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 only behavioral interventions in 2014.[3] We conducted a surveillance process to assess the need to update the original 2011 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 suggested. We identified technical experts on the topic to provide input 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 information 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 A). We restricted literature searches for KQs to studies published from 2010 to November 2015 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 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 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 B). If one reviewer concluded that the article could be eligible for the review based on the abstract, we retained it. Following abstract review, two reviewers independently assessed the full text of each included study using a standardized form (Appendix B) that included questions stemming from our inclusion and exclusion criteria. A senior reviewer resolved disagreements between reviewers.

We conducted all abstract and full text reviews using the DistillerSR online screening application (Evidence Partners Incorporated, Ottawa, Ontario). Appendix C includes a list of excluded studies and the reasons for exclusion. Data extracted for each study are available via the Systematic Review Data Repository (http://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 B includes our risk of bias assessment form, and Appendix D 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 3 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 3. Quality scoring algorithm

Definition and Scoring Algorithm	Rating
Score algorithm for internal validity quality 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 4): study limitations, consistency in direction of the effect, directness in measuring intended outcomes, precision of effect, and reporting bias. Strength of evidence is assessed separately for major intervention-outcome pairs and incorporates data from the entire body of reviewed evidence on behavioral interventions (i.e., comparative studies—both RCTs and prospective and retrospective cohort studies—reported in the 2011 review[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 4. 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 E.

Peer Review and Public Commentary

Researchers and clinicians with expertise in treating children with ASD and individuals representing stakeholder and user communities will provide external peer review of this report. The draft report will be posted on the AHRQ Web site for 4 weeks to elicit public comment. We will address all reviewer comments, revise the text as appropriate, and document 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.

References

1. Methods Guide for Effectiveness and Comparative Effectiveness Reviews. AHRQ Publication No. 10(14)-EHC063-EF. Rockville, MD: Agency for Healthcare Research and Quality. January 2014. Chapters available at: www.effectivehealthcare.ahrq.gov

2. Warren Z, Veenstra-VanderWeele J, Stone W, Bruzek JL, Nahmias AS, Foss-Feig JH, Jerome RN, Krishnaswami S, Sathe NA, Glasser AM, Surawicz T, McPheeters ML. Therapies for Children With Autism Spectrum Disorders. Comparative Effectiveness Review No. 26. (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290-2007-10065-I.) AHRQ Publication No. 11-EHC029-EF. Rockville, MD: Agency for Healthcare Research and Quality. April 2011. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

3. Weitlauf AS, McPheeters ML, Peters B, Sathe N, Travis R, Aiello R, Williamson E, Veenstra-VanderWeele J, Krishnaswami S, Jerome R, Warren Z. Therapies for Children With Autism Spectrum Disorder: Behavioral Interventions Update. Comparative Effectiveness Review No. 137. (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290-2012-00009-I.) AHRQ Publication No. 14-EHC036-EF. Rockville, MD: Agency for Healthcare Research and Quality; August 2014. www.effectivehealthcare.ahrq.gov/reports/final.cfm.

4. Berkman ND, Lohr KN, Ansari M, McDonagh M, Balk E, Whitlock E, Reston J, Bass E, Butler M, Gartlehner G, Hartling L, Kane R, McPheeters M, Morgan L, Morton SC, Viswanathan M, Sista P, Chang S. Grading the Strength of a Body of Evidence When Assessing Health Care Interventions for the Effective Health Care Program of the Agency for Healthcare Research and Quality : An Update. Methods Guide for Comparative Effectiveness Reviews (Prepared by the RTI -UNC Evidence-based Practice Center under Contract No. 290-2007-10056-I).AHRQ Publication No. 13 (4)-EHC130-EF. Rockville, MD: Agency for Healthcare Research and Quality. November 2013. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm

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. **Note:** when limited to 2011, retrieval is 3593		

Table B-2. Sensory Integration
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
Notes: Imported 211 (51 duplicates discarded)		

Table B-3. Sensory Integration
Database: PsycInfo

Search	Records
SU.EXACT.EXPLODE("Sensory Integration") AND SU.EXACT.EXPLODE("Autism") Limited to 2010-2015	39
Notes: Imported 27, discarded 12 duplicates	

