

Massage Therapy in Infants and Children under 5 Years of Age: Protocol for an Overview of Systematic Reviews and A Systematic Review

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Protocol

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Abstract

Introduction: Massage is a popularly used complementary and alternative therapy. Previous randomised controlled trials have examined the effects of massage on children, and several systematic reviews have been conducted to synthesise these data. This study aims to assess and summarise the current evidence from published systematic reviews of controlled clinical trials on the practice of paediatric massage, specifically in infants and children aged < 5 years.

Methods and analysis: This protocol was developed based on the *Cochrane Handbook of Systematic Reviews of Interventions* and the *Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols*. The online databases MEDLINE, Embase, Health Technology Assessment Database, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Allied and Complementary Medicine, China National Knowledge Infrastructure, and Wanfang Data will be searched from the inception to June 2020 for evidence of the treatment effects. We will include systematic reviews of randomised control trials in infants and children aged < 5 years. Two reviewers will independently screen the articles for inclusion as per the eligibility criteria. They will extract information from the included studies and assess the methodological quality of the included studies. In addition, a systematic review of the adverse effects of massage on infants and children aged < 5 years will be included in this overview. We will present the treatment effects and adverse effects narratively. The pooled effect estimates for meta-analysed outcomes from the included studies will be extracted when possible. Additionally, we will generate a figure to show the recommendation level of massage therapy for each condition included according to the evidence quality of the studies included in the systematic reviews.

Discussion: This overview of systematic reviews will summarise the current evidence on massage, specifically for infants and children aged < 5 years. We will comprehensively present the positive effects and adverse effects of this intervention.

Trial registration number: CRD42020186003

Background

Child (aged < 5 years) and infant health is a major public health concern worldwide [1] Certain medical conditions, such as preterm complications, diarrhoeal diseases, and congenital muscular torticollis, will greatly impair infant and child development if not properly treated. For example, the complications of premature birth may lead to cerebral palsy, impaired learning, vision and hearing problems, behaviour and psychological problems, and chronic health issues [2]. Patients with congenital muscular torticollis symptoms or comorbidities usually suffer from cosmetic problems and other associated physical dysfunctions [3, 4]. Diarrhoeal disease is the second leading cause of death and malnutrition in children aged < 5 years [5]. Therefore, timely diagnosis and interventions are crucial in treating and improving these paediatrics conditions.⁶

Although evidence-based treatments are available, the use of Complementary and Alternative Medicine (CAM) has been increasingly popular among paediatric patients worldwide. In the US, 11.8% of children have used some form of CAM in 2007 [7], whereas a survey in 2016 showed that 20% of households with children in Canada used CAM therapies [8]. It has been reported that the 12-month prevalence of CAM usage in children was 18.4% in Australia [9]. The prevalence of CAM therapies was higher in Asia and Europe, where the mean prevalence was 45% across 20 European countries [10] and approximately 65.3% in Korea [11]. In general, children are more likely to receive CAM treatment due to parents' prior experience and positive perception of CAM [12]. Parents choose CAM therapies over conventional medicine for their children because a particular CAM treatment was considered effective and due to fear of side effects of medications, dissatisfaction with conventional medicine, and the need for more personal attention [13]. Medications such as antibiotics and chemotherapeutics can induce toxicities and have negative influences on the enteric immune system in children and adults [14]. CAM modalities, such as skin-to-skin contact and mind-body therapies, are often necessary in paediatrics, due to their relative safety, affordability, and ease of implementation. Parents are more likely to use CAM for strengthening the immune system, physical stabilisation, and maintaining the health of their children [7, 15, 16].

