

Chiropractic spinal manipulation of children under 12

Independent review



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Executive summary

On 8 March 2019, the Council of Australian Governments (COAG) Health Council (CHC) noted community concerns about spinal manipulation on children performed by chiropractors and agreed that there was a need to consider whether public safety was at risk.

On behalf of the CHC, the Victorian Minister for Health, the Hon. Jenny Mikakos MP, instructed Safer Care Victoria (SCV) to undertake an independent review of the practice of chiropractic spinal manipulation on children under 12 years. The findings of this review are to be provided to the Minister for reporting to the CHC.

To provide expert guidance and advice to inform the review, SCV established an independent advisory panel. The panel included expertise in chiropractic care, academic allied health, health practitioner regulation, healthcare evidence, governance, paediatrics and paediatric surgery, and musculoskeletal care, and had consumer representation.

The panel's role was to provide advice to assist SCV in scoping the review, interpretation of the findings, and in developing their recommendations. In order to provide this advice, the panel decided to undertake a public consultation as well as consider evidence from the relevant complaints and regulatory bodies alongside a systematic review of the literature.

The review comprised a search for evidence of harm, a review of evidence of effectiveness, an online public consultation and an online consultation with health practitioners. Detailed descriptions of these different components of the review are provided in this report.

The scope of the review included spinal manipulation in children under 12 years of age. Spinal manipulation as defined in Section 123 of the *Health Practitioner Regulation National Law Act 2009* (National Law) is one of many techniques performed by chiropractors. For the purpose of collecting all relevant evidence, the panel agreed to a definition of spinal manipulation aligned to that defined in Section 123 of National Law. Spinal manipulation was defined as "any technique delivered by any health professional that involves a high velocity, low amplitude thrust beyond the physiological range of motion, impacting the spine, within the limits of anatomical integrity."

The panel also determined that, while the recommendations are focused primarily on the chiropractic profession, other professions permitted to do spinal manipulation will likely be implicated should there be legislative or policy implications as a result of this review. Section 123 of National Law restricts the practice of spinal manipulation of the cervical spine to four health professions: chiropractic, osteopathy, medical and physiotherapy.

Further content regarding the review process and in-depth findings have been detailed in this report.

SUMMARY OF FINDINGS

Review of evidence of harm

An extensive search was undertaken to identify evidence of harm sustained by children who had received spinal manipulation. This included a literature review by Cochrane Australia, capture of patient complaints and practitioner notification data from Australian complaints and regulatory agencies, capture of Australian insurance claim data from the primary insurers for registered chiropractors, and stakeholder feedback from both online consultations. This extensive search identified very little evidence of patient harm occurring in Australia. In particular, there were no patient complaints or practitioner notifications that arose from significant harm to a child following spinal manipulation.

Three individual case reports were the only evidence of serious harm identified. Each of these reports related to spinal manipulative techniques performed outside of Australia and not limited to chiropractors. The practices described in these reports are not reflective of Australian chiropractic techniques. This does not mean spinal manipulation in children is not associated with any risk of any adverse effects. An extensive literature review did identify transient or minor adverse events but the prevalence was very low, albeit possibly more common in very young children.

There are two principle reasons why the search did not find strong evidence of harm in Australia. First, it is unlikely that spinal manipulation, as defined within the scope of the review, is a technique that is being routinely applied in Australia to young children or those with an immature spine. Second, skilled chiropractic care requires the practitioner to modify the force applied based on the age and developmental stage of the child. This means that children, particularly very young children, under the care of an Australian chiropractor are not likely to be receiving high impact manipulations.

Nonetheless, it is clear that spinal manipulation in children is not wholly without risk. Any risk associated with care, no matter how uncommon or minor, must be considered in light of any potential or likely benefits. This is particularly important in younger children, especially those under the age of 2 years in whom minor adverse events may be more common.

Review of evidence of effectiveness

SCV commissioned Cochrane Australia to undertake a systematic review of the effectiveness and safety of spinal manipulation of children under 12 years for any condition or symptom, irrespective of the profession providing treatment.

The major finding of this review is that the evidence base for spinal manipulation in children is very poor. In particular, no studies have been performed in Australia.

Specifically, the comprehensive review of the literature failed to identify any strong evidence for the effectiveness of spinal manipulation for a variety of conditions for which children are widely offered chiropractic manipulations. These conditions included colic, enuresis, back/neck pain, headache, asthma, otitis media, cerebral palsy, hyperactivity and torticollis.

