback riding. Investigators noted limited positive effects on engagement in classroom activities associated with therapy balls. The review concluded that evidence for effectiveness of sensory-based interventions remains unclear.

Two other reviews focused broadly on interventions to improve social participation, play, adaptive behavior, education, and repetitive behavior included few studies addressing sensory challenges (n=3) and noted insufficient evidence for effects on social communication[47] and positive effects on self-care in one RCT.[46]

Other Reviews

Auditory Integration. One Cochrane review of auditory integration approaches for people with ASD included six RCTs with moderate to high risk of bias.[44] The review reported some improvements in language and challenging behaviors in small studies with disparate outcome

measures and limited followup but concluded that interventions overall were ineffective for individuals with ASD.

Music Therapy. Another Cochrane review of 10 studies (n=165 children with ASD), including materials such as theses and study designs including single subject studies, assessed music therapy and reported significant improvements in social interaction within and outside the therapy context and in communication and social reciprocity in the therapy context.[52] Nonverbal communication in non-therapy contexts was not significantly improved. The review concluded that music therapy may improve social interaction, communication, social reciprocity skills in children with ASD. These results differ from those reported in the current review, likely because we included only comparative studies of music therapy with at least 10 participants.

Massage. One review of massage therapy for children with ASD included six comparative studies and reported some positive effects of massage on symptom severity, communication, and sensory outcomes; however, investigators considered all trials to have high risk of bias.[43] The review concluded the evidence for massage as an ASD treatment is limited and methodologic limitations do not allow firm conclusions.

Applicability

Children in studies meeting our review criteria are similar to the general population of children with ASD and associated sensory challenges in that they represent the heterogeneity of impairments and behavioral challenges associated with ASD. Some studies included children with limited functional speech[31, 34] and/or intellectual disability.[35], others included children with higher cognitive abilities and milder ASD symptom profiles.[22, 39] Differences in severity of expression of ASD or in comorbid conditions may limit applicability of findings to children with levels of symptom expression.

Interventions typically used differing approaches incorporating sensory-focused strategies; thus, findings reported here may not be replicated with interventions using different combinations of strategies or targeting different aspects of sensory functioning. Many of the interventions required expertise in specific sensory-related strategies that likely limit their generalizability to community settings; some lacked manualization, and as a consequence likely have limited replicability/community extension. Others were specifically designed to be conducted by parents, under the supervision of a trainer.

In terms of comparison or control interventions, virtually all "control" participants in the included studies were receiving some level of treatment, aside from participants in one RCT.[38] Some studies attempted to document additional interventions through parent report to demonstrate that baseline rates were comparable across groups, whereas others required that no new interventions be added during the study duration. Outcomes may differ among children receiving different concomitant therapies.

Outcomes also varied across studies, but most studies incorporated commonly used measures of autism symptom severity, behavior, language, and sensory difficulties. Many of these were based upon parent report, although an increasing number used standardized interactive or observational measurement strategies. Some studies also incorporated outcomes of key importance to parents/caregivers that simultaneously attempted to balance assessing comparability between treatment groups with the heterogeneity inherent in ASD.[21, 22] Use of validated, standardized measures improves potential generalizability of findings by helping to

establish a shared understanding of progress and to compare outcomes across different intervention modalities and studies. Standardized measures supplemented with more individualized assessment strategies can also help to improve sensitivity by measuring smaller effects and incorporating elements of children's individual family or treatment context.

Treatment duration ranged from a week to 10 months, and most studies reported outcomes immediately following the end of treatment, making durability of effects difficult to assess. Few studies attempted to assess characteristics of the child, family, provider, or intervention approach that may affect outcomes, or whether outcomes extended to other settings and environments. However, the use of control groups, treatment fidelity checks, and replicable and manualized intervention protocols establishes a promising baseline for future investigations.

Given the heterogeneity of these studies, and the heterogeneity of children with ASD, the extent of generalizability to the overall population of children with ASD and sensory challenges is limited and difficult to assess.

Implications for Clinical and Policy Decisionmaking

This review provides limited evidence for decisionmaking about interventions targeting sensory challenges. The small body of comparative literature provides some evidence to support sensory integration-based and touch/massage-based interventions for some children; both interventions positively affected sensory challenges and motor skills. Studies were typically short term and included few children, however, so our confidence in these effects is low.

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, and components that may drive effectiveness. Though not explicitly assessed in the studies reported here, harms associated with these approaches are likely minimal and caregivers and clinicians must balance the need to ameliorate sensory challenges with the costs of time, effort, and costs and demands of other interventions that a child may receive. As such, caregivers and referring providers should assess the possible benefits of specific sensory-focused intervention modalities based upon the individual needs of the child, broader family goals and capacities, and interventions of more established effectiveness. In this capacity, some practice groups have recommended clear communication regarding the limits of intervention.[53, 54]

Limitations of the Comparative Effectiveness Review Process

We included studies published in English only and did not include unpublished data or data in theses or conference proceedings. 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 published in other languages.

We also included only comparative studies of interventions with a sensory-specific focus and including at least 10 children with ASD. This undoubtedly means that most single-subject design studies are not included in this review. Single-subject designs can be helpful in assessing response to treatment in very short timeframes and under very tightly controlled circumstances, but they typically do not provide information on longer-term or functional outcomes. Such studies are useful in demonstrating effects, yielding initial evidence that an intervention merits further study or in identifying whether a particular approach to treatment is likely to be helpful for a specific child. Our goal was to identify and review the best evidence for assessing the effectiveness of interventions targeting sensory challenges in children with ASD, with an eye toward utility in the larger population of children with ASD. By definition, "populations" in single-subject design studies are likely to be idiosyncratic and therefore unlikely to provide information that is generalizable. We also included summaries of other recent reviews to attempt to mitigate any loss of information associated with this criterion.

We also note that other approaches to categorizing sensory-focused interventions could be used and that consensus on a categorization approach is lacking. We chose to group studies based on the core strategies used in each intervention. In some cases this approach functionally grouped interventions that may have used specific, manualized techniques with others that used only a subset of those techniques (e.g., Ayres-based sensory integration and sensory integration models that may have used some Ayres strategies). As noted, no alternative analytic approaches (e.g., considering Ayres-based approaches and other sensory integration approaches as separate categories) would have changed our overall strength of evidence assessment.

This review was also focused specifically on children with ASD and specifically on interventions targeting sensory challenges. Sensory approaches may be used with individuals with other impairments, and findings may be generalizable to children with ASD; however, including studies in children with other conditions was beyond the scope of the current review.

We also recognize that interventions with a primarily educational or behavioral focus may also address sensory-related outcomes, but inclusion of any intervention approach reporting a sensory-related outcome was outside the scope of the current review. Similarly, we focused on child-related outcomes and did not address measures of parent stress, despite the key importance of the outcome and family context. Finally, we used a non-validated 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 (median 34 total) and typically limited duration of intervention and followup after intervention. Populations across studies were heterogeneous in terms of sensory challenges, ASD severity, age, and intellectual and adaptive functioning. Roughly half of studies (12 of 23) did not control for concomitant interventions or report assessment of treatment fidelity. Few used an appropriate statistical analysis (e.g., correction for multiple testing). Ten of 23 studies did not use blinded outcome assessors.

Interventions, even within our broader categories, used differing sensory-specific approaches in differing combinations of components, settings, and duration. Longer-term outcomes are limited as is our ability to determine effects of intervention on the underlying sensory challenges themselves. Potential harms of interventions were addressed in only one study, and few studies assessed potential factors that may modify effectiveness or drive effects of interventions. Studies

often used multicomponent strategies, and teasing apart effects of specific components is not currently possible.