Massage therapy

Among the different CAM modalities, massage therapy is one of the most commonly used in the paediatric population. Massage is a complementary and alternative therapy that involves manipulating the soft tissues of the body for improving health conditions [17]. Massage for infants and children requires unique approaches (e.g. manipulations, frequency, locations, strength, permission of children), which determine the effects of this intervention [6, 18]. The prevalence of use of massage in children among all types of CAM ranged from 8% to 25% in UK, US, Australia, and Canada [8, 9, 19, 20]. Massage therapy is popular in the treatment of particular health conditions in children, such as cancers, pulmonary disease, and sickle cell disease [21]. Massage therapy was ranked the second most common CAM therapy in two studies [21, 22]. In a survey on the prevalence of massage for cerebral palsy, 80% of the children were found to have received this therapy [23]. In general, massage therapies applied to children are collectively known as paediatric massage, and the application of paediatric massage is usually based on life experience or clinical cases. Some paediatric massage types have their specific theoretical system, such as paediatric *tuina*, which is an independent modality of traditional Chinese medicine (TCM) therapies and is based on TCM meridian theories. This paediatric massage type works well in infants and children aged < 6 years, especially those aged < 3 years [6]. Massage has been used in many paediatric conditions, such as abdominal pain [24], diarrhoea [25], constipation [26], anorexia [27], autism spectrum disorder [28], attention deficit hyperactivity disorder [29], eczema [30], preterm complications [31], asthma [32], and congenital muscular torticollis (CMT) [33]. Until now, there has been no established international treatment guideline on the usage of massage therapy in children.

The mechanisms of massage are still not fully understood. Some researchers believe that massage might help promote the body to heal itself and return to homeostasis. The receptors in the skin detect a range of stimuli, such as light touch or pressure, and transmit the signals from the periphery to synapses

in the central nervous system. Subsequently, the brain integrates these signals into effective actions via the regulation of the neuroendocrine-immune network [34]. Some researchers put forth that the gate control theory may explain the mechanism of massage for pain management. According to this theory, massage increases large nerve fibre (fibres that carry sensations of pressure and touch to the spinal cord) activity, which inhibits the effects of small nerve fibres (fibres that carry pain signals to the spinal cord) [35]. Massage could correct deformity in conditions of the musculoskeletal system through manipulations in specific directions. For example, infants with CMT are strongly recommended to receive stretching manipulation in the reverse direction to the atypical posture to elongate shortened muscles as long as they are identified [36]. Previous clinical trials suggested that massage has potential effects on many paediatric conditions, such as anxiety [37], pain [38], sleep disturbance [39], gastrointestinal functioning [40], immune functioning [41], cognitive problems [42], and emotional disorders [43]. A number of systematic reviews have also been conducted to gather evidence of massage therapy in paediatrics [27, 44, 45, 46]. Field conducted a narrative review on summarising the literature on massage therapy in the past decade and showed that this intervention may have beneficial effects on many paediatric conditions [47]. Although massage is commonly used in infants and children with various conditions, the evidence of the therapeutic effects is not strong enough to support its usual use due to the biases of many previous studies. Furthermore, there has been no systematic overview, specifically on infants and children aged < 5 years. Therefore, we designed this overview of systematic reviews to further summarise the existing evidence of massage for the conditions of infants and children aged < 5 years.

Aims

- (1) This overview of systematic reviews aims to summarise the existing evidence on the treatment effects of massage therapy in infants and children aged < 5 years.
- (2) The embedded systematic review aims to examine the adverse effects of massage therapy on infants and children aged < 5 years.

Methods And Analysis

This protocol of overview of systematic reviews follows the guidelines of the *Cochrane Handbook of Systematic Reviews of Interventions* [48], and the *Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P)* [49]. The eligibility criteria for the clinical question guiding this overview are presented in the PICOTSS (patient, intervention, comparators, outcomes, timing, setting, and study design) format (Table 1). We will also perform a supplementary systematic review to summarise the evidence of the adverse effects of massage on infants and children aged < 5 years. The methods of this review are based on the criteria of conducting systematic reviews of adverse events in the *Cochrane Handbook of Systematic Reviews of Interventions* [50], and the *CRD's guidance for undertaking reviews in health care* [51]. Key points of the search eligibility and strategies are outlined in Table 2.

Criteria for considering reviews for inclusion

Types of studies

We will include published systematic reviews and randomised controlled trials (RCTs).

Types of participants

We will include systematic reviews in which participants are infants and children aged < 5 years.

Types of interventions

We will include systematic reviews that examine the effects and/or safety of massage therapy for infants and children aged < 5 years. Massage is defined as manipulations conducted on the soft tissue of a child's body, which might include kneading, grasping, pressing, pushing, nipping, rotating, stretching, rubbing, and so forth [52]. This intervention can be used for treating or preventing diseases, improving the situation of medical conditions, promoting growth, health preservation, improving immunity, among others. We will include all types of massage therapies.