There was low certainty (weak) evidence that spinal manipulation may be beneficial for modestly reducing crying time in children with colic, or for reducing the number of wet nights in children with enuresis. For both conditions the evidence was also consistent with either no or worsening effects.

For the other conditions – headache, asthma, otitis media, cerebral palsy, hyperactivity, and torticollis – there was no evidence that spinal manipulation was effective.

Based on this review of effectiveness, spinal manipulation of children cannot be recommended for:

- headache
- asthma
- otitis media
- cerebral palsy
- hyperactivity disorders
- torticollis.

The possible, but unlikely, benefits of spinal manipulation in the management of colic or enuresis should be balanced by the possibility, albeit rare, of minor harm.

Public consultation

SCV wished to hear from parents and guardians of children who had accessed chiropractic spinal care, exploring their experiences, both positive and negative. This was achieved through an online consultation process using the Victorian Government's Engage.Vic platform. Through this platform, 21,824 submissions were received from members of the public who had accessed chiropractic spinal care for a child under 12 years. This is the largest number of submissions received to date through Engage.Vic or any public stakeholder engagement.

The public responses indicated very strong consumer satisfaction. Of all respondents, 99.7% (21,750) reported a positive experience with the chiropractic care of their children. The overwhelming majority of parents/guardians reported that chiropractic spinal care helped their child, with 98% (21,474) indicating that their child improved after treatment. It was clear that parents/guardians appreciated the time that their child's chiropractor took to listen to their child's symptoms and to engage with them and their child. A sentiment that was strongly expressed was the right of a parent/guardian to choose their child's care.

Parents/guardians reported that they accessed chiropractic care for their child for a wide range of conditions and complaints, including maintaining general health and wellbeing. The most common conditions included posture concerns, colic, neck pain, difficulty with breastfeeding, back pain and headache.

A very small minority of respondents – 0.3% (74) – reported a negative experience. These experiences mostly related to concerns about the cost of treatment with no improvement in the condition, excessive use of X-rays, or perceived pressure to avoid medications or advice previously provided by other practitioners, including medical practitioners.

Health practitioner consultation

SCV wished to hear from registered health practitioners – chiropractors, medical practitioners and other health practitioners – about perceived benefits of or concerns with spinal manipulation in children. This was also achieved through an online consultation process using the Engage.Vic platform.

A total of 2735 responses were received from practitioners, 85% (2315) of whom had provided spinal care to a child under 12 in the past three years. Of those providing care, 99.5% (2303) were chiropractors, 80.8% (1871 out of 2315) had treated children aged 0–3 months, and 88.5% (2049 out of 2315) had treated children aged 0–24 months. The most common benefits of spinal manipulation reported by practitioners were relief from pain, better sleep quality, more relaxed or settled child, able to feed and latch better, and improved mobility or range of motion.

There were responses from 13 practitioners who had provided care to a child who had previously received spinal care from a different practitioner. These responses raised concerns about the risk of delayed access to appropriate care as a result of seeking non-evidence based spinal care (e.g. delayed diagnosis of scoliosis). No examples or experiences of serious harm were reported through this consultation.

SUMMARY OF RECOMMENDATIONS

These recommendations are based on the findings as outlined earlier in this report. In arriving at the recommendations, SCV has sought to strike a balance between diverse, and, at times, directly opposed, views. In particular, SCV sought to make recommendations that would both respect a parent's or guardian's right to choose appropriate healthcare options for their child while ensuring that children, particularly the very young who are less able to communicate adverse effects, are safe.

This was not easy. To say that the lack of strong evidence of either effectiveness or serious harm failed to provide robust foundations for recommendations would be an understatement. Nonetheless, in the absence of evidence of effectiveness and the awareness of the potential for harm expressed by the need for Section 123 of the National Law, SCV took a 'first do no harm' approach.

