

## **Highlights:**

- The use of complementary and alternative medicine for childhood attention and hyperactivity problems is common.
- Massage therapy seems to be beneficial for Attention Deficit/Hyperactivity Disorder (ADHD), but there has been no systematic review to summarize the evidence before.
- Individual studies suggested that massage therapy was superior to exercise therapy, relaxation therapy, and the wait-list control.
- A pooled meta-analysis of the 4 RCTs seemingly suggested that traditional Chinese medicine massage (*Tuina*) was better than methylphenidate in terms of improving ADHD symptoms, but the results were at high risk of bias.

**Title: Massage Therapy for the Treatment of Attention Deficit/Hyperactivity Disorder (ADHD) in Children and Adolescents: A Systematic Review and Meta-analysis**

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**Support:** No financial support

**Number of words:** 4872 words (excluding cover page, abstract, acknowledgement, references, and tables)

**Number of figures:** 4

**Number of tables:** 5

**Conflict of interest:** All authors declared there is no conflict of interest.

## 1. BACKGROUND

Attention deficit/hyperactivity disorder (ADHD) is one of the most prevalent of childhood neurobehavioral disorders, which has three core symptoms – inattention, impulsivity, and hyperactivity.<sup>1</sup> A national survey of children's health estimated that 6.1 million children aged 2 to 17, living in the U.S. (approximately 9.4%) had received a diagnosis of ADHD as of 2016.<sup>2</sup> In China, according to a systematic review of 36 studies, the incidence of ADHD in children and adolescents up to the age of 18 was approximately 5.7%.<sup>3</sup> Individuals with symptoms of ADHD have been found to have strained family relations,<sup>4</sup> academic problems,<sup>5</sup> and negative social relations.<sup>6</sup> About two thirds (63.8%) of children with current ADHD have one or more comorbidities, with behavioral and conduct disturbance (51.5%) being the most common, followed by anxiety (32.7%), depression (16.8%), autism spectrum disorder (13.7%), and Tourette syndrome (1.2%).<sup>2, 7</sup>

The American Academy of Pediatrics (AAP) recommends the use of medications and behavioral therapy to treat ADHD symptoms.<sup>8</sup> Both medications and behavioral therapy are effective at improving ADHD symptoms and related academic, organizational, behavioral, emotional, and functional impairments in children and adolescents.<sup>9</sup> Medications produce symptomatic improvements in the short term, however, the effect is not sustained after the discontinuation of treatment. Medications such as stimulants may have adverse side effects including headaches, decreased appetite, sleep disturbances, stomachaches, nausea, irritability, dizziness, decreased weight, and mild increases in blood pressure levels.<sup>10</sup> In addition, medication therapy alone is insufficient to improve dysfunctions associated with ADHD.<sup>11</sup>

Evidence-based behavioral treatments include behavioral parent training, behavioral classroom management, and behavioral peer interventions, all of which are strongly recommended for children and adolescents of all ages with ADHD, but especially for preschool-aged children.<sup>2, 8</sup> Behavioral therapy provides more opportunities for

communication between parents or other caregivers and children, which in turn improves their relationship and also enhances the efficacy of the treatments. However, the cost of behavioural therapy is high and a significant amount of family involvement is required.<sup>8</sup> There are also problems such as variations in the practice of behavioral therapy relating to the knowledge of the trainer and a lack of prescription patterns that have been proven to be safe and effective.<sup>12</sup>

Besides conventional therapies, many pediatric ADHD patients have used complementary and alternative therapies such as biofeedback therapy, dietary therapy, herbal therapy, attention training, massage, homeopathy, and acupuncture.<sup>13</sup> More than 50% of patients in the U.S. have used complementary and alternative therapies.<sup>14</sup>

Massage therapy is a type of complementary and alternative therapy.<sup>15</sup> During massage treatment, therapists use their hands to touch and exert pressure on a subject's body.<sup>16</sup> Massage involves a number of techniques such as causing friction, pressing, rubbing, grasping, pinching, and kneading.<sup>17</sup> There are many styles of massage, such as Swedish massage, Thai massage, Traditional Chinese Medicine massage (TCM massage), and so on. All involve manual manipulations on a subjects' body. However, different types of massage have corresponding theories and manipulations. For instance, TCM massage, which is also called *tuina*, is based on TCM meridian theory, and is aimed at stimulating specific acupoints or meridians on the surface of the body to achieve therapeutic effects. From TCM perspective, the pathogenesis of ADHD is the abnormal exuberance of yang, which can be relieved by specific approaches of massage.<sup>18</sup> A recent review of randomized controlled trials (RCTs) suggests that massage therapy may have beneficial effects on prenatal depression, hypertension, cancer, and dementia.<sup>19</sup> In general, massage therapy has three kinds of beneficial effects: affective effects, which are related to emotions and feelings; physiological effects, which are connected to the essential processes of an organism; and behavioral effects, which are associated with people's reactions to circumstances.<sup>20</sup> The mechanism by which massage

brings about therapeutic effects may be related to the stimulation of pressure receptors, which enhances vagal activity and reduces cortisol levels.<sup>19</sup>

Previous reviews seemed to suggest that massage therapy is beneficial for individuals with ADHD and related conditions. A systematic review on massage therapy identified 2 RCTs on ADHD, 2 RCTs on autism, 1 RCT on depression, and 1 RCT on aggression, suggesting that massage therapy has beneficial effects on pediatric populations in the affective, physiological, and behavioral dimensions.<sup>20</sup> A review of TCM treatments for ADHD suggested that TCM massage therapy was effective at improving ADHD symptoms when combined with pharmacologic treatment or used alone, and had fewer side effects than pharmacologic treatments.<sup>18</sup> However, there has been no systematic review specifically on massage therapy for ADHD in children and adolescents. We therefore decided to fill this gap in the literature, in order to provide experts and patients with up-to-date evidence that can be used to make a rigorous evaluation of the effectiveness of therapy and to guide clinical practice. We conducted this systematic review and meta-analysis to summarize the current evidence on the effects and safety of massage therapy for the treatment of ADHD in children and adolescents.

## **2. METHODS**

### **2.1 Search Strategy and Selection of Studies**

#### **2.1.1 Types of studies**

We included reports on randomized controlled trials (RCTs), quasi-randomized controlled trials (quasi-RCTs), non-randomized controlled trials (NRCTs), controlled before-and-after studies (CBAs), and case series studies of massage for the treatment of ADHD in children and adolescents.

#### **2.1.2 Types of subjects**

We included studies that targeted children and adolescents aged 18 years or younger who had been diagnosed with ADHD, Attention Deficit Disorder (ADD), or Hyperkinetic Disorder (HKD) according to established diagnostic criteria such as Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria or the International Classification of Diseases (ICD) criteria; or a cut-off score based on a validated questionnaire (e.g., Conners' Parent Rating Scale); or a diagnosis made by their case doctors or by other established criteria. We did not exclude the studies if the participants had other comorbidities.