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

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

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

□ Yes □ No □ Cannot Determine

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

□ Yes □ No □ Cannot Determine

4. Addresses one of the following:

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

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

□ Yes □ No □ Cannot Determine

5a. Record total N with ASD:

_____

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

1. Study population is children with autism between the ages of 2 and 12 years (mean+SD ≤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

1. . Medication plus behavioral intervention for aggression in autism. Brown University Child & Adolescent Psychopharmacology Update. 2010;12(8):4-5 2p. PMID: 105068473. Language: English. Entry Date: 20101001. Revision Date: 20150711. Publication Type: Journal Article. Journal Subset: Biomedical.X-1, X-2, X-3

2. . Aripiprazole effective in treating irritability in autistic youth. Brown University Child & Adolescent Psychopharmacology Update. 2010;12(2):4-5 2p. PMID: 105306069. Language: English. Entry Date: 20100312. Revision Date: 20150711. Publication Type: Journal Article. Journal Subset: Biomedical.X-2, X-6

3. . Autism spectrum disorders. Diagnosis and management involve time and patience. Harv Ment Health Lett. 2010 Sep;27(3):4-5. PMID: 20941863.X-1

4. . Massachusetts & New Hampshire. Insurance; autism spectrum disorders. Ment Phys Disabil Law Rep. 2010 Sep-Oct;34(5):812. PMID: 21197720.X-1

5. . Extending trust. Nature Neuroscience. 2010 August;13(8):905. doi: http://dx.doi.org/10.1038/nn0810-905. PMID: 2010410948.X-1

6. . Current world literature. Curr Opin Neurol. 2010 Apr;23(2):194-201. doi: 10.1097/WCO.0b013e328338cade. PMID: 20216346.X-1, X-2

7. . Mental health. Nursing Times. 2010;106(31):7- 1p. PMID: 105077539. Language: English. Entry Date: 20101001. Revision Date: 20150711. Publication Type: Journal Article.X-1, X-2

8. . FDA warns maker of product used as alternative autism treatment. Contemporary Rehab. 2010;66(4):7- 1p. PMID: 105111455. Language: English. Entry Date: 20101126. Revision Date: 20150711. Publication Type: Journal Article.X-1, X-2

9. . Lack of evidence for antidepressant use in autism. Contemporary Rehab. 2010;66(4):11- 1p. PMID: 105111459. Language: English. Entry Date: 20101126. Revision Date: 20150711. Publication Type: Journal Article.X-1, X-2

10. . Divalproex sodium for irritability in autism. Brown University Child & Adolescent Psychopharmacology Update. 2010;12(7):7- 1p. PMID: 105045860. Language: English. Entry Date: 20100827. Revision Date: 20150711. Publication Type: Journal Article.X-1, X-2

11. . Clozapine for aggression in adolescent autism. Brown University Child & Adolescent Psychopharmacology Update. 2010;12(5):8- 1p. PMID: 105193002. Language: English. Entry Date: 20150227. Revision Date: 20150711. Publication Type: Journal Article.X-1, X-2

12. . Drug & device news. Medical Malpractice Law & Strategy. 2010;27(8):5- 1p. PMID: 105201156. Language: English. Entry Date: 20100709. Revision Date: 20150711. Publication Type: Journal Article. Journal Subset: Biomedical.X-1, X-2

13. . Keep your eye on. Brown University Child & Adolescent Behavior Letter. 2010;26(4):2- 1p. PMID: 105155628. Language: English. Entry Date: 20100507. Revision Date: 20150711. Publication Type: Journal Article. Journal Subset: Biomedical.X-1, X-2

14. . Oxytocin improves social interaction in autistic patients. Brown University Child & Adolescent Psychopharmacology Update. 2010;12(4):7-8 2p. PMID: 105162352. Language: English. Entry Date: 20100521. Revision Date: 20150711. Publication Type: Journal Article. Journal Subset: Biomedical.X-1, X-2

15. . Briefly noted. Mental Health Weekly. 2010;20(7):7-8 2p. PMID: 105120514. Language: English. Entry Date: 20100402. Revision Date: 20150711. Publication Type: Journal Article.X-1, X-2