Improving safety

| Recommendation 1 | Spinal manipulation, as defined in Section 123 of National Law, should not be provided to children under 12 years of age, by any practitioner, for general wellness or for the management of the following conditions: developmental and behavioural disorders, hyperactivity disorders, autism spectrum disorders, asthma, infantile colic, bedwetting, ear infections, digestive problems, headache, cerebral palsy and torticollis. Section 123 of National Law defines spinal manipulation as "moving the joints of the cervical spine beyond a person's usual physiological range of motion using a high velocity, low amplitude thrust." |
|------------------|--|
| | This recommendation is based on the lack of evidence of effectiveness for these conditions and the current statement on advertising regarding inappropriate claims of benefit, made by the Chiropractic Board of Australia. ² |
| Recommendation 2 | All national boards of the health practitioners permitted to perform spinal manipulation (chiropractic, osteopathy, medical and physiotherapy) should consider Recommendation 1 when reviewing their current policies, if any, on spinal manipulation of children. |
| Recommendation 3 | Prior to treatment, practitioners offering spinal manipulation for children should provide parents or guardians with written information about the proposed benefits and possible risks of care. |
| | In their statement on paediatric care, the Chiropractic Board of Australia already expects practitioners to provide parents such information. This recommendation would require that the information is provided in written form. |
| Recommendation 4 | The national boards should periodically review notification data to identify any trends or evidence of harm that may require changes in policy, in line with the principles of risk-based regulation. |

¹ Health Practitioner Regulation National Law Act 2009 (https://www.legislation.qld.gov.au/view/html/inforce/current/act-2009-045#sec.123)

² Chiropractic Board of Australia Statement on advertising (2016) (https://www.chiropracticboard.gov.au/News/2016-03-07-statement-on-advertising.aspx)

Improving quality

| Recommendation 5 | Given the lack of Australian-based clinical trial evidence, the practitioner groups permitted to provide spinal manipulation (chiropractic, osteopathy, medical and physiotherapy) urgently undertake research to develop an evidence base for spinal manipulation on children, ceasing practice where the evidence shows no benefit. |
|------------------|--|
| | Health Ministers should consider whether relevant funding bodies (e.g. NHMRC, MRFF) specifically allocate funding for a priority targeted research call to address this evidence gap. |
| Recommendation 6 | Practitioner groups that provide spinal manipulation (chiropractic, osteopathy, medical and physiotherapy) must lead on developing evidence-based guidance on spinal manipulation of children for both practitioners and consumers, using National Health and Medical Research Council endorsed methods. |
| | Such guidance material should form the basis of written information for parents, advising them of proposed benefits and potential risks of intended care (see Recommendation 3). |
| Recommendation 7 | Consideration should be given by the Chiropractic Board of Australia to various models of advanced training in paediatric chiropractic care, particularly in spinal manipulation. |
| | In the longer term, the post registration training on offer to chiropractors with a special interest in paediatric care should be assessed against the evidence-based guidelines. |

Eliminating false advertising

| Recommendation 8 | The Australian Health Practitioner Regulation Agency (AHPRA) and the national boards should continue to audit practitioners in the application of their guidance regarding advertising. |
|-------------------|--|
| Recommendation 9 | The national boards should consider whether explicitly prohibitive advertising statements are issued regarding spinal manipulation in children where there is evidence of no benefit, as detailed in Recommendation 1. |
| Recommendation 10 | Health Ministers should consider increasing penalties for advertising offences under Section 133 of the National Law, where a registered practitioner claims benefits of spinal manipulation in children that have no evidence base (see Recommendation 1). |
| | The current penalty for advertising offenses under Section 133 of the National Law is a maximum of \$5000 for an individual and \$10,000 for a corporation. These are substantially lower than penalties allowable under the National Law for falsely claiming to be a registered practitioner (\$60,000 for an individual and \$120,000 for a corporation) or for misleading advertising under Australian consumer law (\$220,000 for an individual). |

Independent review

BACKGROUND

The *Health Practitioner Regulation National Law Act 2009* (National Law) recognises the protected practice of spinal manipulation of the cervical spine. Section 123 of the National Law restricts the practice of spinal manipulation of the cervical spine to four health professions; chiropractic, osteopathy, medical and physiotherapy. The definition of spinal manipulation for the purpose of this restriction "means moving the joints of the cervical spine beyond a person's usual physiological range of motion using a high velocity, low amplitude thrust".³

The restriction on practice to the four health professions was introduced as a proactive step to protect the public from a high-risk technique being performed on them by inadequately trained providers.

At the time of introduction, it was noted that the evidence base for the technique, both with regards to effectiveness or harm, was limited. Nonetheless, implicit in the restriction was the acknowledgement that spinal manipulation, particularly rotary or forceful manipulation of the cervical spine, has inherent risks of harm.