### **2.1.3 Types of intervention**

To be included, the studies should have included massage therapy as an intervention. Massage was defined as the manipulation of the soft tissues of the body by hands in order to produce effects on the muscular, vascular, and nervous systems.<sup>21</sup> There was no restriction on its theoretical basis or cultural practice. Massage could be delivered by therapists, parents, or other health care professionals.

### **2.1.4 Types of comparison**

For studies that had a control group, possible control interventions could be no treatment, placebos, or other standard treatments such as pharmacological treatments, psychological treatments, or physiotherapies.

### **2.1.5 Types of outcome measures**

We included studies that assessed improvements in the core symptoms of ADHD, including inattention, impulsivity, and hyperactivity, measured using validated rating scales. Other secondary outcomes included intelligence, school or academic performance, moods and behavior, family and social outcomes, quality of life, and adverse events.

## **2.2 Search methods for the identification of studies**

We searched PubMed, EMBase, the Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL, Allied and Complementary Medicine (AMED), PsycINFO, the

Chinese Scientific Journal Database (COVIP), China National Knowledge Infrastructure (CNKI), WanFang Data, the Chinese Biomedical Literature Database (CBM), Taiwan Electronic Periodical Services, and the Index to Taiwan Periodical Literature System from the inception of the coverage of those databases to November 2017. For English databases, the following group terms were used for searching: (massage OR *tuina* OR *anmo* OR acupuncture) AND (ADHD OR ADD OR ADDH OR HKD OR hyperact\* OR hyperkinetic OR attention deficit\*) AND (child\* OR adolescen\* OR bab\* OR juvenil\* OR infant\* OR teen\* OR youth OR pediatric\* OR toddler OR preschool\*). For Chinese databases, equivalent Chinese group terms were searched. We imposed no language restrictions.

### **2.3 Data collection and analysis**

Two review authors (SC Chen and YM Yu) independently searched and screened the citations against the eligibility criteria. The full reports of potentially eligible articles were retrieved and inspected to assess their relevance against the inclusion criteria. Reference lists of relevant review papers were screened for potential studies. Disagreements were resolved through discussion. In the event that a consensus could not be reached, we would seek the opinion of the third reviewer (WF Yeung). For each included study, the following data were extracted independently by two reviewers (SC Chen and YM Yu): (1) general information on the study; (2) design and setting of the study; (3) participants in the study; (4) interventions used (types of manipulations, intensity and frequency of the manipulations, selected locations or acupoints, number of treatment sessions, background of the therapists); (5) outcomes, results, and follow-up periods; (6) adverse events. To assess the quality of the included studies, two reviewers (SC Chen and YM Yu) independently assessed each study using the Cochrane Collaboration tool for RCTs, quasi-RCTs, NRCTs, and CBAs,<sup>22</sup> and the Joanna Briggs Institute's Case Series Critical Appraisal Tool.<sup>23</sup> Disagreements between the two reviewers were resolved by discussion and by consulting a third reviewer (WF Yeung) when necessary. The Cochrane

Collaboration tool assesses the following seven domains: sequence generation, allocation concealment, blinding of the participants and personnel, blinding of the assessor, incomplete outcome data, selective reporting, and other biases. Each domain was rated as being of a low risk of bias, a high risk of bias, or an unclear risk of bias. Since information that permits a definitive rating of high risk or low risk is often unavailable, a designation of “probably yes” and “probably no” was proposed to make a more specific final risk of bias declarations.<sup>24</sup> For the domains rated as “unclear”, we would try to conclude it as “probably high risk” or “probably low risk” in order to make it easier for understanding the quality of the included studies. <sup>24</sup>The Joanna Briggs Institute’s Case Series Critical Appraisal Tool assesses the following 10 domains: inclusion criteria, outcome measures, diagnostic criteria, inclusion consecutiveness, inclusion completion, the demographics of the participants, information on the participants, outcomes or follow-up results, presenting sites/clinics, and the statistical analysis. Each domain was appraised as yes, no, unclear, or not applicable. The statistical analysis was conducted using Cochrane Collaboration’s Review Manager Software (Review Manager 5.3). For dichotomous outcomes, we reported relative risks (RR) with 95% confidence intervals (CI). For continuous outcomes, we pooled the data using the mean difference (MD) with a 95% CI for the same outcome measure, and the standardized mean difference (SMD) with a 95% CI if different rating scales were used in different trials for the same outcome. Heterogeneity between studies was evaluated using Cochran's Q statistic, which used a more liberal p-value cut-off if 0.10 to indicate statistical heterogeneity. The data were synthesized using random-effects models, taking into account the potential for heterogeneity among the included studies (Higgins 2009). The overall quality of the evidence for the prespecified outcomes was assessed using the GRADE system.<sup>25</sup> The Grade system assess both internal and external validity, such as limitations in study design or Execution, consistency of effect, imprecision of results, indirectness of evidence, and publication bias.<sup>25</sup> The summary of



findings tables were generated using the GRADEpro software.<sup>26</sup> The justification of decisions to down- or upgrade the quality of studies were in footnotes.

### **3. RESULTS**

The search yielded 572 citations, of which 224 were duplicated and 325 were excluded for reasons of irrelevance. The full-texts of 23 potentially eligible articles were retrieved for further assessment. Among the 23 studies, 11 using massage therapy for ADHD in children and adolescents were included, while the other 12 were excluded (Figure 1). One RCT was reported in two articles published in 1999 and 2003 by two different authors. The later article was included, since the full-text of the earlier article was not available.

#### **3.1 Characteristics of the included studies**

Table 1 presents the characteristics of the 11 included studies. Among them were 8 RCTs<sup>27-34</sup> and 3 case series studies<sup>35-37</sup>. Seven of the studies had been conducted in China,<sup>27, 30, 32-36</sup> 2 in the United States,<sup>28, 29</sup> 1 in Canada,<sup>31</sup> and 1 in Switzerland.<sup>37</sup> The sample size in the included studies ranged from 13 to 180, with a total of 787 subjects. The subjects ranged in age from 3 to 18 years. All included studies reported more male than female participants. Among the 11 studies, only 3 reported dropouts, but the reasons for dropping out were not mentioned.<sup>28, 29, 31</sup> The criteria used to diagnose ADHD varied between these studies (Table 1). The most commonly used diagnostic criteria were the DSM criteria,<sup>28, 29, 31, 36, 37</sup> which included the DSM-IV criteria,<sup>29, 31, 36, 37</sup> and the DSM-III criteria.<sup>28</sup> Four studies used the Chinese Classification of Mental Disorders, 3<sup>rd</sup> Revision (CCMD-3) criteria,<sup>27, 30, 33, 34</sup> and two of these used the ICD, 10<sup>th</sup> Revision criteria in addition to the CCMD-3 criteria.<sup>27, 34</sup> Two studies did not use any standardized diagnostic system.<sup>32, 35</sup> In the 8 RCTs, massage was compared with methylphenidate in 4 studies,<sup>27, 30, 33, 34</sup> with exercise therapy and a wait-list group in 1 study,<sup>31</sup>

with relaxation therapy in 1 study,<sup>28</sup> with sensory integration training in 1 study,<sup>32</sup> and with a wait-list control in 1 study.<sup>29</sup>