Despite these limitations, investigators have made significant improvements in incorporating commonly used measures of symptom severity, behavior, language, and sensory difficulties to facilitate comparisons across studies. Parent-reported outcomes are necessary in this population of children, many of whom may not be able to complete aspects of assessments; however, studies are increasingly incorporating standardized interactive or observational measurement strategies. As noted above, the increasing use of treatment fidelity measures and replicable intervention protocols establishes a promising baseline for future investigations. Investigators in the area are also well-aware of the challenges of conducting research using a disparate and variously defined set of approaches in a highly heterogeneous population and have made strides in incorporating outcome measures that attempt to balance heterogeneity and comparative effectiveness and measures of intervention fidelity.[15]

Research Gaps and Areas for Future Research

Improving research in this area should also include considerations of power and sample size. Sample size was frequently insufficient to allow firm conclusions. In addition, researchers should continue to provide adequate detail as they describe their populations and interventions to allow for replicable research. Ideally, investigators publish the treatment manuals they develop, which are then referenced in later research; despite gains in this area, many studies made general references to their use of an underlying approach without specifying the ways in which they used or modified the technique. Lack of detail about the intervention makes it difficult to assess the applicability of individual studies, to synthesize groups of studies, or to replicate studies.

Duration of treatment and followup were generally short, and the extent to which effects of therapies could be expected to continue after cessation of treatment is not clear.
While some approaches may not hypothesize such durability (i.e., approaches designed for ongoing use with improvements associated with continued treatment), such data are ultimately necessary for guiding pragmatic implementation and setting realistic expectations of effects for clinicians and families.

In addition, few studies adequately accounted for concomitant interventions that might confound observed effectiveness. Accounting for concomitant interventions should be standardized in future research.

As noted, more studies used a common set of outcome measures, but the extent to which these measures assess changes in potential underlying sensory-related impairments is not clear, and understanding whether intervention can alter potential impairments in sensory processing (vs. altering behavioral responses in the short term) is a critical need. Translational work to understand the relationship between sensory symptoms and their potential neurobiology would inform intervention design.

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 intervention and limited characterization of the extent or type of sensory challenges children experience at baseline. Interventions targeting sensory challenges by their nature often employ multiple components, and data on whether specific functional components of the interventions drive effectiveness are currently unavailable. Component analyses in this field would be productive for refining intervention approaches and for assessing applicability and generalizability of the results.

In line with this need, we recommend future consideration of the ways in which the cultural context of the child and family may affect the applicability or effectiveness of specific interventions. The setting of interventions may also influence effects, and understanding the role of context broadly in contributing to effects is an important need. As noted, understanding the extent to which findings from studies of these interventions in children with other conditions are applicable to children with ASD may help to bolster the evidence base.

Conclusions

Some interventions targeting sensory challenges may lead to modest improvements primarily in sensory- and ASD symptom severity-related outcomes; however, the evidence base for any category of intervention is small, and durability of effects beyond the immediate intervention period is unclear. Sensory integration-based approaches improved outcomes related to sensory challenges and motor skills, and studies of massage reported improvements in sensory responses and ASD symptoms. Environmental enrichment was also associated with improvements in nonverbal cognitive skills in the short-term. Auditory integration-based approaches did not improve language outcomes. Some positive effects were associated with other approaches studied (music therapy, weighted blankets) but findings in these small studies were not consistent. Data on longer-term results are lacking, as are data on characteristics that modify outcomes, generalizability of findings, and components of interventions that may drive effects. In sum, while some therapies may hold promise and warrant further study, substantial needs exist for continuing improvements in methodologic rigor in the field.

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Acronyms and Abbreviations

ABC	Autism Behavior Checklist
ADOS	Autism Diagnostic Observation Schedule
AHRQ	Agency for Healthcare Research And Quality
ASD	Autism Spectrum Disorder
CARS	Childhood Autism Rating Scale
CER	Comparative Effectiveness Review
DSM	*Diagnostic and Statistical Manual*
G	Group
GAS	Goal Attainment Setting
IQ	Intelligence Quotient
KQ	Key Question
n	Number
NR	Not Reported
NS	Not Significant
OT/SI	Occupational Therapy with Sensory Integration
PDDBI	Pervasive Development Disorder Behavior Inventory
PDD-NOS	Pervasive Developmental Disorder – Not Otherwise Specified
PICOTS	Population, Intervention, Comparator, Outcome, Timing, Setting
PLS	Preschool Language Scale
QST	Qigong Sensory Training
RCT	Randomized Controlled Trial
SI	Sensory Integration
SOE	Strength of Evidence
SSC	Sense And Self-Regulation Checklist
TEP	Technical Expert Panel
VABS	Vineland Adaptive Behavior Scales

Appendix A. Detailed Methods

Topic Surveillance and Review Protocol

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*.[1] The topic for the original report[2] was nominated by Autism Speaks in a public process using the Effective Health Care website. AHRQ published an update addressing behavioral interventions in 2014.[3] 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 approaches to address sensory challenges and medical approaches (reported in a separate update). These areas reflect both areas of clinical relevance and sufficient newly published literature for a review update. Given the different foci of these interventions (i.e., sensory challenges and challenging behaviors) and subsequent differences in study populations, we report findings in two separate reviews.

Based also on the surveillance process and discussions with stakeholders, we revised the KQ addressed in the 2011 report 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 therapies for children with ASD, we used four key databases: the MEDLINE® medical literature database via the PubMed® interface; EMBASE (Excerpta Medica Database), an international biomedical and pharmacological

literature database via the Ovid® interface; the Cumulative Index of Nursing and Allied Health Literature (CINAHL), and PsycINFO®. Search strategies for KQs applied a combination of controlled vocabulary (Medical Subject Headings [MeSH] and Emtree headings) to focus specifically on interventions targeting sensory challenges in children with ASD and harms of interventions (Appendix B). We restricted literature searches for KQs to studies published from 2010 to September 2016 to reflect literature available since the publication of the 2011 review. We will update searches while the report is undergoing peer review.

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 and other trial registries for information about relevant ongoing trials and to confirm that we have obtained available publications of results from completed trials.

Inclusion and Exclusion Criteria

Table A-1 outlines inclusion criteria. We required that eligible 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 recognize that these study design criteria excluded single-subject or single-case experimental designs that have been used to study interventions targeting sensory challenges. These studies are challenging to incorporate in a meaningful way in comparative effectiveness reviews, which attempt to evaluate the effectiveness of interventions at the population level. To mitigate the exclusion of such studies; however, we include summaries of recent reviews that have included such studies and discuss our findings in light of those in other reviews (see Findings in Relation to What is Known).

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. Studies also included only children with a diagnosis of ASD (or data reported separately for children with ASD).

Table A-1. Inclusion criteria

Category	Criteria
Study Population	Children ages 2-12 with ASD (mean age plus standard deviation is ≤ 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

Category	Criteria
	reviews Studies must have relevant population and ≥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 -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

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 Key Questions for inclusion or exclusion, using an Abstract Review Form (Appendix C). 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 C) 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 D 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://srdr.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

Studies were too heterogeneous to allow for meta-analyses. We summarized data for Key Questions qualitatively using summary tables.

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*.[1] This risk of bias approach considers factors related to study design, diagnostic approach, participant ascertainment, intervention characteristics, outcomes measurement, and statistical approach and includes questions such as: Did the authors report differences in or hold steady all concomitant interventions? Were outcomes coded and assessed by individuals blinded to the intervention status of the participants? For randomized controlled trials, was there an intent-to-treat analysis? Two senior investigators assessed each included study independently with disagreements resolved through discussion. Appendix C includes our risk of bias assessment form, and Appendix E includes the risk of bias 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 described above individually and 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 on questions related to randomization and diagnostic approach to be considered low risk of bias. Scores were calculated first by domain and then summed and weighted as described in Table A-2 to determine overall study risk. 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 (10 total points).