Types of comparisons

We will include systematic reviews of RCTs that compare the effects between massage therapy and other interventions, control interventions, or no intervention. The comparisons include waitlist control, placebo or sham controls, positive controls, pharmacological treatments, combinations of treatments, and usual or standard care. Studies comparing the effects of different kinds of massage therapies, or between massage and other complementary and alternative therapies, will be excluded.

Types of outcomes

Primary and secondary outcomes will not be limited due to the diversity of diseases and conditions. Where possible, when assessing study quality, we will consider the use of validated research tools to measure outcomes related to children and their caregivers.

Children

- Physical outcomes (e.g. blood pressure, pain assessment, pulse rate, weight change, length of hospital admission, readmission).
- Psychological outcomes (e.g. anxiety, depression, insomnia, fears, behavioural regression, self-esteem, mood, fears, and month-child attachment).
- Developmental outcomes (e.g. weight gain, intelligence, the ability to learn knowledge).

Caregivers

- Physical outcomes (e.g. blood pressure, pulse rate, weight change).
- Psychological outcomes (e.g. economic pressure, anxiety, depression, self-esteem, mood, fears)

Safety of interventions

- All adverse events (e.g. an increase in anxiety after receiving an intervention, high dropout rate) [50]

Timing

We will include systematic reviews of RCTs of any duration, treatment period, and treatment frequency.

Setting

We will include systematic reviews of RCTs that have been conducted in any setting. The intervention could be implemented anywhere, such as hospitals and at home. The therapists could be parents, caregivers, paediatricians, experts, practitioners, or other qualified personnel. The clinical trials could be pilot studies, feasibility studies, fully powered studies, or other phases. There are no limitations in other aspects of the setting.

Table 1. Eligibility criteria using the PICOTSS (Patients, Interventions, Comparators, Outcomes, Timing, Setting, and Study Design) format
<p>Patients</p> <ul style="list-style-type: none"> · Infants and children aged < 5 years
<p>Intervention</p> <ul style="list-style-type: none"> · Massage therapy
<p>Comparators</p> <ul style="list-style-type: none"> · Waitlist control · Placebo · Positive controls · Pharmacological treatments · Combinations of treatments · Usual care · Standard care
<p>Outcomes</p> <ul style="list-style-type: none"> · <i>Children</i> <ul style="list-style-type: none"> § Physical outcomes (e.g. pain assessment, pulse rate, length of hospital admission, readmission) § Psychosocial outcomes (e.g. anxiety, depression, insomnia, fears, behavioural regression) § Developmental outcomes (e.g. weight gain, intelligence, ability of learning knowledge) · <i>Caregivers</i> <ul style="list-style-type: none"> § Physical outcomes (e.g. blood pressure) § Psychological outcomes (e.g. economic pressure, anxiety, depression) · <i>Safety of interventions</i> <ul style="list-style-type: none"> § All adverse events (e.g. an increase in anxiety after receiving an intervention, high drop-out rate)
<p>Timing</p> <ul style="list-style-type: none"> · Studies of any duration
<p>Setting</p> <ul style="list-style-type: none"> · Studies of any setting
<p>Study Design</p> <ul style="list-style-type: none"> · Systematic reviews with randomized controlled trials

Table 2. Key points of the protocol of systematic review of adverse events of massage for infants and children aged < 5 years

Participants

- Infants and children aged < 5 years

Intervention

- Massage therapy

Comparators (if possible)

- Waitlist
- Placebo
- Positive controls
- Pharmacological treatments
- Combinations of treatments
- Usual care
- Standard care

Outcomes

- Any adverse events associated with the intervention

Timing

- Studies of any duration

Setting

- Studies of any setting

Study Design

- Randomized trials, cohort studies, case-control studies, case reports, and case series

Searching methods

- Useful information will be extracted from the included systematic reviews
- Free-text searching
- Index term attached with floating subheadings searching: MEDLINE and Embase
- Hand searching: google scholar

Data extraction

- Target condition
- Study type

<ul style="list-style-type: none"> · Number of participants · Intervention setting · Age of participants · Adverse event
<p>Data analysis</p> <ul style="list-style-type: none"> · Adverse events will be summarized and presented narratively
<p>Assessment of risk of bias</p> <ul style="list-style-type: none"> · Cochrane risk-of-bias tool (RoB 2) for randomized trials [53] · Non-randomized Studies of Interventions (ROBINS-I) tool for non-randomized studies [54]
<p>Data synthesis</p> <ul style="list-style-type: none"> · Adverse events will be listed and summarized narratively · High drop-out rate (20% or higher) will be considered as an adverse effect