### 3.2 Characteristics of the intervention

Table 2 presents the characteristics of the interventions. Standardized approaches to massage were used in 5 studies, namely 2 on Western massage<sup>28, 29, 31</sup> and the other 3<sup>30, 32, 35</sup> on TCM massage. An individualized approach was adopted in 6 studies, with 5 focusing on TCM massage, in which the manipulations and acupoints were selected according to the TCM pattern diagnosis;<sup>27, 33, 34, 36, 37</sup> and 1 examining Western massage, where a combination of different massage techniques were used, such as Swedish, craniosacral, and manual lymph drainage manipulations, according to the condition of the subjects.<sup>31</sup> Among the studies on TCM massage therapy, the most commonly used acupoints or regions were *Xinshu (BL 15)*, *Ganshu (BL 18)*, *Baihui (GV 20)*, *Kangong*, *Shenshu (BL 23)*, *Sishencong (EX-HN 1)*, *Pishu (BL 20)*, *Zusanli (ST 36)*, *Abdomen*, *Tianmen (BL 2)*, *Taiyang (EX-HN 5)*, *Quchi (LI 11)*, *Spine*, and *Daling (PC 7)* (Table 3 and Figure 2). The duration of the massage intervention ranged from 6 to 40 minutes, with 30 minutes being the most common. The treatment period was mostly 1 month, but ranged from 10 days to 6 months. The number of treatment sessions ranged from 1 to 360. The frequency ranged from 2 times per day to once per week, with most being once per day. The manipulations were performed by parents in 1 study<sup>31</sup> and by therapists in the other 10 studies.

### 3.3 Quality assessment

#### 3.3.1 Randomized Controlled Trials

None of the included RCTs described the procedure of random sequence generation or the allocation concealment, and hence were rated as having an unclear risk of bias in both domains, (Figure 3). For the blinding of the participants and personnel, all of the studies adopted interventions that were completely different from massage therapy as the basis for comparison,

including exercise therapy,<sup>31</sup> relaxation therapy,<sup>28</sup> a wait-list control,<sup>29</sup> Sensory Integration Training therapy,<sup>32</sup> and medication (methylphenidate).<sup>27, 30, 33, 34</sup> In all of these studies it was found to be impossible to completely blind the subjects and manipulators. Hence, the domain was rated as high risk of performance bias. With regard to a detection bias, only 2 studies mentioned the blinding of the assessors,<sup>28, 29</sup> and one clearly mentioned that the assessor was the therapist and was not blinded.<sup>31</sup> The blinding of the outcome assessor was not mentioned in the remaining studies and all were rated as being of an unclear risk of detection bias. Five studies reported no dropouts,<sup>27, 30, 32-34</sup> while the remaining studies did not provide sufficient information on dropouts.<sup>28, 29, 31</sup> Five studies reported all of the pre-specified outcomes,<sup>27-29, 32, 33</sup> and 3 studies failed to report all or sufficient pre-specified outcomes.<sup>30, 31, 34</sup> For those domains rated as unclear, we considered that the procedure are probably not being conducted and were rated as probably high risk of bias.<sup>24</sup>

### *3.3.2 Case series studies*

For all three case series studies, the inclusion criteria, the demographics of the participants, such as age and gender, the treatment sites, the outcomes, and the follow-up results were clearly reported (Table 4). Two did not report the clinical information of the participants,<sup>36, 37</sup> and 2 failed to report the treatment sites.<sup>35, 36</sup> None mentioned whether the inclusion of participants was completed during the recruitment period. All used the effective rate as the outcome measure, not validated assessment tools, despite the fact that it would have been appropriate to conduct a statistical analysis.

## **3.3 Outcome measures**

The outcome measures varied among the included studies. The most commonly used outcome measure was the effective rate (8 studies),<sup>27, 30, 32-37</sup> which was defined as the proportion of subjects who had demonstrated at least some improvements in their ADHD symptoms after treatment. Two studies used both the score from employing Conners' Rating Scale and the

effective rate.<sup>27, 34</sup> Five studies used the score obtained from Conners' Rating Scale as the outcome measure<sup>27-29, 31, 34</sup>, but three failed to report the result.<sup>28, 31, 34</sup>

### **3.4 Effects of the interventions**

#### *3.4.1 Monotherapy versus other therapies and no treatment*

##### *3.4.1.1 Massage therapy versus no treatment*

A study found that, compared with a wait-list control, subjects in the massage group demonstrated significantly better improvements in their anxious-passive score (MD = -11.7; 95%CI [-17.84, -5.56]; P = 0.0002) and asocial score (MD = -8.60; 95%CI [-15.87, -1.33]; P = 0.02) as measured by Conners' Teacher Rating Scale, but no significant differences in other factors measured by Conners' Teacher Rating Scale, or in their salivary cortisol level or Children's Pain/Fear Thermometer Rating Scale score.<sup>29</sup>

##### *3.4.1.2 Massage therapy versus relaxation therapy*

A single study reported that Western massage therapy was more effective than relaxation therapy, as measured using Conners' Teacher Rating Scale, and that teachers had observed that those who received Western massage therapy spent more time on tasks in the classroom. However, it was not possible to estimate the effect size of this study due a lack of statistical details on the outcomes, although we had contacted the authors to retrieve the information.<sup>28</sup>

##### *3.4.1.3 Massage therapy versus Methylphenidate*

The pooled-analysis of 4 studies comparing the effects of TCM massage therapy and methylphenidate showed that TCM massage therapy was better than methylphenidate in terms of the effective rate (RR = 1.39; 95%CI: 1.16, 1.66; P = 0.0004)( Figure 4),<sup>27, 30, 33, 34</sup> but that there was considerable heterogeneity ( $I^2 = 75\%$ ) (Figure 4). One study also reported an improvement in hyperactivity (MD = -9.31; 95%CI [-11.43, -7.19]; P <0.00001) and in ADHD Scale scores according to TCM patterns (MD = -0.23; 95%CI [-0.33, -0.13]; P <0.00001), which also showed that massage had better effects on those with ADHD.<sup>27</sup>

#### *3.4.1.4 Massage therapy versus exercise therapy versus no treatment*

A three-arm study, which compared Western massage to exercise therapy and a wait-list control suggested that the massage group had a better Conners' Parent Rating Scale score at both weeks 6 and 12, and a better Conners' Teacher Rating Scale score at week 6. However, it was not possible to estimate the effect size of this study because statistical details of the outcomes were missing. The study also showed that both the massage and exercise groups of ADHD children experienced a positive effect in terms of improved concentration, flexibility, mood, sleep, and social functioning, as assessed by the nurse. However, the researchers who conducted the study admitted that they failed to quantitatively report the outcomes due to low compliance with the intervention and a high attrition rate.<sup>31</sup>