Table A-2. Quality scoring algorithm

Definition and Scoring Algorithm	Rating
• ≥8/10 points, including a ++ on study design and ++ on diagnostic approach	Low risk of bias
• ≥6/10 points, including at least a + on intervention	Moderate risk of bias
• ≤5/10 points	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*[1] and are based on consideration of five domains (Table A-3): 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[2] 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 A-3. Domains used to assess strength of evidence[a]

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: • Direction of effect: Effect sizes have the same sign (that is, are on the same side of no effect or a minimally important difference). • Magnitude of effect: The range of effect sizes is similar.
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: • Outcome being graded is considered intermediate in a review that is focused on clinical health outcomes (such as morbidity, mortality). • Data do not come from head-to-head comparisons but rather from two or more bodies of evidence to compare. • 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.
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.

[a] Excerpted from Berkman et al. 2013[4]

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 F.

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.

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Appendix B. Search Strategies

Table B-1.Treatment/intervention
Interface: PubMed; Database: Medline

	Search	Records
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 B-2. Sensory integration search in CINAHL
Interface: EBSCO host; Database: CINAHL

	Search	Records
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 "Sensory Motor Integration") OR (MH "Psychomotor Performance+") OR (MH "Motor Skills+")	15,630
7	(MH "Occupational Therapy") OR (MH "Pediatric Occupational Therapy")	15,278
8	sensory	12,670
9	#7 AND #8	512
10	#6 OR #9	15,853
11	#5 AND #10	461
12	#11 limited to 2010-2015	263
13	#12 limited to English language	262

Table B-3. Sensory integration search in PsycInfo
Database: PsycInfo

Search	Records
SU.EXACT.EXPLODE("Sensory Integration") AND SU.EXACT.EXPLODE("Autism") Limited to 2010-2015	39

Appendix C. Screening and Quality Assessment Forms

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

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

□ 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. 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 ≤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 D. 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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11. AHRQ Comparative Effectiveness Reviews Therapies for Children With Autism Spectrum Disorders: A Review of the Research for Parents and Caregivers. Comparative Effectiveness Review Summary Guides for Consumers. Rockville (MD): Agency for Healthcare Research and Quality (US); 2005. X-1

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X-2
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Appendix E. Risk of Bias Ratings

Table E-1. Risk of bias assessments

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
Srinivasan 2016[1, 2]	+	+	+	-	+	-	+	+	NA	+	+	+	-	+	+	+	-	-	Moderate
Ghas-emtabar 2015[3]	+	-	+	NA	-	-	+	+	NA	+	-	-	-	+	+	+	-	-	High
Silva 2015[4]	+	+	-	-	+	+	+	+	+	+	+	+	+	+	+	+	+	-	Moderate
Woo 2015[5]	+	+	+	-	++	+	+	+	-	+	+	+	+	+	-	+	+	-	Low
Gringras 2014[6]	+	+	+	+	++	+	-	+	-	+	+	+	+	+	+	+	+	-	Moderate
Iwanaga 2014[7]	+	-	+	NA	+	+	+	+	-	+	-	-	+	+	+	+	-	-	High
Latham 2014[8]	+	+	+	-	++	+	+	+	NA	+	+	+	-	+	+	+	-	-	High
Porges 2014[9] **(Trial 1 and 2)**	+	+	+	-	++	-	-	+	-	+	-	-	-	-	-	+	+	-	High
Schaaf 2014[10]	+	+	+	+	++	+	+	+	NA	+	+	+	+	+	+	+	+	-	Moderate
Thompson 2014[11]	+	+	+	+	++	+	-	+	NA	+	+	+	+	+	+	+	-	-	Moderate

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
Silva 2013[12]	+	-	+	NA	+	-	+	NA	NA	+	+	-	-	+	+	+	-	-	High
Woo 2013[13]	+	+	+	-	+	+	+	-	-	+	-	-	+	+	+	+	+	-	Moderate
Gattino 2011[14]	+	+	-	+	++	-	+	+	NA	+	+	+	+	+	+	+	+	+	Low
Pfeiffer 2011[15]	+	+	+	+	++	+	+	+	NA	+	+	+	+	+	+	+	+	-	Low
Silva 2011[16]	+	+	+	-	++	+	+	+	-	+	-	NA	+	+	+	+	+	+	Moderate
Piravej 2009[17]	+	+	+	+	++	-	+	-	-	+	-	+	-	+	+	+	-	-	High
Silva 2009[18]	+	+	+	-	+	-	-	+	-	+	+	-	+	+	+	-	-	-	High
Fazlioglu 2008[19]	+	+	+	+	++	-	+	+	NA	+	-	-	-	+	+	+	-	-	High
Kim 2008[20]	+	+	+	-	++	-	-	+	-	-	-	NA	+	+	+	+	+	-	High
Lee 2008[21]	+	-	+	NA	+	-	+	+	-	+	-	-	-	+	+	+	-	-	High
Corbett 2007[22]	+	+	+	-	++	+	+	-	NA	+	-	-	-	+	+	+	+	-	Moderate
Silva 2007[23]	+	+	+	+	++	+	+	+	-	+	NA	-	+	+	+	+	+	-	Moderate
Mudford 2000[24]	+	+	+	-	+	-	+	+	-	+	-	-	-	+	+	+	+	-	Moderate

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Appendix F. Applicability of Findings

Table F-1. Applicability of evidence for sensory integration

Domain	Description of applicability of evidence
Population	Studies included children ages 2 up to 12 years and vast majority were males (80% or higher in all studies). Most studies included children with difficulty processing and integrating sensory information. Mean IQ was reported in three studies with values ranging from 90 to 110. The fourth study recruited children aged 7 to 11 from a special education program the majority of whom were non-verbal. Participants were often receiving concomitant behavioral and or pharmacological treatments.
Intervention	Sensory integration.
Comparators	Comparators included fine motor intervention, group therapy and usual care.
Outcomes	Outcomes included sensory problems, cognition, verbal, motor, speech, and behavior. Assessment using Japanese version of MAP, Goal Attainment Scaling, Pediatric Evaluation of Disability Inventory, PDDBI, VABS, Sensory Evaluation for Children, Sensory Processing Measure, and Social Responsiveness Scale. Treatment duration ranged from 6 weeks up to 10 months with no long-term follow-up.
Setting	Two studies were conducted in the United States and one each in Japan and Turkey.

PDDBI = Pervasive Developmental Disorders Behavior Inventory; VABS = Vineland Adaptive Behavior Scale; MAP = Miller Assessment for Preschoolers

Table F-2. Applicability of evidence for environmental enrichment

Domain	Description of applicability of evidence
Population	Participants ranged in age from 3 to 12 years old and were exclusively male in one study. The second study restricted to ages 3 to 6 and included a small number of female participants (14%). Most were receiving concomitant behavior therapies. Autism diagnosis was confirmed by ADOS scoring in both studies.
Intervention	Sensorimotor enrichment- daily exposure to multiple sensori motor stimuli.
Comparators	The comparator for both studies was standard care.
Outcomes	Outcomes included change in autism severity measured by CARS and ADOS and cognition determined by Leiter-R Visualization and Reasoning scores. Sensory reactivity was assessed using the Short Sensory Profile. Interventions were 6 months duration in both studies.
Setting	Both studies were conducted at the same academic medical center in the United States.

ADOS = Autism Diagnostic Observation Scale; CARS = Childhood Autism Rating Scale

Table F-3. Applicability of evidence for auditory integration

Domain	Description of applicability of evidence
Population	Children ranged from ages 3-13 years. All participants had a diagnosis of autism and were low-functioning, having significant cognitive and/or language delays.
Intervention	Auditory integration using the Tomatis method or a more generalized training protocol.
Comparators	Both studies used a crossover design comparing auditory integration to placebo within individual subjects.
Outcomes	Outcomes included behavior, cognitive and language skills obtained from direct observation and parent reports. Assessment tools used included VABS, Reynell Language Development Scales, Leiter International Performance Scale, ADOS, Stanford- Binet Intelligence Scale, Peabody Picture Vocabulary test, and Expressive One Word Vocabulary test. Both interventions were less than 1 month duration.
Setting	One study was conducted in the United States and one in the United Kingdom.