16. . For the record. Journal of Reproductive Medicine. 2010;55(1-2):2A-A 1p. PMID: 105160564. Language: English. Entry Date: 20100409. Revision Date: 20150711. Publication Type: Journal Article.X-1, X-2

17. . Autism spectrum disorders and the gut. Consensus recommendations for evaluation and treatment. Harv Ment Health Lett. 2010 Apr;26(10):4. PMID: 20499455.X-1, X-2, X-3

18. . NAC effective for self-injurious behavior in 4-year-old with ASD. Brown University Child & Adolescent Psychopharmacology Update. 2010;12(5):7-8 2p. PMID: 103840426. Language: English. Entry Date: 20150227. Revision Date: 20150710. Publication Type: Journal Article. Journal Subset: Biomedical.X-1, X-2, X-3, X-4

19. . No "magic pill" for autism spectrum disorders. Although medication prescriptions are common, there is little evidence they do any good. Harv Ment Health Lett. 2011 Aug;28(2):4. PMID: 21980632.X-1

20. . Autism spectrum disorders revisited. Several recent studies raise new questions about cause and prevention. Harv Ment Health Lett. 2011 Oct;28(4):1-3. PMID: 22125823.X-1

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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
Woo 2015[1]	+	+	+	NR	++	+	+	+	-	+	+	+	+	+	-	+	+	-	Low
Ghas-emtabar 2015[2]	+	-	+	NA	-	-	+	+	NA	+	-	-	-	+	+	+	-	-	High
Silva 2015[3]	+	+	-	-	++	+	+	+	+	+	+	+	+	+	+	+	+	-	Moderate
Iwanaga 2014[4]	+	-	+	NA	+	+	+	+	-	+	-	-	+	+	+	+	-	+	High
Thompson 2014[5]	+	+	+	+	+	+	-	+	NA	+	+	+	+	+	+	+	-	-	Moderate
Schaaf 2014[6]	+	+	+	+	+	+	+	+	NA	+	+	+	+	+	+	+	+	-	Moderate
Gringras 2014[7]	+	+	+	+	+	+	-	+	-	+	+	+	+	+	+	+	+	-	Moderate
Latham 2014[8]	+	+	+	NR	-	+	+	+	NA	+	+	+	-	+	+	+	-	-	Moderate
Silva 2011[9]	+	+	+	+	-	-	+	+	-	+	+	+	+	+	+	+	+	+	Moderate
Porges 2014[10] (Trial 1 and 2)	+	+	+	NR	++	-	-	+	-	+	-	-	-	-	-	+	+	-	High

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
Woo 2013[11]	+	+	+	NR	+	+	+	NR	NR	+	-	-	+	+	+	+	+	-	Moderate
Silva 2013[12]	+	-	+	NA	+	-	+	NA	NA	+	+	-	-	+	+	+	-	-	High
Pfeiffer 2011[13]	+	+	+	+	+	+	+	+	NA	+	+	+	+	+	+	+	+	-	Low
Piravej 2009[14]	+	+	+	+	+	-	+	-	-	+	-	+	-	+	+	+	-	-	High
Silva 2009[15]	+	+	+	-	-	-	-	+	-	+	+	-	+	+	+	+	-	-	High
Kim 2008[16]	+	+	+	-	+	-	-	+	-	+	-	-	-	+	+	+	+	-	High
Fazlioglu 2008[17]	+	+	+	+	-	-	+	+	NA	+	-	-	-	+	+	+	-	-	High
Silva 2007[18]	+	+	+	-	+	+	+	+	-	+	-	-	+	+	+	+	+	-	Moderate
Corbett 2007[19]	+	+	+	-	+	+	+	-	NA	+	-	-	-	+	+	+	+	-	Moderate
Mudford 2000[20]	+	+	+	-	+	-	+	+	-	+	-	-	-	+	+	+	+	-	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 or filtered music.
Comparators	Two studies used a crossover design comparing auditory integration to placebo within individual subjects. Two compared filetered and unfiltered music/sound.
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. All interventions were less than 1 month duration.
Setting	Studies were 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 a single study in 7 to 12 year olds. 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.
Comparators	Comparators included unfiltered music, headphone control, toy play 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, and parent questionnaires on hearing sensitivity. Interventions were of short duration ranging from 1 up to 16 weeks with no long-term follow-up. The Iranian study in school aged children assessed social skills two months after intervention.
Setting	Studies were conducted in 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	Qigong studies were conducted in preschool aged children (3-6 years) enrolled in early intervention preschools. Another study enrolled subjects aged 4 to 14 years. Majority of study participants were male. The severity of ASD including degree of intellectual disability was not well characterized.
Intervention	Qigong sensory training, traditional massage.
Comparators	Comparators were observation or waitlist controls and senspry integration.
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 studies were of 2-5 months duration.
Setting	All qigong studies were conducted in the United States. One massage study was conducted in Thailand.