#### *3.4.1.5 Massage therapy combined with sensory integration training versus sensory integration training alone*

One study, which used the effective rate as the outcome measure for the improvement of ADHD symptoms, reported that the combination of massage therapy and sensory integration training therapy resulted in a higher effective rate than the single use of sensory integration training therapy (RR = 1.64; 95%CI: [1.25, 2015]; P = 0.0004).<sup>32</sup>

#### *3.4.2 Case-series studies*

All of the 3 case-series studies on TCM massage showed that most subjects experienced at least some improvements in ADHD symptoms after receiving TCM massage, as assessed by the effective rate. The effective rates of these studies ranged from 85.0% to 98.0%, with a mean of 93.5%.<sup>35-37</sup>

#### *3.4.3 Adverse events*

Two studies reported adverse events.<sup>27, 32</sup> One reported that 1 subject in the TCM massage group exhibited aggressive behavior after the first week of treatment, which was controlled

after the second week of treatment. One reported that 1 subject (2.6%) in the TCM massage group suffered from diarrhea.<sup>32</sup>

#### 3.4.4 Overall quality of the evidence

Table 5 presents the overall quality of the evidence using the GRADE system.<sup>25</sup> The certainty of the findings were low or very low in general due to limitations of the study designs, small sample size and number of studies, and large heterogeneity.

## 4. DISCUSSION

To the best of our knowledge, the present systematic review is the first to summarize the current evidence on the use of massage for the treatment of ADHD. There were few available studies on this topic. A meta-analysis of the 4 RCTs found that TCM massage was better than methylphenidate in terms of improving ADHD symptoms. Individual studies showed that massage therapy was superior to exercise therapy, relaxation therapy, and the wait-list control. When compared with using a sensory integration training control alone, the combination of using massage therapy and sensory integration training was significantly more efficacious in improving ADHD symptoms. All of the included studies had at least one domain with a high risk of bias. Hence, despite the apparent positive findings, it would be premature to conclude that massage therapy is an effective strategy for treating ADHD in children and adolescents.

The methodological quality of the included RCTs was generally poor. Limitations included unclear randomization and allocation concealment methods, incomplete reporting of outcome data, a lack of monitoring of adverse events and validated outcome measures, as well as a high risk of biases related to a failure to blind participants and outcome assessors. Further trials using high-quality methodologies should be conducted to confirm the efficacy of massage on ADHD in children and adolescents. Furthermore, the results should be reported according to the Consolidated Standards of Reporting Trials (CONSORT).

Lack of blinding of the participants and parents was a major limitation of the included studies. The included studies used control interventions that were very different in nature from massage; hence, it was impossible to blind the participants. It is likely that the relationship developed between manipulators, parents, and participants during massage therapy could have had positive impacts on ADHD symptoms, such as anxiety, aggression, and depression. It would not be possible to control for such non-specific effects during massage therapy by using a wait-list control or a medication comparison group. Therefore, to control for such non-specific effects during massage, comparisons should be made with other interventions involving a similar amount of interaction between the manipulators and the recipients. An attempt to do so was made in some of the included studies by including a relaxation therapy,<sup>28</sup> exercise therapy,<sup>31</sup> or sensory integration training<sup>32</sup> group as a comparison group. One study used a group of subjects under 5 years of age being treated with methylphenidate as a comparison group, which was not appropriate since according to the AAP's clinical practice guideline for ADHD medication therapy should not be used on preschool-aged children due to the probable impairments associated with the medication.<sup>33</sup>

Besides the interaction between manipulators and recipients, massage also involves non-specific effects such as touching and physical pressure stimulation on skin. To study the specific effects of massage, a well-developed sham massage control is needed, although there is still a great deal of debate over whether a sham intervention is an ideal control for procedural interventions in which non-specific effects comprise much of the treatment effects. Taking TCM massage, for instance, this kind of massage is conducted on the basis of meridian theory which, similar to acupuncture, deems that specific manipulations, strengths, and directions on specific acupoints can produce therapeutic effects for different conditions and diseases.<sup>38</sup> However, some researchers have argued that there is little difference in effect between stimulation on acupoints and non-acupoint sites.<sup>39, 40</sup> To examine the specific effects of TCM

massage, a sham intervention group can be included in future studies. This sham intervention could involve general physical touching of non-specific acupoints or regions, minimal strength, or manipulations that are regarded as non-therapeutic actions<sup>41</sup> according to theories on massage. It should be more feasible to blind young recipients than adults, as they may have less experience and knowledge of massage treatments. A qualitative study exploring the subjects' perceptions and attitudes on sham acupressure concluded that even without being informed about the possibility that a sham intervention might be used, the majority still perceived that there might have been a placebo arm to the study and thought that this was acceptable.<sup>42</sup> Further RCTs could include a sham intervention control to test the specific effects of massage.

Eight studies used the effective rate as the outcome measure, with 5 of them using it as the sole outcome measure. The effective rate, which is defined as the proportion of subjects that demonstrate at least some improvement after receiving the intervention or treatment, is one of the most commonly used outcome measures in clinical studies in China.<sup>43</sup> However, the method for assessing the effective rate and the criteria for defining improvement were vague and differed across studies, leading to difficulties in comparing the results with other clinical studies that used standardized outcome measures. Further trials should use validated outcome measures to assess specific outcomes.

Individualized massage therapy was examined in 6 (5 on TCM massage and 1 on Western massage) out of the 11 included studies. The manipulations and regions or acupoints to be used were individualized according to the subjects' symptoms. It is believed that an individualized approach is superior to a standardized approach. However, in none of the included studies was a head-to-head comparison made of the difference between an individualized and a standardized approach; thus, the additional benefit to be gained by implementing individualization remains uncertain. A further study should be conducted to



explore the difference between individualized therapy and standardized therapy, especially in the area of TCM massage treatment because it has been advocated that TCM treatments should be individualized according to the TCM pattern.

Only 2 studies reported adverse effects associated with massage therapy, including diarrhea and an increase in aggressive behavior, but the severity of these effects was not reported. It is not possible to determine whether massage is safe, since only few studies reported adverse effects. The frequency and severity of adverse events may vary with the site and technique of manipulation. Therefore, further studies should record and report the adverse effects in detail to allow for an assessment to be made of the safety of massage.

This review has some limitations. We only included major English and Chinese databases in our search, which may cause us to miss some relevant studies in other languages, although we did not impose any language restrictions. Despite a comprehensive search, we ultimately included only a few RCTs, and their control interventions and outcome measures varied, which limited the possibility of performing a meta-analysis. We only included experimental studies in our search, which may have missed evidence from other study types, such as observational cohort studies. Furthermore, a majority of the included studies did not report adverse events; hence, not enough information was available to assess the safety of massage therapy.