ADOS = Autism Diagnostic Observation Scale; VABS = Vineland Adaptive Behavior Scale

Table F-4. Applicability of evidence for music therapy

Domain	Description of applicability of evidence
Population	Most studies were conducted in preschool aged children except for two studies that included children up to age 12. The severity of ASD varied widely with some studies including mild to moderate ASD and others including children with severe ASD based on CARS scores and including verbal and non-verbal participants.
Intervention	Music therapy, filtered music.
Comparators	Comparators included unfiltered music, headphone control, toy play, robotic interventions, tabletop activities, and no intervention
Outcomes	Outcomes included social engagement, social skills, speech and language, joint attention and non-verbal social communication, and hearing sensitivity. The instruments used to assess changes included VSEEC, SSRS, PDDBI, ESCS, measures of joint attention, and parent questionnaires on hearing sensitivity. Interventions were of short duration ranging from 1 up to 16 weeks with no long-term follow-up. One Iranian study in school-aged children assessed social skills two months after intervention.
Setting	Studies were conducted in the United States, Brazil, Australia, Korea and Iran.

CARS = Childhood Autism Rating Scale; VSEEC = Vineland Social-Emotional Early Childhood ; SSRS = Social Skills Rating System; PDDBI = Pervasive Developmental Disorders Behavior Inventory; ESCS = Early Social Communication Scales

Table F-5. Applicability of evidence for massage/touch therapy

Domain	Description of applicability of evidence
Population	Participants ranged in age from 3 to 16 years across studies. Majority of study participants were male. The severity of ASD including degree of intellectual disability was not well characterized.
Intervention	Qigong sensory massage, other massage
Comparators	Comparators were observation or waitlist controls andmassage plus sensory intervention and attachment therapy alone.
Outcomes	Outcomes included sensory impairment, adaptive behavior, autistic behavior, language skills, social abilities, and bowel and sleep abnormalities. Measurement instruments included Sensory Profile, ABC, VABS, PDDBI, and parent questionnaires to describe bowel and sleep patterns. The massage studies were of 4-5 months duration.
Setting	Studies were conducted in the United States and Korea

ABC = Autism Behavior Checklist; VABS = Vineland Adaptive Behavior Scale; PDDBI = Pervasive Developmental Disorders Behavior Inventory

Appendix G. Detailed Table of Findings

Table G-1. Key findings in studies of interventions targeting sensory challenges

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
Sensory Integration-based Approaches			
Iwanaga 2014[1] Retrospective Cohort G1: Sensory integration therapy (SIT), 8/8 G2: Group therapy (GT), 12/12 8 – 10 months/EOT High ROB	Age, months G1: 56.8 ± 9.0 G2: 56.3 ± 6.8 IQ G1: 100.7 ± 9.6 G2: 94.8 ± 9.1	Japanese Miller Assessment for Preschoolers Total Score G1: ND G2: ND Index Score G1: ND G2: ND Coordination Index Score G1: ND G2: ND Nonverbal Index Score G1: ND G2: ND Complex Index Score G1: ND G2: ND Verbal Index Score G1: ND G2: ND	**Mean change score from baseline** Japanese Miller Assessment for Preschoolers (mean gain) Total Score G1: 34.38 ± 21.98 G2: 8.25 ± 11.69 G1 vs. G2: p=0.005 Foundation Index Score G1: 34.13 ± 34.21 G2: 11.33 ± 25.54 G1 vs. G2: p=ns Coordination Index Score G1: 46.75 ± 36.26 G2: 8.92 ± 17.87 G1 vs. G2: p=0.008 Nonverbal Index Score G1: 45 ± 24.26 G2: 8.25±36.6 G1 vs. G2: p=0.016 Complex Index Score G1: 30.75 ± 20.73 G2: 3.83 ± 31.2 G1 vs. G2: p=0.034 Verbal Index Score G1: 13 ± 44.26 G2: 14.67±31.2 G1 vs. G2: p=ns

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
Schaaf 2014[2] RCT G1: Sensory integration, 17/17 G2: Usual care, 15/14 10 weeks/EOT Moderate ROB	Age, months G1: 71.35 ± 14.90 G2: 72.33 ± 10.81 IQ (Full scale) G1: 89.75 ± 18.74 G2: 91.86 ± 11.93	Goal Attainment Scaling (GAS) G1: ND G2: ND Pediatric Evaluation of Disability Inventory (PEDI) Functional skills - Self-Care G1: ND G2: ND Functional skills - Mobility G1: ND G2: ND Functional skills - Social G1: ND G2: ND Caregiver assistance – Self-care G1: ND G2: ND Caregiver assistance – Mobility G1: ND G2: ND Caregiver assistance – Social G1: ND G2: ND Pervasive Developmental Disorders Behavior Inventory (PDDI) G1: ND G2: ND	**Mean change score from baseline** Goal Attainment Scaling (GAS) G1: 56.53 ± 12.38 G2: 42.71 ± 11.21 G1 vs. G2: p=0.003 Pediatric Evaluation of Disability Inventory (PEDI) Change scores Functional skills - Self-Care G1: 10.2 ± 22.6 G2: 1.12 ± 5.6 G1 vs. G2: p=ns Functional skills - Mobility G1: 6.57 ± 23.8 G2: 6.38 ± 15.1 G1 vs. G2: p=ns Functional skills - Social G1: 9.3 ± 17.4 G2: 4.4 ± 13.8 G1 vs. G2: p=ns Caregiver assistance – Self-care G1: 16.6 ± 23 G2: -0.43 ± 8.6 G1 vs. G2: p=0.008 Caregiver assistance – Mobility G1: 4.8 ± 24.1 G2: 0.22 ± 11.8 G1 vs. G2: p=ns Caregiver assistance – Social G1: 14.4 ± 23.4 G2: -1.8 ± 19

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
		Vineland Behavior Scales-II (VABS) G1: ND G2: ND	G1 vs. G2: p=0.039 Pervasive Developmental Disorders Behavior Inventory (PDDI) Change scores S/P Approach G1: -5.9 ± 10.8 G2: -0.67 ± 5.9 G1 vs. G2: p=ns R/R G1: -6.5 ± 13.7 G2: -1.77 ± 6.3 G1 vs. G2: p=ns Arouse G1: -7.1 ± 11.6 G2: -3.3 ± 6.0 G1 vs. G2: p=ns Vineland Behavior Scales-II (VABS) Change scores Communication G1: 5.06 ± 10.9 G2: -3.38 ± 18.6 G1 vs. G2: p=ns Daily Living Skills G1: 4.2 ± 11.6 G2: -3.0 ± 18.5 G1 vs. G2: p=ns Socialization G1: 3.8 ± 11.8 G2: -6.7 ± 21.8 G1 vs. G2: p=ns Composite G1: 15.1 ± 44.7 G2: 0.0 ± 8.1 G1 vs. G2: p=ns