Indeed, at the time of introducing the restriction on practice the Australian Chiropractors Association (ACA) (formerly the Chiropractors Association of Australia) advocated for tougher restrictions. Specifically, the ACA argued for the restricted practice to include whole spine manipulation and to exclude health practitioners not specifically registered and/or suitably qualified to perform spinal manipulation.⁴

It is also generally acknowledged that children are more vulnerable to injury from spinal manipulation than adults. This is because excessive movements beyond physiological norm and safety are made possible by the incomplete anatomical development of the child, particularly a very young child.

In 2017, the Chiropractic Board of Australia (the Board) released a position statement on paediatric care. This statement references the Code of Conduct for registered chiropractors and guidelines for advertising, including the Board's specific statement on advertising.⁵ The Board continues to monitor compliance with their guidance and act when required.

The following is an excerpt from the Board's June 2017 position statement:

The Board expects practitioners to make sure their clinical practice is consistent with current evidence and/or best-practice approaches. Practitioners should critically evaluate their strengths and weaknesses and use continuing professional development (CPD) and other educational tools to ensure their knowledge and skills are appropriate for their work.

³ Australian Health Practitioner Regulation Agency: Reporting a criminal offence (https://www.ahpra.gov.au/Notifications/Raise-a-concern/Reporting-acriminal-offence.aspx)

⁴ Parliament of Australia: Chapter 2 Design of The National Registration and Accreditation Scheme for Doctors and Other Health Workers (https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Completed_inquiries/2008-10/registration_accreditation_scheme/report/c02)

⁵Chiropractic Board of Australia Statement on advertising (2016) (https://www.chiropracticboard.gov.au/News/2016-03-07-statement-on-advertising.aspx)

The Board expects practitioners to:

- discuss their proposed management plan with the patient's parent and/or guardian
- inform the parent and/or guardian about the quality of the acceptable evidence and explain the basis for the proposed treatment
- provide patients (or parent and/or guardian) with information about the risks and benefits of the proposed treatment and the risks of receiving no treatment
- understand that children have significant anatomical, physiological, developmental and psychological differences and needs from adults and that their healthcare management requires specific skills and expertise; including informed consent, examination, diagnosis, referral of 'red flags' and contraindications to care
- modify all care and treatment (including technique and force) to suit the age, presentation and development of the patient
- promptly refer patients to the care of other registered health practitioners when they have conditions or symptoms outside a chiropractor's scope of practice, for example 'red flags', and
- communicate effectively with other health practitioners involved with the care of the patient such as the patient's general practitioner or paediatrician.⁶

In August 2018, a Melbourne-based chiropractor posted on social media a video of a technique being performed on a two-week-old baby. This video generated much public concern at the time. In February 2019, the video was brought to the attention of the Victorian Minister for Health, after which prompt action was taken to urge the Australian Health Practitioner Regulation Agency (AHPRA) to take immediate action.

In an interview with ABC Radio Melbourne, the president of the Australian Chiropractors Association, Anthony Coxon, said he was "disturbed" by some of what was shown in the video, and he welcomed the investigation by the chiropractic board and AHPRA. "There are things within that video that I have concerns over," he said.⁷

In response to the concerns noted by the CHC and to protect the public, on 14 March 2019 the Board published the *Interim policy on spinal manipulation for infants and young children.*⁸ In this policy, the Board advised "chiropractors to not use spinal manipulation to treat children under two years of age." The interim policy was to be in place pending the outcomes of an independent review by SCV – this review.

The Victorian Minister for Health, the Hon. Jenny Mikakos MP, asked SCV, as Victoria's healthcare quality and safety improvement agency, to lead an independent review into chiropractic spinal manipulation of children under 12 years.

⁶ Chiropractic Board of Australia: Statement on paediatric care (2017) (https://www.chiropracticboard.gov.au/Codes-guidelines/Position-statements/Statement-of-Paediatric-care.aspx)

⁷ ABC News: Cranbourne chiropractor manipulates baby's spine in 'deeply disturbing' video (https://www.abc.net.au/news/2019-02-20/chiropractor-baby-video-appalling-says-victorian-health-minister/10827976)

⁸ Chiropractic Board of Australia Interim policy on spinal manipulation for infants and young children (2019) (https://www.chiropracticboard.gov.au/Codes-guidelines/Position-statements.aspx)

INDEPENDENT EXPERT ADVISORY PANEL

Role of the panel

SCV established an independent expert advisory panel to oversee and advise on the review, enabling SCV to make findings and provide recommendations to the Victorian Minister for Health by October 2019.