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

Appendix G. Detailed Tables 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			
Iwanaga 2014[1] Retrospective Cohort G1: Sensory integration therapy (SIT), 8/8 G2: Group therapy (GT), 12/12 8 – 10 months/EOT Moderate 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
Schaaf 2014[2] RCT G1: Sensory integration, 17/17 G2: Usual care, 15/14 10 weeks/EOT Low RoB	Age, months G1: 71.35 ± 14.90 G2: 72.33 ± 10.81 IQ (Full scale) G1: 89.75 ± 18.74	Goal Attainment Scaling (GAS) G1: ND G2: ND Pediatric Evaluation of Disability Inventory (PEDI)	**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

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: 91.86 ± 11.93	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 Vineland Behavior Scales-II (VABS) G1: ND G2: ND	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 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

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: -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
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	**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 p<0.05; ES=0.125 GAS-Teacher rated G1 > G2 p<0.01; ES=0.360

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
		Responsiveness Scale - Total G1: 82.95 ± 6.37 G2: 82.71 ± 9.10	
Fazlioglu et al. 2008[4] RCT G1: Sensory Integration, 15/15 G2: Control (Special Education), 15/15 12 weeks/EOT High RoB	Age 7-11 years 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			
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	**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

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
		IQ Score G1: 82.96 ± 5.17 G2: 76.63 ± 4.96 SSP – Atypical Sensory Responses G1: 113.75 ± 4.76 G2: 129.3 ± 4.29	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 SSP – Atypical Sensory Responses G1: 125.11 ± 5.42 G2: 132.15 ± 4.09 G1 vs. G2: p=0.037
Auditory Integration			
Mudford 2000[7] RCT G1: Auditory integration, 21/21 G2: Control Treatment, 21/21 10 days (2 session/day)/EOT Moderate RoB	Age 9.42 yrs ± 29 mos 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 3-7 IQ (range) 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
Porges 2014[10] RCT	Age NR	Parent questionnaire Hearing sensitivity	**EOT** Parent questionnaire Hearing sensitivity

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: Filtered music, 28/28 G2: Headphones only, 36/36 1 week/EOT High RoB	IQ NR	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)	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)
Porges 2014[10] RCT G1: Filtered music, 50/50 G2: Unfiltered music, 32/32 1 week/EOT	Age (in 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)	**EOT** Parent questionnaire Hearing sensitivity G1: 10 (43) G2: 2 (13) G1 vs. G2: p=0.040 Affect

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
High RoB		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)	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			
Ghasemtabar 2015[9] 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[11] RCT G1: Family-centered music therapy (FCMT), 12/11 G2: Early intervention programme,	Age, months G1: 43.92 ± 6.46 G2: 47.00 ± 7.18	VSEEC - Social Interaction G1: 49.1 ± 12.4 G2: 45.09 ± 8.13 SRS	**Change scores from baseline** VSEEC - Social Interaction G1: 22.4 ± 10.1 G2: 0.9 ± 11.9

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
11/10 16 weeks/EOT Moderate RoB	IQ G1: NR G2: NR	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	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
Kim 2008[12] RCT G1: Music Therapy, 15/10 G2: Toy Play, 15/10 12 weekly, 30 min sessions/EOT High RoB	Age 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 [13] 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 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	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 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

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
		Childhood Autism Rating Scale – total score G1: 39.7 ± 6.6 G2: 38 ± 7.8	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 [14] 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
Silva 2011[15] RCT G1: Qigong massage, 28/24 G2: Wait-list control, 19/18 4 months/EOT Moderate RoB	Age G1 + G2: 58 (months) 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	**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