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
Pfeiffer 2011[3] RCT G1: SI treatment, 20/20 G2: Fine motor, 17/17 6 weeks/EOT Low ROB	Age, months G1: 100.00 ± 24.78 G2: 110.47 ± 24.78 IQ NR	Vineland Adaptive Behavioral Scales Communication G1: 62.90 ± 13.39 G2: 64.24 ± 9.62 Socialization G1: 63.90 ± 17.71 G2: 64.24 ± 9.33 Motor G1: 60.70 ± 13.20 G2: 61.00 ± 11.24 Composite G1: 66.80 ± 16.66 G2: 70.18 ± 14.07 Sensory Processing Measure - Total G1: 68.50 ± 5.62 G2: 67.88 ± 7.28 Social Responsiveness Scale - Total G1: 82.95 ± 6.37 G2: 82.71 ± 9.10	**EOT** Vineland Adaptive Behavioral Scales NR Sensory Processing Measure - Total G1 vs. G2: p=ns Social Responsiveness Scale - Total G1 vs. G2: p=ns GAS-Parent rated G1 > G2 G1 vs. G2: p<0.05; ES=0.125 GAS-Teacher rated G1 > G2 G1 vs. G2: p<0.01; ES=0.360
Fazlioglu et al. 2008[4] RCT G1: Sensory Integration, 15/15 G2: Control (Special Education), 15/15 12 weeks/EOT High ROB	Age G1 + G2: 7-11 IQ NR	Sensory Evaluation Form for Children with Autism G1: 98.2 ± 19.3 G2: 95.8 ± 17	Sensory Evaluation Form for Children with Autism G1: 66.5 ± 11.4 G2: 97.3 ± 17.8 G1 vs. G2: p<0.05
Environmental Enrichment-based Approaches			

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
Woo 2013[5] RCT G1: Sensorimotor enrichment group + standard care, 13/13 G2: Standard care, 15/15 6 months/EOT Moderate ROB	Age G1 + G2: 6.6 ± 2.5 IQ NR	CARS – Autism Severity, mean ± se G1: 34.38 ± 0.72 G2: 38.07 ± 1.71 Leiter-R – Nonverbal Test Scale G1: 48.46 ± 5.52 G2: 46.2 ± 6.36 EOWPV – Expressive Language Scale G1: ND G2: ND	**EOT** CARS – Autism Severity G1: 31.12 ± 1.46 G2: 37.61 ± 1.67 G1 vs. G2: p=0.03 Leiter-R – Nonverbal Test Scale G1: 57.23 ± 5.5 G2: 43.7 ± 6.89 G1 vs. G2: p=0.008 Change in EOWPV – Expressive Language Scale G1: 4.7 G2: 4.67 G1 vs. G2: p=ns
Woo 2015[6] RCT G1: Standard care + sensorimotor enrichment, 64/28 G2: Standard care, 27/22 6 months/EOT Low ROB	Age G1: 4.76 ± 1.14 G2: 4.54 ± 1.10 IQ G1: 82.96 ± 5.17 G2: 76.63 ± 4.96	ADOS – Severity G1: ND G2: ND RDLS Receptive Language G1: 36.19 ± 4.64 G2: 33.37 ± 4.79 Expressive Language G1: 31.46 ± 4.14 G2: 31.47 ± 4.82 Leiter-R Nonverbal Test Score G1: 35.85 ± 4.76 G2: 32.63 ± 6.07 IQ Score G1: 82.96 ± 5.17 G2: 76.63 ± 4.96 SSP – Atypical Sensory Responses G1: 113.75 ± 4.76	**EOT** ADOS – Severity G1: 6 (21) G2: 0 (0) G1 vs. G2: p=0.01 RDLS Receptive Language G1: 43.62 ± 4.14 G2: 37 ± 4.95 G1 vs. G2: p=0.048 Expressive Language G1: 38.65 ± 4.16 G2: 37.16 ± 4.94 G1 vs. G2: p=ns Leiter-R Nonverbal Test Score G1: 49.19 ± 5.48 G2: 40.05 ± 6.25 G1 vs. G2: p=0.024 IQ Score G1: 91.38 ± 5.58 G2: 78.16 ± 4.49 G1 vs. G2: p=0.037

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
		G2: 129.3 ± 4.29	SSP – Atypical Sensory Responses G1: 125.11 ± 5.42 G2: 132.15 ± 4.09 G1 vs. G2: p=0.037
Auditory Integration-based Approaches			
Mudford 2000[7] RCT G1: Auditory integration, 21/21 G2: Control Treatment, 21/21 10 days (2 session/day)/EOT Moderate ROB	Age G1 + G2: 9.42 years ± 29 months IQ NR	ABC-Hyperactivity 23.7 ± 9.4 NCBRF-Hyperactivity 13.9 ± 5.5	**Mean change from baseline** ABC-Hyperactivity G1: 0.3 ± 3.6 G2: -4.1 ± 3.9 NCBRF-Hyperactivity G1: -0.3 ± 2 G2: -2 ± 2.2
Corbett 2008[8] RCT G1: Tomatis Sound Therapy/Placebo, 11/11 G2: Placebo/Tomatis Sound Therapy, 11/11 25 days (2 blocks)/EOT Moderate ROB	Age G1 + G2: 3-7 IQ (range) G1 + G2: 52-83	PPVT G1: 20.83 ± 28.52 G2: 32.20 ± 25.21 EOWVT G1: 16.50 ± 21.11 G2: 25.20 ± 19.82	**EOT** PPVT G1: 22.83 ± 29.36 G2: 47.20 ± 24.45 EOWVT G1: 21.50 ± 23.30 G2: 34.40 ± 25

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
Porges 2014[9] RCT G1: Filtered music, 28/28 G2: Headphones only, 36/36 1 week/EOT High ROB	Age NR IQ NR	Parent questionnaire Hearing sensitivity G1: 18 (50) G2: 12 (43) Affect G1: 16 (44) G2: 17 (61) Eye contact G1: 27 (75) G2: 17 (61) Behavioral organization G1: 19 (53) G2: 16 (57) Emotional control G1: 18 (50) G2: 12 (43) Spontaneous speech G1: 27 (75) G2: 23 (82) Receptive speech G1: 26 (72) G2: 23 (82) Listening G1: 29 (81) G2: 24 (86) Spontaneity G1: 25 (69) G2: 20 (71) Relatedness G1: 30 (83) G2: 23 (82)	**EOT** Parent questionnaire Hearing sensitivity G1: 9 (50) G2: 1 (8) G1 vs. G2: p=0.017 Affect G1: 3 (19) G2: 1 (18) Eye contact G1: 11 (41) G2: 4 (24) Behavioral organization G1: 5 (26) G2: 0 (0) G1 vs. G2: p=0.027 Emotional control G1: 3 (17) G2: 0 (0) Spontaneous speech G1: 13 (48) G2: 4 (17) G1 vs. G2: p=0.022 Receptive speech G1: 8 (31) G2: 2 (9) Listening G1: 12 (41) G2: 2 (8) G1 vs. G2: p=0.006 Spontaneity G1: 12 (48) G2: 4 (20) Relatedness G1: 9 (30) G2: 3 (13)

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
Porges 2014[9] RCT G1: Filtered music, 50/50 G2: Unfiltered music, 32/32 1 week/EOT High ROB	Age, months G1: 53.33 ± 15.95 G2: 56.74 ± 9.25 IQ NR	Parent questionnaire Hearing sensitivity G1: 23 (46) G2: 16 (50) Affect G1: 32 (64) G2: 19 (59) Eye contact G1: 30 (60) G2: 20 (63) Behavioral organization G1: 28 (56) G2: 17 (53) Emotional control G1: 33 (66) G2: 19 (59) Spontaneous speech G1: 41 (82) G2: 25 (78) Receptive speech G1: 45 (90) G2: 26 (81) Listening G1: 37 (74) G2: 21 (66) Spontaneity G1: 22 (44) G2: 14 (44) Relatedness G1: 32 (64) G2: 21 (66)	**EOT** Parent questionnaire Hearing sensitivity G1: 10 (43) G2: 2 (13) G1 vs. G2: p=0.040 Affect G1: 8 (25) G2: 4 (21) Eye contact G1: 10 (33) G2: 8 (40) Behavioral organization G1: 8 (29) G2: 3 (18) Emotional control G1: 8 (24) G2: 0 (0) G1 vs. G2: p=0.019 Spontaneous speech G1: 21 (51) G2: 11 (44) Receptive speech G1: 4 (9) G2: 4 (15) Listening G1: 11 (30) G2: 6 (29) Spontaneity G1: 8 (36) G2: 5 (36) Relatedness G1: 11 (34) G2: 6 (29)
Music Therapy-based Approaches			
Srinivasan 2016[10, 11]	Age	Training Specific	Joint Attention Test –