## **5. Conclusions**

In summary, massage has been reported to be more effective than methylphenidate control, routine care, and no treatment, and to have a superior effect when combined with sensory integration training than the use of sensory integration training alone in the treatment of ADHD in children and adolescents. However, we found that the reviewed studies were generally of low methodological quality and that there were limitations in the design of the control. Hence, the seemingly promising results should be interpreted with caution. Further studies with an

improved methodological design are warranted to determine the efficacy and safety of massage for ADHD in children and adolescents.

**Authors' Contribution**

SCC conceived the study. JY, YYH, LKPS and JJY provided experts' opinion to the systematic review protocol. SCC and YMY searched, screened, and extracted the information of the included studies, independently. WFY, SCC, and YMY conducted the assessment. WFY and SCC analyzed the data and drafted the manuscript. JY, YYH, LKPS and JJY revised the manuscript. All authors approved the final version accepted for publication.

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**Figure 1. Inclusion Flowchart**

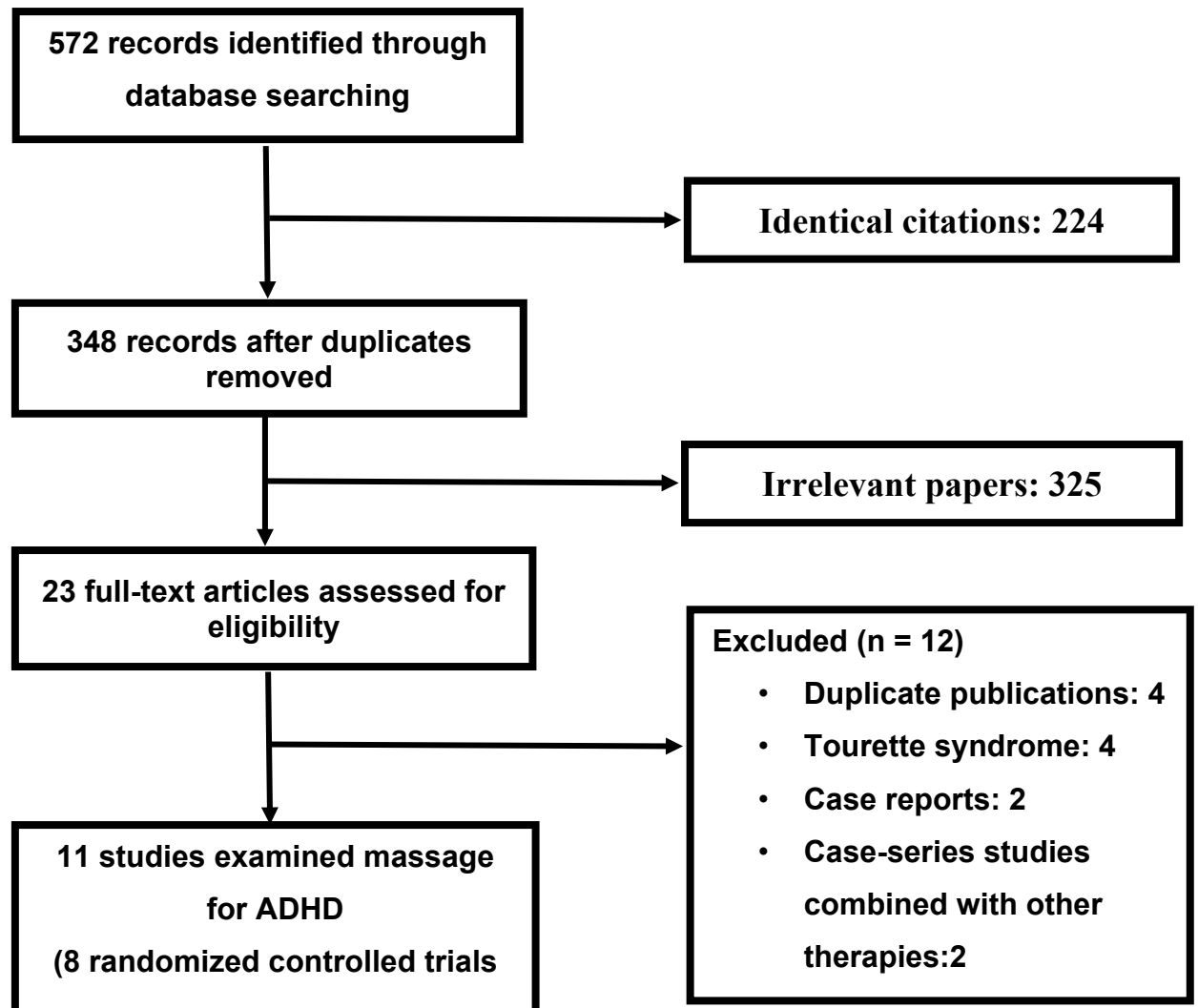
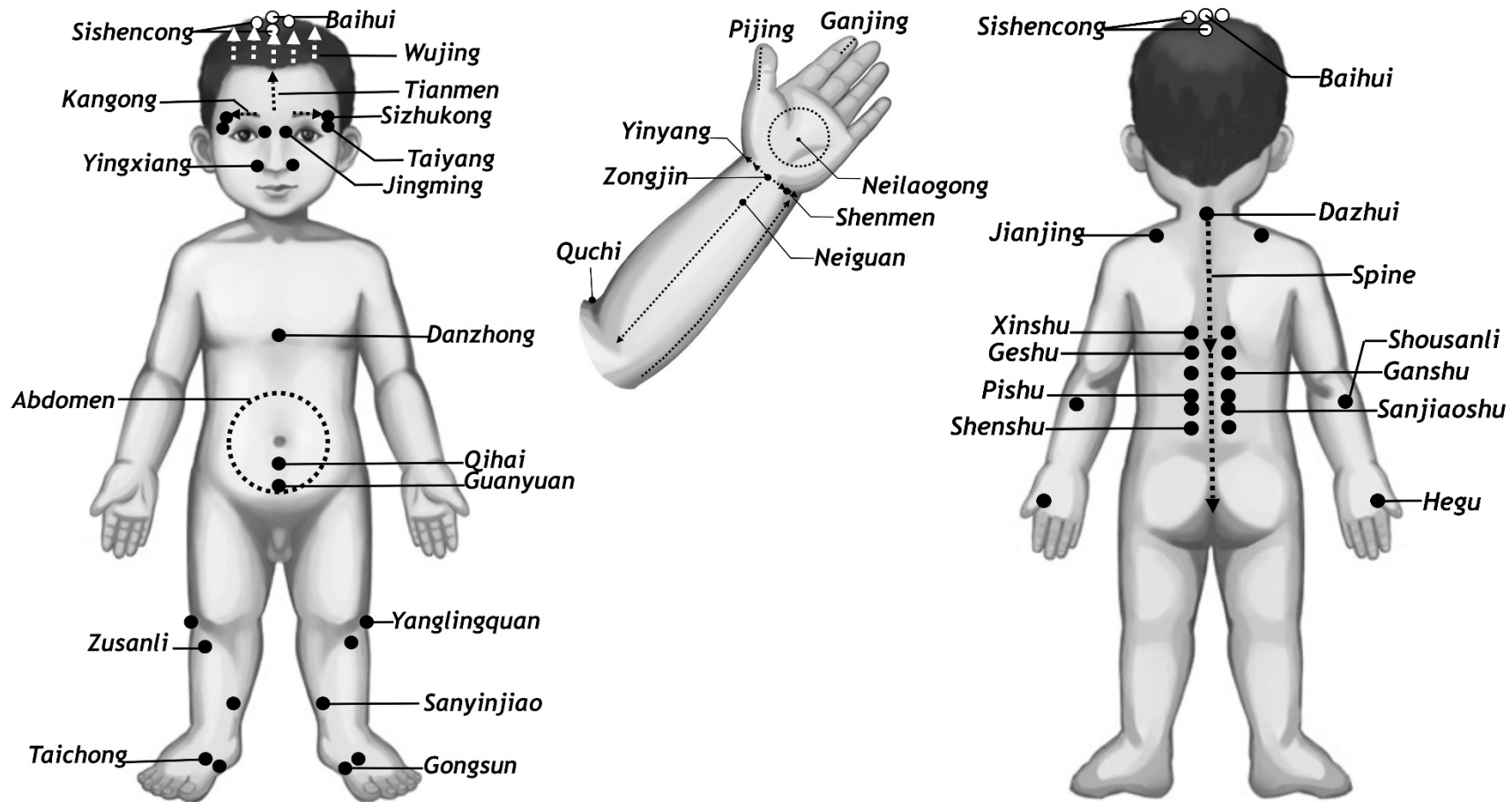