Specifically, the panel was engaged to:

- develop and endorse the scope of the resulting review
- set the parameters for the literature searches and systematic review
- determine the questions to be asked through the public and health practitioner consultations
- use all evidence gathered to inform SCV's findings and final recommendations.

The panel met on nine occasions throughout a six-month review period to provide oversight and consider information as it became available.

Panel membership

The Minister for Health appointed the Chief Executive Officer of SCV to chair the panel. Panel members were selected to include experts in chiropractic care, academic allied health, healthcare evidence, governance, paediatrics and paediatric surgery, and musculoskeletal care. Reflecting how SCV approaches all matters of healthcare improvement, the advisory panel had strong and effective consumer representation.

| Professor Euan Wallace AM | Panel Chair, Chief Executive Officer, Safer Care Victoria |
|--|---|
| Dr Alison Wray | Paediatric Neurosurgeon, Royal Children's Hospital |
| Professor Andrew Wilson | Chief Medical Officer, Safer Care Victoria |
| Mr David Harding | Physiotherapist, Paediatric Orthopaedic Clinic, Monash Children's Hospital |
| Adj. Associate Professor Donna Markham | Chief Allied Health Officer, Safer Care Victoria |
| Ms Emma Gierschick | Consumer representative |
| Dr Genevieve Keating | Chiropractor, Educator and Director, Dynamic Neuro-development |
| Professor Katrina Williams | Professor of Paediatrics and Head of Department, Monash University and Paediatrician, Developmental Paediatrics, Monash Health |
| Ms Keree Bradshaw | Consumer representative |
| Adj. Associate Professor Matthew Fisher | Chief Executive Officer, Australian Chiropractors Association |
| Mr Michael Johnson | Paediatric Orthopaedic Surgeon, Royal Children's Hospital |
| Professor Terry Haines | Professor and Head of School, School of Primary and Allied Health Care, Monash |
| Dr Wayne Minter AM | Chair, Chiropractic Board of Australia |

The Terms of Reference for this review can be found in **Appendix A** of this report.

¹⁰ Safer Care Victoria Chiropractic spinal manipulation of children under 12

SCOPE OF THE REVIEW

The announcement of the review generated significant public interest and some concern. When the review was announced, the footage shared in the media appeared to show potentially harmful manipulative techniques being performed by Australian-registered chiropractors.

During the design of this review it was recognised that there are strong and diverse views of chiropractic care, both among the public and health practitioners. Reflecting this, it was a purposeful decision that the advisory panel established by SCV was not only expert but also diverse and included experienced consumer representation.

In advising SCV on the scope of the review, the independent expert advisory panel recommended SCV include both a public and practitioner consultation, and a systematic review of evidence to inform overall findings and the development of evidence-based recommendations.

Section 123 of National Law restricts the practice of spinal manipulation to four health professions: chiropractic, osteopathy, medical and physiotherapy. Based on the events that triggered the review, the recommendations are necessarily focused on the chiropractic profession. However, it was clear from the outset that findings related to the technique, as defined in Section 123 of National Law, would likely have implications for the other three professions permitted to perform spinal manipulation in children.

SCV noted that the findings of this review could potentially have a significant impact on the scope of practice of chiropractors, osteopaths, physiotherapists, and medical practitioners. Further, given the widespread interest in the review and it was noted that review findings may attract the attention of overseas regulators.

To adequately consider the safety and efficacy of spinal manipulation in children, the early meetings of the panel focused on agreeing the following parameters:

- chiropractic practices or adjustments considered in scope
- conditions typically treated by the identified practices
- age ranges or groupings aligned to the relevant practices.