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
RCT G1: Rhythm Group, 12/11 G2: Robot Group, 12/11 G3: Standard Care, 12/11 8 weeks/EOT Moderate ROB	G1 + G2: 5-12 IQ NR	Measure – Response to Social Bids (total word count) Early NR Training Specific Measure – Response to Social Bids (total word count) Mid NR Training Specific Measure – Response to Social Bids (total word count) Late NR Training Specific Measure - Verbalization to social partners (percent duration) Early – Trainer NR Training Specific Measure - Verbalization to social partners (percent duration) Early - Adult Model NR Training Specific Measure - Verbalization to social partners (percent duration) Mid – Trainer NR Training Specific Measure -	Total Score G1 vs G2 vs G3, p=NS; SMD=0.55, CI (SMD)=-0.13 to 1.24 G1 vs G2 vs G3, p=NS; SMD=0.25, CI (SMD)=-0.38 to 0.89 G1 vs G2 vs G3, p=NS; SMD=0.71, CI (SMD)=-0.01 to 1.43 Training Specific Measure – Response to Social Bids (total word count) Early G1: 4.4 ± 4.19 G2: 5.92 ± 7.04 G3: 4.5 ± 3.9 Training Specific Measure – Response to Social Bids (total word count) Mid G1: 3.8 ± 3.29 G2: 7.25 ± 6.74 G3: 7.33 ± 8.81 Training Specific Measure – Response to Social Bids (total word count) Late G1: 9.8 ± 8.53 G2: 7.67 ± 7.6 G3: 5.67 ± 4.16 Training Specific Measure - Verbalization to social partners (percent duration) Early – Trainer G1: 6.1 ± 5.7 G2: 3.9 ± 4.2 G3: 12.1 ± 8.6 Training Specific

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
		Verbalization to social partners (percent duration) Mid - Adult Model NR Training Specific Measure - Verbalization to social partners (percent duration) Late – Trainer NR Training Specific Measure - Verbalization to social partners (percent duration) Late - Adult Model NR Training Specific Measure - Vocalization patterns NR Training Specific Measure - Verbalization patterns NR	Measure - Verbalization to social partners (percent duration) Early - Adult Model G1: 2.1 ± 2.3 G2: 1.9 ± 1.1 G3: 2 ± 1.6 Training Specific Measure - Verbalization to social partners (percent duration) Mid – Trainer G1: 12.8 ± 14.5 G2: 5.1 ± 5.3 G3: 14.5 ± 11.3 Training Specific Measure - Verbalization to social partners (percent duration) Mid - Adult Model G1: 1.8 ± 1.9 G2: 3.4 ± 1.7 G3: 2.2 ± 1.9 Training Specific Measure - Verbalization to social partners (percent duration) Late – Trainer G1: 14.8 ± 15 G2: 6.3 ± 6.1 G3: 14.4 ± 8.6 Training Specific Measure - Verbalization to social partners (percent duration) Late - Adult Model G1: 2.2 ± 2.3 G2: 5.4 ± 4.2 G3: 2.6 ± 2.4 Training Specific Measure - Vocalization

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
			patterns G2 vs G1,G3, p<0.002; SMD=0.75 to 0.76 Training Specific Measure - Verbalization patterns G1 vs G3, p=NS G3 vs G1,G2, p=0.001; SMD=0.78
Ghasemtabar 2015[12] Non-RCT G1: Music therapy, 13/13 G2: Control, 14/14 45 days/EOT High ROB	Age G1: 8.96 ± 1.36 G2: 9.23 ± 1.54 IQ NR	Social skills rating system G1: 27.69 ± 4.76 G2: 26.92 ± 4.49	Social skills rating system **(EOT)** G1: 30.55 ± 4.0 G2: 27.34 ± 3.54 **(Follow-up 2 mos)** G1: 30.61 ± 4.25 G2: 26.85 ± 3.82
Thompson 2014[13] RCT G1: Family-centered music therapy (FCMT), 12/11 G2: Early intervention programme, 11/10 16 weeks/EOT Moderate ROB	Age, months G1: 43.92 ± 6.46 G2: 47.00 ± 7.18 IQ NR	VSEEC - Social Interaction G1: 49.1 ± 12.4 G2: 45.09 ± 8.13 SRS G1: 105.4 ± 27.1 G2: 106.2 ± 26.1 MBCDI Speech and Language G1: 180 ± 108 G2: 170 ± 109 PCRI G1: 194.3 ± 23.1 G2: 191.6 ± 19.4	**Change scores from baseline** VSEEC - Social Interaction G1: 22.4 ± 10.1 G2: 0.9 ± 11.9 G1 vs. G2: p<0.001 SRS G1: -7.7 ± 17.3 G2: -1.4 ± 11.5 G1 vs. G2: p=ns MBCDI Speech and Language G1: 78.9 ± 73.4 G2: 58.7 ± 79.8 G1 vs. G2: p=ns PCRI G1: 8.0 ± 9.19 G2: 0.2 ± 10.3 G1 vs. G2: p=ns

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
Gattino 2011[14] RCT G1: Relational music therapy + clinical routine activities, 12/12 G2: Clinical routine activities, 12/12 7 months/EOT Low ROB	Age G1 + G2: 9.75 ± 1.39 IQ NR	CARS-Verbal Communication G1: 2.67 ± 0.49 G2: 2.54 ± 0.33 CARS-Non-Verbal Communication G1: 2.42 ± 0.42 G2: 2.08 ± 0.47 CARS-Social Communications G1: 12.29 ± 1.78 G2: 11.38 ± 1.65	CARS-Verbal Communication G1: 2.54 ± 0.45 G2: 2.58 ± 0.44 G1 vs G2, p=0.50; SMD=0.39 (95% CI= 0.21 to 0.57) CARS-Non-Verbal Communication G1: 2.5 ± 0.37 G2: 2.33 ± 0.54 G1 vs G2, p=0.35; SMD=0.39 (95% CI= 0.08 to 0.86) CARS-Social Communications G1: 12.25 ± 1.54 G2:11.92 ± 1.24 G1 vs G2, p=0.34; SMD=0.39 (95% CI=70.08 to 0.86)
Kim 2008[15] RCT G1: Music Therapy, 15/10 G2: Toy Play, 15/10 12 weekly, 30 min sessions/EOT High ROB	Age, months G1 + G2: 51.20 ± 12.08 IQ NR	PDDBI Level of agreement at pre-Rx: 0.19	PDDBI Level of agreement at post-Rx: 0.67 G1 vs. G2: p=ns
Massage/Touch			
Silva et al. 2015 [16] RCT G1: Qigong massage, 55/42 G2: Control, 48/42 5 months/EOT Moderate ROB	Age G1 + G2: 2-5 IQ NR	Aberrant Behavior Checklist G1: 82.4 ± 25.9 G2: 83.1 ± 25.9 VABS-Daily Living Skills G1: 34.3 ± 17.7 G2: 37.5 ± 20 VABS-Socialization	Aberrant Behavior Checklist G1: 62.4 ± 26.6 G2: 75.7 ± 28.6 G1 vs. G2: p=0.006 VABS-Daily Living Skills G1: 42.7 ± 19.1 G2: 45.9 ± 22.7 G1 vs. G2: p=NR