Search methods for the identification of reviews

For objective 1, we will search the following databases, from inception to June 2020: Ovid MEDLINE, Embase, Health Technology Assessment Database (HTA), the Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects (DARE), Allied and Complementary Medicine (AMED), China National Knowledge Infrastructure (CNKI), and Wanfang Data. The search includes six English databases and two Chinese databases, covering the major databases for international publications and literature published in Chinese. We have developed the searching strategies for the Embase database using free-text words and subheadings (Table 3), and search strategies for other databases will be built up accordingly. The following keywords will be used: (massag* OR touch OR tactile stimulation OR anmo OR acupressure OR *tuina* OR manipulat*) AND (newborn* OR child* OR baby OR babies OR infant* OR youth OR paediatric* OR paediatric* OR toddler* OR pre-school* OR pre-school*). To search the Chinese databases, the corresponding Chinese keywords will be used. We will contact the authors of the studies if necessary information is missing from the publications. References for the included studies will be searched for useful information. To address the on-going systematic reviews, we will also search the PROSPERO database to identify the registered relevant systematic reviews. We will not impose any time or language restrictions. Information on adverse effects from the included systematic reviews may not be comprehensive. To supplement this, the index term, free-text searching approach, and 'Grey' literature hand-searching will be used for identifying articles with information on adverse effects. We will extract data on infants and children aged < 5 years.

Table 3. Embase Search strategy	
Code	Keywords
1	(massag* OR touch OR tactile stimulation OR anmo OR acupressure OR tuina OR manipulat*).mp
2	exp massage/
3	exp tactile stimulation/
4	exp acupressure/
5	exp manipulative medicine/
6	1 or 2 or 3 or 4 or 5
7	(newborn* OR child* OR baby OR babies OR infant* OR youth OR pediatric* OR paediatric* OR toddler* OR preschool* OR pre-school*).mp
8	exp child/ or exp child care/
9	exp newborn/ or exp newborn care/
10	exp infant care/ or exp infant/
11	exp juvenile/
12	exp pediatrics/
13	exp toddler/
14	exp preschool child/
15	7 or 8 or 9 or 10 or 11 or 12 or 13 or 14
16	exp "systematic review"/ or exp meta analysis/ or exp "review"/
17	6 and 15 and 16

For objective 2, we will extract information on the adverse effects from the included systematic reviews. In addition, we will search the following databases using both the index terms approach and the free-text searching approach from inception to June 2020: MEDLINE, Embase. Subheadings will be attached to the index term 'massage'. The subheadings for donating data in MEDLINE and Embase databases will be used as follows: Massage/adverse effects (MEDLINE) and Massage/side effects (Embase). Text words for synonyms of 'adverse effects' and related terms will be searched using the following keywords from inception to June 2020: (massag* OR touch OR tactile stimulation OR *anmo* OR acupressure OR *tuina* OR manipulat*) AND (newborn* OR child* OR baby OR babies OR infant* OR youth OR paediatric* OR paediatric* OR toddler* OR pre-school* OR pre-school*) AND (safe OR safety OR side effect* OR undesirable effect* OR treatment emergent OR adverse effect*). We will also perform hand-searching for reports, conference proceedings, journals, and theses for useful information. Data on infants and children aged < 5 years will be extracted and summarised.

Data collection and analysis

Selection of reviews

Two authors (SCC and CSY) will independently screen the results of the electronic search by title and abstract. For both objectives, we will obtain the full-text report of the systematic reviews and studies deemed appropriate and uncertain, and subsequently apply the PICOTSS eligibility criteria to determine the final inclusion list. Studies that do not meet the inclusion criteria will be excluded. We will resolve disagreements between review authors through discussion or consultation with an additional reviewer (WFY) when necessary. We will provide a PRISMA flow diagram documenting the screening and review the selection process.

Data extraction and management

Two authors (SCC and CSY) will independently extract data using a standardised form. Discrepancies will be resolved by discussion or consultation with an additional reviewer (WFY) if necessary.