Figure 2. Acupoints or regions selected in the included studies using TCM pediatric massage for treating ADHD

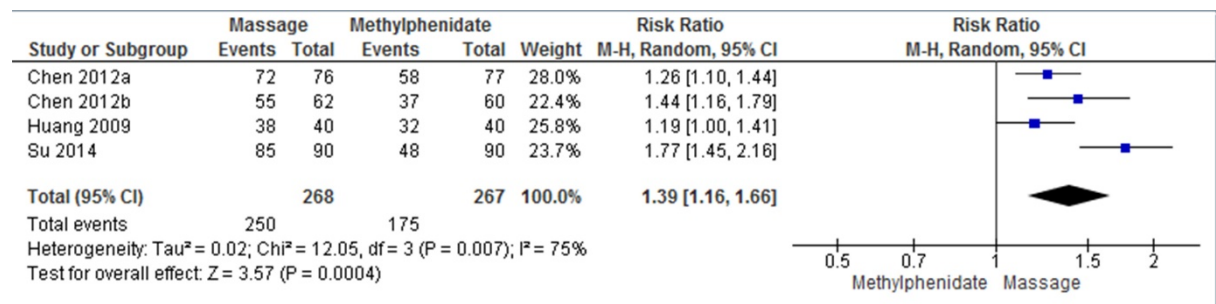




**Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Chen 2012a							
Chen 2012b							
Field 1998							
Huang 2009							
Khilnani 2003							
Maddigan 2003							
Su 2014							
Sun 2014							

**Figure 4. Massage therapy versus Methylphenidate**



**Table 1. Characteristics of the Included Studies**

No.	1 <sup>st</sup> author (year)	Setting/ Manipulator	Mean age, yr (range)/ %female	Sample size (treatment/ control)	Comorbidity	Exclusion criteria	Diagnostic system	Control intervention (duration)	Outcome measures	Follow- up
<b>Randomized controlled trials</b>										
1	Khilnani (2003)	S/TP	13(7-18)/ 20%	30(15/15)	Nil	- Other complex issues; - <i>T scores</i> fell below 60.	DSM-IV	Wait-list group. 2*20 mins/wk (1m)	- Cortisol - Children's Pain/Fear Thermometer Rating - Happy Face Scale - CTRS	Nil
2	Maddigan (2003)	(HP + HM)/P	NR/ NR	13(NR)	Nil	NR	DSM-IV	Exercise therapy. 1*6-20 mins/wk. (6wk) + home care Wait-list group.	- CTRS - CPRS - A clinical assessment	Questionnaire (wk-12) Phone call (wk-9, 15)
3	Field (1998)	S/TP	14.6(NR)/ NR	28(14/14)	Nil	NR	DSM-III	Relaxation therapy. 1*15 mins/d (10d)	- Happy Face Scale - Fidgeting score - CES-D - The Empathy Scale - Observed time on task - CRS	Nil
4	Chen (2012)	HP/TP	NR (6-14)/ NR	153(76/77)	Nil	- Normal children with ADHD symptoms; - Mental retardation, hearing impairment; - Severe diseases in heart, liver, kidney and nervous system.	- ICD-10 - CCMD-3 - CPT	Methylphenidate 0.5mg (kg.d) max 30mg/d. (28d)	- Effective rate - ADHD symptom score by TCM pattern assessment - CRS	Nil
5	Chen (2012)	HP/TP	NR (6-14)/ 17.2%	122(62/60)	ODD	Mental retardation.	- ICD-10 - CCMD-3 - CPT test	Methylphenidate 0.5mg (kg.d) max 30mg/d. (28d)	- Effective rate - ADHD symptom score by TCM pattern assessment - CRS	Nil

6	Huang (2009)	HP/TP	NR (6-13)/ NR	80(40/40)	Nil	NR	CCMD-3	Methylphenidate 0.5mg(kg.d) (35d with 7d washing off)	- Effective rate - ADHD symptom score by TCM pattern assessment - Behavioral scale	6m
7	Sun (2014)	HP/TP	NR(NR)/ NR	76(39/37)	Nil	Mental retardation, childhood psychosis, anxiety, behavior disorder or nervous system diseases.	Medical history	Sensory Integration Training. (6m)	- Effective rate	Nil
8	Su (2014)	HP/TP	T: NR (3-10)/ 44.4% C: NR (4-11)/ 26.7%	180(90/90)	Nil	NR	CCMD-3	Methylphenidate. (35d with 7d washing off)	- Effective rate	Nil
<b>Case-series clinical studies</b>										
9	Sun (2010)	HP/TP	7.5(4-10)/ 25.6%	39	Nil	Mental retardation, childhood psychosis, anxiety, behavior disorder or nervous system diseases.	Information from teachers and parents; Clinical assessments and tests	Nil	- Effective rate	Nil
10	Dai (2006)	HP/TP	NR (5-7)/ 27.2%	33	Nil	NR	DSM-IV	Nil	- Effective rate	Nil
11	Wang (2005)	HP/TP	NR (5-7)/ 27.2%	33	Nil	- Abnormal mental development - Mental disorders - Behavior disturbance	DSM-IV	Nil	- Effective rate	Nil

Abbreviations: **S**, School; **HP**, Hospital; **HM**, Home; **TP**, Therapist; **P**, Parent; **NR**, Not report; **T**, Treatment group; **C**, Control group; **CES-D**, Center for Epidemiologic Studies Depression Scale; **CTRS**, Conners' Teacher Rating Scale; **CPRS**, Conners' Parent Rating Scale; **CRS**, Conners' Rating Scales; **DSM-III**, Diagnostic and statistical manual of mental disorders, the 3rd version; **DSM-IV**, Diagnostic and statistical manual of mental disorders, the 5th version; **CCMD-3**, Chinese classification of mental disorders, the 3rd version; **CPT**: Continuous performance test; **ICD-10**, International classification of diseases, the 10th version; **T Score**, In accordance with Conners' Scale, the child's psychologist will total the scores from each area of the test, such as social problems and emotional distress. He/She will assign the raw scores to the correct age group column within each scale. The scores will then be converted to standardized scores, known as T-score.