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
		G1: 36 ± 14.4 G2: 40.7 ± 17.4 Self-regulatory difficulties G1: 57.6 ± 11.2 G2: 57.4 ± 13.4 Abnormal Sensory Response G1: 39.7 ± 9.1 G2: 41.3 ± 10.3 Childhood Autism Rating Scale – total score G1: 39.7 ± 6.6 G2: 38 ± 7.8	VABS-Socialization G1: 45.7 ± 16.3 G2: 48.6 ± 21 G1 vs. G2: p=NR Self-regulatory difficulties G1: 45.1 ± 11.5 G2: 54 ± 14.5 G1 vs. G2: p=0.00006 Abnormal Sensory Response G1: 30.4 ± 9.8 G2: 38.6 ± 11.6 G1 vs. G2: p=0.00002 Childhood Autism Rating Scale – total score G1: 38.2 ± 6.6 G2: 37.7 ± 7.8 G1 vs. G2: p=ns
Silva et al. 2013[17] RCT G1: Qigong massage + qigong sensory training, 97/97 G2: Control, 32/32 5 months/EOT High ROB	Age G1: 3.87 ± 1.11 G2: 4.16 ± 0.95 IQ NR	Autism Parenting Stress Index G1: 24.35 ± 10.62 G2: 24.42 ± 11.62 Abnormal Tactile Response – total score G1: 20.91 ± 7.13 G2: 22.31 ± 8.52 Self-regulatory difficulties G1: 45.43 ± 11.21 G2: 50.94 ± 15.69	Autism Parenting Stress Index G1: 15.76 ± 8.16 G2: 21.53 ± 11.08 G1 vs. G2: p=0.001 Abnormal Tactile Response – total score G1: 15.57 ± 6.86 G2: 21.34 ± 8.41 G1 vs. G2: p<0.001 Self-regulatory difficulties G1: 34.3 ± 10.88 G2: 49.03 ± 15.45 G1 vs. G2: p<0.001

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
Silva 2011[18] RCT G1: Qigong massage, 28/24 G2: Wait-list control, 19/18 4 months/EOT Moderate ROB	Age, months G1 + G2: 58 IQ NR	Teacher ABC Autism Severity score G1: 76.3 ± 19.6 G2: 76.7 ± 30.1 PDDBI Sensory G1: 56.4 ± 10.6 G2: 56.5 ± 11.5 Maladaptive Behavior G1: 60.9 ± 13.0 G2: 61.8 ± 15.8 Social/Language/Communication Abilities G1: 49.9 ± 11.4 G2: 51.6 ± 12.1 SSC Sense G1: 38.1 ± 12.1 G2: 40.6 ± 14.6 Self-Regulation G1: 49.1 ± 11.7 G2: 48.9 ± 12.7 Autism Composite Score G1: 59.8 ± 11.1 G2: 60.2 ± 15.9	**EOT** ABC Autism Severity score G1: 56.1 ± 26.4 G2: 75.3 ± 38.9 G1 vs. G2: p=ns PDDBI Sensory G1: 50.1 ± 11.8 G2: 55.6 ± 10.0 G1 vs. G2: p=0.032 Maladaptive Behavior G1: 52.3 ± 14.9 G2: 61.3 ± 15.2 G1 vs. G2: p=0.003 Social/Language/Communication Abilities G1: 53.0 ± 10.7 G2: 53.1 ± 12.2 G1 vs. G2: p=ns SSC Sense G1: 28.5 ± 12.2 G2: 39.4 ± 12.6 G1 vs. G2: p=0.001 Self-Regulation G1: 39.2 ± 14.7 G2: 49.2 ± 11.6 G1 vs. G2: p=0.00002 Autism Composite Score G1: 50.9 ± 14.8 G2: 58.9 ± 12.3 G1 vs. G2: p=NR
Piravej 2009[19] RCT G1: Traditional Thai massage + sensory integration therapy, 30/30	Age G1: 4.84 ± 1.86 G2: 4.48 ± 1.8 IQ	CPRS-Conduct Problem G1: 0.69 ± 0.31 G2: 0.59 ± 0.34 CPRS-Learning	CPRS-Conduct Problem G1: 0.6 ± 0.26 G2: 0.63 ± 0.33 G1 vs. G2, p=0.03

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
G2: Sensory integration therapy, 30/30 8 weeks/EOT High ROB	ND	Problem G1: 1.86 ± 0.55 G2: 2.02 ± 0.56 CPRS-Psychosomatic G1: 0.41 ± 0.45 G2: 0.43 ± 0.34 CPRS-Impulsivity-Hyperactivity G1: 1.62 ± 0.6 G2: 1.65 ± 0.65 CPRS-Anxiety G1: 0.76 ± 0.53 G2: 0.62 ± 0.49 CPRS-Hyperactivity G1: 1.45 ± 0.51 G2: 1.53 ± 0.48 CTRS-Conduct Problem G1: 0.98 ± 0.38 G2: 1.11 ± 0.27 CTRS-Hyperactivity G1: 1.59 ± 0.49 G2: 1.8 ± 0.36 CTRS-Inattention-Passivity G1: 1.56 ± 0.41 G2: 1.67 ± 0.27 CTRS-Hyperactivity Index G1: 11.5 ± 9.23 G2: 13.9 ± 7.67 Sleep Diary G1: 11.5 ± 9.23 G2: 13.9 ± 7.67	CPRS-Learning Problem G1: 1.76 ± 0.48 G2: 1.87 ± 0.53 G1 vs. G2, p=ns CPRS-Psychosomatic G1: 0.41 ± 0.32 G2: 0.39 ± 0.25 G1 vs. G2, p=ns CPRS-Impulsivity-Hyperactivity G1: 1.44 ± 0.4 G2: 1.69 ± 0.57 G1 vs. G2, p=ns CPRS-Anxiety G1: 0.62 ± 0.56 G2: 0.73 ± 0.5 G1 vs. G2, p=0.01 CPRS-Hyperactivity G1: 1.32 ± 0.41 G2: 1.42 ± 0.42 G1 vs. G2, p=ns CTRS-Conduct Problem G1: 0.64 ± 0.35 G2: 0.71 ± 0.26 G1 vs. G2, p=ns CTRS-Hyperactivity G1: 1.24 ± 0.5 G2: 1.49 ± 0.37 G1 vs. G2, p=ns CTRS-Inattention-Passivity G1: 1.18 ± 0.51 G2: 1.34 ± 0.36 G1 vs. G2, p=ns CTRS-Hyperactivity Index

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
			G1: 1.1 ± 0.49 G2: 1.28 ± 0.4 G1 vs. G2, p=ns Sleep Behavior-Sleep Diary G1: 5.33 ± 3.28 G2: 8.2 ± 6.83 G1 vs. G2, p=ns
Silva et al. 2009[20] RCT G1: Qigong Sensory Training, 25/25 G2: Waitlist Control, 21/21 5 months/EOT High ROB	Age, months G1: 65.2 ± 20.7 G2: 53.3 ± 18.7 IQ NR	ABC – total score G1: 48.5 ± 20.8 G2: 64.3 ± 33.8 PDDI – Maladaptive Behavior Score (Parent) G1: 56.8 ± 11.5 G2: 59.5 ± 10.7 PDDI - Maladaptive Behavior Score (Teacher) G1: 50.9 ± 10.4 G2: 56.5 ± 13.3 PDDI – Social/Language/Communication score (Parent) G1: 57.5 ± 6.8 G2: 49 ± 13.1 PDDI – Social/Language/Communication score (Teacher) G1: 53.7 ± 9.7 G2: 47 ± 13 PDDI – Sensory score (Parent) G1: 54.2 ± 9.6 G2: 56 ± 9.6	ABC – total score G1: 33.9 ± 18.6 G2: 59.4 ± 35.4 G1 vs. G2: p=0.003 PDDI – Maladaptive Behavior Score (Parent) G1: 45.6 ± 10.8 G2: 57.5 ± 10.4 G1 vs. G2: p=0.0003 PDDI - Maladaptive Behavior Score (Teacher) G1: 44 ± 7.6 G2: 49.7 ± 12.2 G1 vs. G2: p=ns PDDI – Social/Language/Communication score (Parent) G1: 56.7 ± 9.7 G2: 49.2 ± 12.8 G1 vs. G2: p=0.007 PDDI – Social/Language/Communication score (Teacher) G1: 56.7 ± 9.7 G2: 47.6 ± 12.1 G1 vs. G2: p=0.010 PDDI – Sensory score