For objective 1, the data extraction form will include the following details:

- Target conditions
- Objectives of the systematic review
- Search time
- Number of included trials and participants
- Details of the participants
- Details of the interventions
- Details of comparison interventions
- Outcomes for which data were reported
- Adverse effects
- Review limitations
- Assessment of methodological quality and risk of bias of the included evidence
- GRADE judgements regarding the quality of evidence where present
- Meta-analysed pooled effect estimates for outcomes in reviews

For objective 2, we will extract the following details of the included studies:

- Target condition
- Study type
- Number of participants
- Intervention setting
- Age of participants

- Adverse event
- Published or not

Assessment of the methodological quality of the included reviews

Two authors (SCC and CSY) will be responsible for the methodological assessment. Discrepancies will be resolved by consensus between the two authors or by consulting a third reviewer (WFY) if necessary.

For objective 1, according to the requirement of the Cochrane handbook, both the methodological quality of the reviews included and the evidence quality of the individual studies included in the reviews must be assessed.

Quality of the included reviews

The methodological quality of the included systematic reviews will be assessed using the AMSTAR 2 (A Measurement Tool to Assess systematic Reviews 2) instrument [55, 56]. AMSTAR 2 assists in evaluating the quality of conducting systematic reviews using 16 distinct items, 7 of which are critical domains that can have an impact on the validity of a systematic review. The seven critical domains include protocol registration before the commencement of the review (item 2), comprehensiveness of the literature search strategy (item 4), justification of exclusion (item 7), risk of bias of the studies included in the reviews (item 9), appropriateness of meta-analytical methods (item 11), consideration of risk of bias when interpreting the results of the review (item 13), and assessment of the presence and likely impact of publication bias (item 15). Each AMSTAR item will be rated as 'Yes' (clearly done) or 'No' (clearly not done or without information) in light of the published systematic review. Some items provide a 'partial Yes' for responding to the situations that we think are worthy of partial adherence to the criteria. AMSTAR 2 assists users in identifying the potential influence of flaws or weaknesses in each domain. Quality of systematic reviews will be rated as 'High' (no or one non-critical weakness), 'Moderate' (more than one non-critical weakness), 'Low' (one critical flaw with or without non-critical weaknesses), or 'Critical low' (more than one critical flaw with or without non-critical weaknesses) [56].

Quality of evidence in the included reviews

We will assess the risk of bias of the individual trials included in the systematic reviews using the Cochrane collaboration's tool (RoB 2) [53], which assesses the risk of bias of randomised trials in six domains as 'Low risk', 'Unclear risk', and 'High risk'. These domains are selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias. The overall quality of evidence across studies for each significant outcome will be assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach [57]. The level of evidence will be determined by assessing the following aspects of the studies: number of studies, study design, risk of bias, inconsistency of the findings, imprecision, indirectness of the estimate, and other considerations, such as publication bias. A risk of bias (RoB) table and a summary of findings (SoF) table based on the methods described in the Cochrane Handbook for Systematic Reviews of Interventions will be built up to convey

key information on the effects of massage intervention for each condition and the overall credibility of the information [48].

For objective 2, we will use the RoB 2 tool to assess the risk of bias of randomised trials [53] and the Non-randomized Studies of Interventions (ROBINS-I) tool for non-randomized studies [54]. Seven domains will be assessed in ROBINS-I, which are bias due to confounding factors, bias in the selection of participants for the study, bias in classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in the measurement of outcomes, and bias in selection of the reported results. These domains will be rated as 'Low risk', 'Moderate risk', 'Serious risk', and 'Critical bias'.

Data synthesis

We will report the results according to the Cochrane Handbook of Systematic Reviews of Interventions. A PRISMA flowchart will be used to present the process of study selection for both the overview and the systematic review. We will perform a qualitative synthesis for each universe of diseases, disorders, or other conditions. The universes will be classified according to the International Classification of Diseases, 11th version (ICD-11), which is the international standard for reporting diseases and health conditions [58].

The problem of double-counting data will be considered prudently because there might be two or more systematic reviews addressing the same question. To minimise the reduplicative information extracted from overlapping trials, the following strategies will be applied:

- If the qualities of these reviews are similar, we will select the one that contributes the most outcome data.
- If the outcomes of these reviews are completely overlapping, we will retain the one with the highest quality.
- If the outcomes of these reviews are partly overlapping, we will completely retain the highest-quality review and partly retain those with lower-quality.
- If the outcomes of these reviews do not overlap, we will retain all.
- If the outcomes of these reviews are completely overlapping and their qualities are similar, we will select the most recent.