**Table 2. Details of the massage intervention**

No.	1st author (year)	Standardized/ Individualized approach	Treatment Content				
			Selected acupoints or regions	Manipulations	Length of session/ Frequency	No. of sessions	Treatment period
<i>Randomized Controlled Trials</i>							
1	Khilnani (2003)	Standardized	head/neck, arms, torso, legs, and back.	moderate-pressure stroking, gentle rocking, stretching	2*20mins/wk	60	1m
2	Maddigan (2003)	Individualized	No detailed description.	Swedish, Craniosacral and Manual Lymph Drainage techniques	1*6-20mins /wk + home care when available	42	6wk
3	Field (1998)	Standardized	- Up and down the neck; - From the neck across the shoulders and back to the neck; - From the neck to the waist and back to the neck along the vertebral column.	moderate pressure, smooth strokes	1*16mins/wk	10	10d
4	Chen (2012)	Individualized	Acupoints: Xinshu (BL 15), Shenshu (BL 23), Ganshu (BL 18), Pishu (BL 20), Daling (PC 7), Laogong (PC 8), Baihui (GV 20), Sishencong (EX-HN 1), Shenmen (HT 7), Neiguan (PC 6), Zusanli (ST 36), Sanyinjiao (SP 6), Sanjiaoshu (BL 22), Abdomen	pressing, trembling, kneading, twisting	1*30mins/d	28	28d
5	Chen (2012)	Individualized	Acupoints: Xinshu (BL 15), Shenshu (BL 23), Ganshu (BL 18), Pishu (BL 20), Daling (PC 7), Laogong (PC 8), Baihui (GV 20), Sishencong (EX-HN 1)	pressing, kneading, twisting	1*30mins/d	28	28d
6	Huang (2009)	Standardized	Acupoints: Xinshu (BL 15), Ganshu (BL 18), Shenshu (BL 23), Daling (PC 7), Laogong (PC 8), Sishencong (EX-HN 1), Baihui (GV 20)	pressing	1*30mins/d	28	28d

7	Sun (2014)	Standardized	Acupoints: Baihui (GV 20), Tianmen (BL 2), Kangong, Taiyang (EX-HN 5), Qihai (CV 6), Guanyuan (CV 4), Quchi (LI 11), Shousanli (LI 10), Neiguan (PC 6), Zusanli (ST 36), Xinshu (BL 15), Gesu (BL 17), Ganshu (BL 18), Shenshu (BL 23), Yanglingquan (GB 34), Taichong (LR 3), Gongsun (SP 4), Shenmen (HT 7), Abdomen, Spine	pressing, pushing, kneading, rubbing, pinching, scrubbing	2*(30-40) mins/d	360	6m
8	Su (2014)	Individualized	Acupoints: Tianmen (BL 2)), Kangong, Taiyang (EX-HN 5), Zongjin, Yinyang, Jianjing (GB 21), Pijing, Ganjing, Xinjing, Shenjing, Feijing, Baihui (GV 20), Sishencong (EX-HN 1), Yingxiang (LI 20), Yuyao (EX-HN 4), Sizhukong (TE 23), Jingming (BL 1), Wujing (on head), Spine, Danzhong (CV 17), Xinshu (BL 15), Ganshu (BL 18), Pishu (BL 20), Dazhui (GV 14), Quchi (LI 11), Hegu (LI 4)	pushing, kneading, grasping, pressing, rubbing, arc-pushing, twisting, rocking, pinching, tapping	1*(25-35) mins/d	28	28d
<b>Case-series clinical trials</b>							
9	Sun (2010)	Standardized	Acupoints: Baihui (GV 20), Tianmen (BL 2), Kangong, Taiyang (EX-HN 5), Abdomen, Qihai (CV 6), Guanyuan (CV 4), Quchi (LI 11), Shousanli (LI 10), Neiguan (PC 6), Shenmen (HT 7), Zusanli (ST 36), Yanglingquan (GB 34), Taichong (LR 3), Gongsun (SP 4), Xinshu (BL 15), Ganshu (BL 18), Gesu (BL 17), Shenshu (BL 23), Spine	pushing, kneading, pinching, part-pushing, rubbing, pressing, scrubbing, twisting	2*(30-40) mins/d	120-300	2-5m
10	Dai (2006)	Individualized	Acupoints: Baihui (GV 20), Sishencong (EX-HN 1), Tianmen (BL 2), Taiyang (EX-HN 5), Jingming (BL 1), Yuyao (EX-HN 4), Sizhukong (TE 23), Yingxiang (LI 20), Wujing (on head), Danzhong (CV 17), Xinshu (BL 15), Ganshu (BL 18), Pishu (BL 20), Jianjing (GB 21), Dazhui (GV 14), Quchi (LI 11), Hegu (LI 4), Abdomen, Zusanli (ST 36)	pushing, pressing, arc-pushing, kneading, trembling, part-pushing, rolling, grasping, tapping, rubbing, pecking, twisting	NR	NR	NR
11	Wang (2005)	Individualized	Acupoints: Baihui (GV 20), Sishencong (EX-HN 1), Tianmen (BL 2), Kangong, Taiyang (EX-HN 5), Jingming (BL 1), Yuyao (EX-HN 4), Sizhukong (TE 23), Yingxiang (LI 20), Renzhong (GV 26), Chengjiang (CV 24), Wujing (on head), Danzhong (CV 17), Spine, Xinshu (BL 15), Ganshu (BL 18), Pishu (BL 20), Shenshu (BL 23), Jianjing (GB 21), Dazhui (GV 14), Quchi (LI 11), Hegu (LI 4), Abdomen, Zusanli (ST 36)	pressing, pushing, kneading, pecking, rolling, pinching, grasping, tapping, rubbing, twisting	NR	1-32	NR