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
			(Parent) G1: 46.2 ± 9.1 G2: 55.3 ± 10 G1 vs. G2: p=0.005
Lee 2008[21] Prospective cohort G1: Massage therapy + attachment promotion program, 23/23 G2: Attachment promotion program, 21/21 4 months/EOT High ROB	Age, months G1: 19 ± 4 G2: 9 ± 12 IQ NR	Social Maturity Scale G1: 63.13 ± 15.76 G2: 51.24 ± 10.48 CARS-Total Score G1: 44.31 ± 0.57 G2: 41.76 ± 5.07	Social Maturity Scale G1: 70.74 ± 16.39 G2: 52.86 ± 10.18 G1 vs G2, p=0.005 CARS-Total Score G1: 37.74 ± 7.49 G2: 39.19 ± 5.43 G1 vs G2, p=NS
Silva 2007[22] RCT G1: Qigong Massage, 8/8 G2: No Treatment, 7/7 5 months/EOT Moderate ROB	Age G1 + G2: 2-6 IQ NR	VABS-Living Skills G1: 28.8 G2: 24.1 VABS-Socialization G1: 29.8 G2: 24.7 VABS-Receptive Language G1: 33.8 G2: 23.6 VABS-Expressive Language G1: 31.5 G2: 24.4 VABS-Gross Motor Skills G1: 37.5 G2: 33.4 VABS-Fine Motor Skills G1: 36 G2: 29 Short Sensory Profile – Total Score	**Mean Change Score from baseline** VABS-Living Skills G1: 9.8 G2: 0.9 G1 vs. G2: p=0.02 VABS-Socialization G1: 10 G2: 4.7 G1 vs. G2: p=0.04 VABS-Receptive Language G1: 8.3 G2: 10.6 G1 vs. G2: p=ns VABS-Expressive Language G1: 8.9 G2: 6.7 G1 vs. G2: p=ns VABS-Gross Motor Skills G1: 6.5 G2: 0.9 G1 vs. G2: p=ns

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
		G1: 16.2 G2: 15.7 ABC-Total Score G1: 71.3 G2: 87.7	VABS-Fine Motor Skills G1: 8.8 G2: 7.6 G1 vs. G2: p=ns Short Sensory Profile – Total Score G1: -5.4 G2: 2.7 G1 vs. G2: p=0.01 ABC-Total Score G1: -13.3 G2: -24.3 G1 vs. G2: p=ns
Tactile Input			
Latham 2014[23] RCT G1: Participation (tactual-kinesthetic experience), 17/17 G2: Observation, 17/17 24-48 hours/EOT High ROB	Age G1: 8.36 ± 2.6 G2: 8.69 ± 3.0 IQ NR	Verbal Scoring **Day 1 – Verbal 1** G1: 8.12 ± 5.52 G2: 6.00 ± 5.20 G1 vs. G2: p=0.041 **Day 1 – Verbal 2** G1: 7.76 ± 5.51 G2: 5.74 ± 5.41 G1 vs. G2: p=0.065 Non-Verbal Scoring **Day 1 – Score 1** G1: 8.10 ± 1.97 G2: 4.60 ± 3.42 G1 vs. G2: p=0.001 **Day 1 – Rating 1** G1: 2.95 ± 1.08 G2: 3.90 ± 1.16 G1 vs. G2: p=0.010	Verbal Scoring **Day 2 – Verbal 3** G1: 8.35 ± 6.06 G2: 5.39 ± 4.76 G1 vs. G2: p=0.031 **Day 2 – Verbal 4** G1: 8.25 ± 5.62 G2: 5.66 ± 5.02 G1 vs. G2: p=0.017 Non-Verbal Scoring **Day 2 - Score 2** G1: 8.35 ± 1.66 G2: 6.13 ± 3.47 G1 vs. G2: p=0.010 **Day 2 – Rating 2** G1: 2.88 ± 0.96 G2: 3.57 ± 1.23 G1 vs. G2: p=0.020
Weighted Blankets			
Gringras 2014[24] RCT G1: Weighted blanket, 36/27 G2: Control blanket, 37/27	Age G1: 8.7 ± 3.3 G2: 9.9 ± 2.8 IQ	% of time blanket in place, n=67 G1: 75.6 ± 25.4 G2: 73.7 ± 25.7	**EOT** % of time blanket in place G1 vs. G2: p=ns

Author, Year Study Design Groups, N Enrollment / N final Treatment Duration/Follow-up Time Point Post-Treatment Risk of Bias	Mean Age, Years ± SD Mean IQ ± SD	Outcome Measure/Baseline Scores, Mean ± SD	Outcome Measure/Post-Treatment Scores, mean ± SD
Crossover trial 73/54 2 weeks/EOT Moderate ROB	NR	TST, n=67 G1: 528.9 ± 127.1 G2: 513.0 ± 154.1 SOL min, n=67 G1: 55.6 ± 37.8 G2: 57.2 ± 42.8 Proportion of nights with ≥ 1 wake, n=67 G1: 0.2 ± 0.3 G2: 0.2 ± 0.3 Average time awake, n=67 G1: 15.6 ± 13.4 G2: 14.6 ± 13.3 TST min, n=65/66 G1: 454.4 ± 62.4 G2: 457.7 ± 64.6 SOL min, n=59 G1: 74.3 ± 48.7 G2: 69.9 ± 43.8 Sleep efficiency, %, n=59 G1: 73.4 ± 9.3 G2: 74.2 ± 7.8 No. of night wakenings, n=65/66 G1: 19.1 ± 6.7 G2: 19.5 ± 6.9 Time awake after sleep onset, n=65/66 G1: 84.1 ± 43.1 G2: 83.8 ± 41.4	TST G1 vs. G2: p=ns SOL min G1 vs. G2: p=ns Proportion of nights with ≥ 1 wake G1 vs. G2: p=ns Average time awake G1 vs. G2: p=ns TST min G1: 452.8 ± 65.0 G2: 455.4 ± 65.8 p=ns SOL min G1: 71.4 ± 48.2 G2: 70.6 ± 44.3 p=ns Sleep efficiency, %, G1: 73.6 ± 9.3 G2: 74.2 ± 8.0 p=ns No. of night wakenings G1: 19.5 ± 7.0 G2: 19.5 ± 6.8 p=ns Time awake after sleep onset G1: 84.6 ± 42.6 G2: 84.5 ± 41.5 p=ns

PDDBI = Pervasive Developmental Disorders Behavior Inventory; VABS = Vineland Adaptive Behavior Scale; MAP = Miller Assessment for Preschoolers; EOT = End of Treatment; GAS = Goal Attainment Scaling; PEDI = Pediatric Evaluation of Disability Inventory; CARS = Childhood Autism Rating Scale; Leiter-R = Leiter International Performance Scale-Revised; EOWPV = Expressive One-Word Picture Vocabulary Test; ADOS = Autism Diagnostic Observation Schedule; RDLS = Reynell Developmental Language Scales; SSP = Short Sensory

Profile; ABC = Autism Behavior Checklist; NCBRF = Nisonger Child Behavior Rating Form; PPVT = Peabody Picture Vocabulary Test; EOWVT = Expressive One Word Vocabulary Test; VSEEC = Vineland Social-Emotional Early Child-hood Scales; SRS = Social Responsiveness Scale; MBCDI = MacArthur-Bates Communicative Development Inventories; PCRI = Parent–Child Relationship Inventory; SC = Sense and Self-Regulation Checklist; TST = Total Sleep Time; SOL = Sleep Onset Latency

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