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
		Autism Composite Score G1: 59.8 ± 11.1 G2: 60.2 ± 15.9	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
Silva et al. 2009[16] RCT G1: Qigong Sensory Training, 25/25 G2: Waitlist Control, 21/21 5 months/EOT Moderate 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 (Parent) G1: 46.2 ± 9.1 G2: 55.3 ± 10 G1 vs. G2: p=0.005
Silva 2007[17] RCT	Age 2-6 years	VABS-Living Skills G1: 28.8 G2: 24.1	**Mean Change Score from baseline** VABS-Living Skills

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: Qigong Massage, 8/8 G2: No Treatment, 7/7 5 months/EOT Moderate RoB	IQ NR	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 G1: 16.2 G2: 15.7 ABC-Total Score G1: 71.3 G2: 87.7	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 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
Piravej 2009[18] RCT G1: Thai traditional massage + sensory integration-based therapy, 30/30 G2: Sensory integration-based therapy, 30/30 8 weeks/EOT	Age G1: 4.84 ± 1.86 G2: 4.48 ± 1.80 IQ NR	CPRS–Conduct problem G1: 0.69 ± 0.31 G2: 0.59 ± 0.34 CPRS–Learning problem G1: 1.86 ± 0.55 G2: 2.02 ± 0.56	CPRS–Conduct problem G1: 0.60 ± 0.26 G2: 0.63 ± 0.33 G1 vs G2, p=0.03 CPRS–Learning problem G1: 1.76 ± 0.48 G2: 1.87 ± 0.53 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
High RoB		CPRS-Psychosomatic G1: 0.41 ± 0.45 G2: 0.43 ± 0.34 CPRS-Impulsivity-hyperactivity G1: 1.62 ± 0.60 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: 1.78 ± 0.46 G2: 2.01 ± 0.34 CTRS-Inattention-passivity G1: 1.56 ± 0.41 G2: 1.67 ± 0.27 CTRS-Hyperactivity index G1: 1.59 ± 0.49 G2: 1.80 ± 0.36 Sleep behavior G1: 11.50 ± 9.23 G2: 13.90 ± 7.67	CPRS-Psychosomatic G1: 0.41 ± 0.32 G2: 0.39 ± 0.25 G1 vs G2, p=NS CPRS-Impulsivity-hyperactivity G1: 1.44 ± 0.40 G2: 1.69 ± 0.57 G1 vs G2, p=NS CPRS-Anxiety G1: 0.62 ± 0.56 G2: 0.73 ± 0.50 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 ± 0.50 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 G1: 1.10 ± 0.49 G2: 1.28 ± 0.40 G1 vs G2, p=NS Sleep behavior G1: 5.33 ± 3.28 G2: 8.20 ± 6.83 G1 vs G2, p=NS
Tactile Input			
Latham 2014[19] RCT	Age G1: 8.36 ± 2.6 G2: 8.69 ± 3.0	Verbal Scoring **Day 1 – Verbal 1**	Verbal Scoring **Day 2 – Verbal 3**

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: Participation (tactual-kinesthetic experience), 17/17 G2: Observation, 17/17 24-48 hours/EOT Moderate RoB	IQ NR	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	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[20] RCT G1: Weighted blanket, 36/27 G2: Control blanket, 37/27 Crossover trial 73/54 2 weeks/EOT Low RoB	Age G1: 8.7 ± 3.3 G2: 9.9 ± 2.8 IQ NR	% of time blanket in place, n=67 G1: 75.6 ± 25.4 G2: 73.7 ± 25.7 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	**EOT** % of time blanket in place G1 vs. G2: p=ns 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

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
		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	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; CPRS-Conner's Parent Rating Scale; CTRS-Conner's Teacher 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 Childhood Scales; SRS- Social Responsiveness Scale; MBCDI- MacArthur-Bates Communicative Development Inventories; PCRI- Parent–Child Relationship Inventory; SSC- Sense and Self-Regulation Checklist; TST-Total Sleep Time; SOL- Sleep Onset Latency

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