**Table 3. Frequency of the acupoints and regions used in the included studies**

No. of studies	Acupoints or regions
8	Xinshu (BL 15), Ganshu (BL 18), Baihui (GV 20)
7	Kangong,
6	Shenshu (BL 23), Sishencong (EX-HN 1)
5	Pishu (BL 20), Zusanli (ST 36), Abdomen, Tianmen (BL 2), Taiyang (EX-HN 5), Quchi (LI 11)
4	Spine, Daling (PC 7)
3	Neilaogong (PC 8), Shenmen (HT 7), Neiguan (PC 6), Jianjing (GB 21), Yingxiang (LI 20), Sizhukong (TE 23), Jingming (BL 1), Wujing (on head), Danzong (CV 17), Dazhui (GV 14), Hegu (LI 4)
2	Qihai (CV 6), Guanyuan (CV 4), Shousanli (LI 10), Geshu (BL 17), Yanglingquan (GB 34), Taichong (LR 3), Gongsun (SP 4)
1	Sanyinjiao (SP 6), Sanjiaoshu (BL 22), Yinyang, Pijing, Ganjing

**Table 4. Assessment of risk of bias in the 3 included case series studies**

<b>Code</b>	<b>JBI Critical Appraisal Checklist for Case Series</b>	<b>Sun (2010)</b>	<b>Dai (2006)</b>	<b>Wang (2005)</b>
<b>1</b>	Were there clear criteria for inclusion in the case series?	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>
<b>2</b>	Was the condition measured in a standard, reliable way for all participants included in the case series?	<b>Unclear</b>	<b>Unclear</b>	<b>Unclear</b>
<b>3</b>	Were valid methods used to identify the condition of all of the participants included in the case series?	<b>Unclear</b>	<b>Yes</b>	<b>Yes</b>
<b>4</b>	Did the case series have consecutive inclusion of participants?	<b>Yes</b>	<b>Unclear</b>	<b>Yes</b>
<b>5</b>	Did the case series have complete inclusion of participants?	<b>Unclear</b>	<b>Unclear</b>	<b>Unclear</b>
<b>6</b>	Was there clear reporting of the demographics of the participants in the study?	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>
<b>7</b>	Was there clear reporting of the clinical information of the participants?	<b>Yes</b>	<b>No</b>	<b>No</b>
<b>8</b>	Were the outcomes or follow-up results of cases clearly reported?	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>
<b>9</b>	Was there clear reporting of the demographic information of the presenting site(s)/clinic(s)?	<b>No</b>	<b>No</b>	<b>Yes</b>
<b>10</b>	Was the statistical analysis appropriate?	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>



Table 5. Summary of findings for the main comparisons

Message Compared to Other Therapies for Attention Deficit/Hyperactivity Disorders in Children and Adolescents						
Patient or population: Attention Deficit/Hyperactivity Disorders in Children and Adolescents						
Setting: Hospital/School/Home						
Intervention: Massage						
Comparison: Control						
Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N <sub>2</sub> of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with Control	Risk with Massage				
Message versus Methylphenidate						
Improvement assessed with: Various rating scales and rating standards	655 per 1,000	<b>911 per 1,000</b> (760 to 1,000)	<b>RR 1.39</b> (1.16 to 1.66)	535 (4 RCTs)	⊕ ⊙ ⊙ ⊙ VERY LOW <sup>a,b</sup>	
Attention deficit and hyperactivity	The mean attention deficit and hyperactivity was <b>0</b>	The mean attention deficit and hyperactivity in the intervention group was 9.31 lower (11.43 lower to 7.19 lower)	-	153 (1 RCT)	⊕ ⊙ ⊙ ⊙ VERY LOW <sup>a,c</sup>	
Message versus Waitlist						
Anxious - Passive assessed with: Conners Teacher Rating Scales	The mean anxious - Passive was <b>0</b>	The mean anxious - Passive in the intervention group was 11.7 lower (17.84 lower to 5.56 lower)	-	30 (1 RCT)	⊕ ⊕ ⊙ ⊙ LOW <sup>d,e,f,g</sup>	Message appears to result in a large reduction in anxious - Passive.
Asocial-Behavior assessed with: Conners Teacher Rating Scales	The mean asocial-Behavior was <b>0</b>	The mean asocial-Behavior in the intervention group was 8.6 lower (15.87 lower to 1.33 lower)	-	30 (1 RCT)	⊕ ⊕ ⊙ ⊙ LOW <sup>d,e,f,h</sup>	Message appears to result in a large reduction in asocial-Behavior.
Hyperactivity assessed with: Conners Teacher Rating Scales	The mean hyperactivity was <b>0</b>	The mean hyperactivity in the intervention group was 6.3 lower (13.6 lower to 1 higher)	-	30 (1 RCT)	⊕ ⊙ ⊙ ⊙ VERY LOW <sup>d,e,f</sup>	
Daydream/Attention Problems assessed with: Conners Teacher Rating Scales	The mean daydream/Attention Problems was <b>0</b>	The mean daydream/Attention Problems in the intervention group was 3.7 lower (10.04 lower to 2.64 higher)	-	30 (1 RCT)	⊕ ⊙ ⊙ ⊙ VERY LOW <sup>d,e,f</sup>	
Sensory Integration Training + Massage versus Sensory Integration Training						
Improvement	595 per 1,000	<b>975 per 1,000</b> (743 to 1,000)	<b>RR 1.64</b> (1.25 to 2.15)	76 (1 RCT)	⊕ ⊙ ⊙ ⊙ VERY LOW <sup>i,j</sup>	
*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the <b>relative effect</b> of the intervention (and its 95% CI). CI: Confidence interval; RR: Risk ratio; MD: Mean difference						

**Table 5. Summary of findings for the main comparisons**

# Massage Compared to Other Therapies for Attention Deficit/Hyperactivity Disorders in Children and Adolescents

**Patient or population:** Attention Deficit/Hyperactivity Disorders in Children and Adolescents

**Setting:** Hospital/School/Home

**Intervention:** Massage

**Comparison:** Control

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with Control	Risk with Massage				
Massage versus Methylphenidate						

**GRADE Working Group grades of evidence**

**High certainty:** We are very confident that the true effect lies close to that of the estimate of the effect

**Moderate certainty:** We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

**Low certainty:** Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

**Very low certainty:** We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

## Explanations

- a. Downgraded due to high risk of bias on limitations of study design and implementation, lack of validated outcome and outcome measures, selective reporting.
- b. Downgraded due to unexplained large heterogeneity ( $I^2 = 75\%$ )
- c. Downgraded due to the sample size of the included study (could not meet the optimal information size criterion)
- d. Downgraded due to limitations of randomization, allocation concealment, and blinding of participants.
- e. Downgraded due to small sample size (did not meet the optimal information size criterion).
- f. Downgraded due to it is an early study with positive result in small sample size.
- g. A large effect size of SMD > 0.8 was found (Cohen's  $d = 1.36$ ).
- h. A large effect size of SMD > 0.8 was found (Cohen's  $d = 0.85$ )
- i. Downgraded due to high risk of bias on randomization, allocation concealment, blinding, validated outcomes and outcome measures.
- j. Downgraded due to the small sample size (did not meet the optimal information size criterion).

## **Author Biographies**

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