We will present the effects of massage therapy based on the most comprehensive reviews with the highest quality. For the overlapping reviews that are not included in the intervention effects analysis, we will report their general information in a table to enable readers to obtain useful data. The AMSTAR 2 instrument, Cochrane RoB tool, and GRADE approach will be used to assess the quality of the reviews.

When possible, we will extract and report pooled effect estimates for meta-analysed outcomes for each review that meets the inclusion criteria. For dichotomous outcomes, relative risks (RRs) with 95% confidence intervals (CIs) will be pooled, while for continuous outcomes, mean differences (MDs) with 95% CIs for the same outcome measure or standardised mean differences (SMDs) with 95% CIs for

different outcome measures will be expressed. For time-to-event data, hazard ratios (HRs) with 95% CIs will be expressed [48]. However, we will not compute an overview meta-estimate due to the heterogeneity in ages and outcomes between trials, the absence of essential data, and the lack of well-established quantification methods.

Adverse effects of massage therapy reported in the systematic reviews will be listed and summarised narratively. The mechanism of adverse effects of therapies for several conditions might be similar in different populations and settings [50]. Therefore, we will collect adverse effects regardless of the condition or how massage therapy was conducted. We will also collect information on adverse effects from the overlapping included systematic reviews. We will consider a high drop-out rate ($\geq 20\%$) as an outcome measure in study reports for adverse effects, since withdrawal might be related to upsetting side effects, stress on subjects, or others [48, 59].

According to the results synthesised from the data on effects and safety issues, we will generate a figure to present the recommendation level of massage therapy for each included condition, considering the gender, age, and other factors. Since the mechanism of treatment effects might be similar on the same outcomes across different conditions, we will also generate a figure to summarise evidence for each outcome, if possible. Sufficient systematic review evidence will be the most important criterion for the generation of the final recommendation level figure, and all adverse effects for each condition will be emphasised and marked.

ETHICS AND DISSEMINATION

Results of this overview will be published in a peer-reviewed academic journal and presented at relevant national or international conferences. The study does not need ethical approval since it will not collect individual information.

Discussion

This overview will provide comprehensive evidence of massage therapy for infants and children aged < 5 years. We will present the treatment effects and adverse effects of massage therapy both quantitatively and qualitatively, if possible. The high mortality rate of infants and children aged < 5 years is a global public health concern. Our results may provide useful information for patients, care givers, healthcare workers, paediatricians, and policy makers.

There will be a systematic review of adverse effects embedded in the overview of systematic reviews to achieve balanced perspectives in accessing massage therapy. This is based on the requirements of the Cochrane handbook, indicating that all reviews ought to consider the adverse effects of an intervention. A summary of the adverse effects of massage therapy is significant since, compared to patients of other age groups, infants and children aged < 5 years are more sensitive to all interventions, and they have difficulties in expressing their feelings. Therefore, the highest priority ought to be given to safety when this age group receive interventions.

There are some limitations to this overview of systematic reviews. First, the depth of this review depends on the availability of the current literature. We have included comprehensive search terms and hand-search of relevant reviews to exhaust the current evidence. Second, some eligible systematic reviews might contain data not only about infants or children aged < 5 years but also for older children and adolescents. This may affect the pooled effects. We will further explore the impact of these studies using sensitivity analyses. Third, we will only include articles in English and Chinese, which might lead to missing relevant data in other languages.

Abbreviations

CAM: Complementary and Alternative Medicine; TCM: traditional Chinese medicine; CMT: congenital muscular torticollis; RCT: randomized controlled trial; HTA: Health Technology Assessment Database; DARE: Database of Abstracts of Reviews of Effects; AMED: Allied and Complementary Medicine; CNKI: China National Knowledge Infrastructure; GRADE: Grading of Recommendations Assessment, Development and Evaluation; ICD: International Classification of Diseases; RR: relative risk; CI: confidence interval; MD: mean difference; SMD: standardised mean differences; HR: hazard ratio.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing Interests

The authors declare that they have no competing interests.

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Authors' contributions

SCC and WFY conceived the topic. SCC, JY, and LKPS participated in the design of this trial. SCC drafted the manuscript. WFY, JCSL and SCCY revised this manuscript. All authors approved the final manuscript.

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