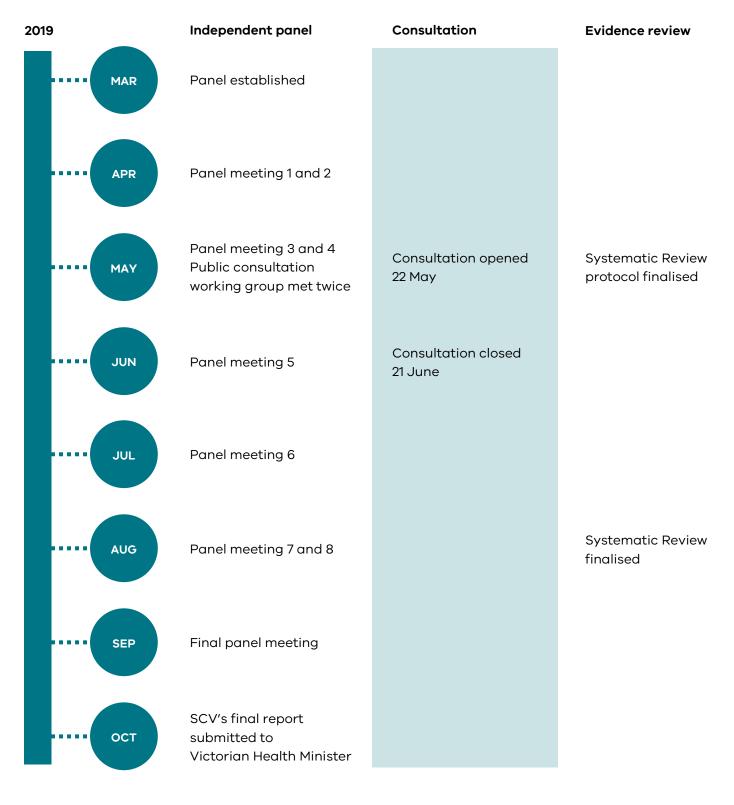
SCV commissioned Cochrane Australia to undertake a systematic review of the safety and effectiveness of spinal manipulation on children under 12 years for any condition or symptom.

For the purpose of collecting all relevant evidence, irrespective of profession, the panel agreed to the definition of spinal manipulation as any technique delivered by any health professional that involves a high velocity, low amplitude (HVLA) thrust beyond the physiological range of motion, impacting the spine, within the limits of anatomical integrity.

Using a definition so closely aligned to that detailed in Section 123 of National Law allowed SCV to align findings to the current legislative position and ensure that any recommendations did not contradict existing legislation. By defining the scope of the review to a technique, it also ensured that evidence searches related to other practitioner groups performing the technique (as defined) were within scope for consideration. However, there was a downside to so tightly defining the technique of spinal manipulation that was within scope. This means that studies were excluded where the author did not provide sufficient detail to confirm the techniques reflected those detailed in Section 123 of National Law. The advisory panel considered this weakness in the approach but agreed that if harm existed, it would most likely arise from the definition of spinal manipulation being used.

It was also agreed by the advisory panel that the scope of the public and practitioner consultation would extend to include all chiropractic spinal care for children under 12 years. This decision was made because it was anticipated that many respondents would not be sufficiently informed to know whether their child or patient had received HVLA manipulation or other chiropractic manipulation. Further, a more general call for experiences was considered necessary to facilitate the inclusive and diverse consultation that SCV was seeking, maximising the reach and allowing access to differing opinions from both the public and practitioners.

REVIEW TIMELINE



Public consultation

Working with patients (consumers), their families and carers is central to how SCV does its work. Noting the extent of public interest following the announcement of this review, inviting public input was critical to capturing personal stories for consideration by the panel.

The panel considered options for consulting with the public and planned the approach and scope of consultation. A public consultation expert was engaged to advise and support the panel during the planning period.

With a goal to open consultation in May 2019, the panel convened a time-limited working group to formulate the content on behalf of the group.

The panel agreed to an online survey targeted to both the public and practitioners interested in sharing their opinions and experiences of chiropractic spinal care. The working group met on two occasions in early May and put significant thought into the sequencing, style, and response options for survey questions. Six different survey pathways were carefully developed so that participants could respond to the pathway most applicable to them. These pathways can be found in Figure 1. The surveys developed included a combination of quantitative and qualitative responses.

The panel agreed to using the Victorian Government's online engagement platform Engage.Vic as the portal for submissions.

As detailed previously, the public consultation was deliberately designed to include all chiropractic spinal care provided to children under 12 years, and not just the specific technique of spinal manipulation. This was agreed by the panel to ensure that, irrespective of how a technique has been communicated to the consumer, all experiences related to chiropractic spinal care of children under 12 were welcomed and considered.

This public consultation was designed to elicit the views, both supportive and unsupportive, of parents/guardians and practitioners, and to explore specific experiences. Public consultation was open from 22 May to 21 June 2019. A total of 29,599 online surveys were submitted from across Australia.

ANALYSIS OF SURVEY INPUTS

SCV engaged market research firm EY Sweeney to undertake an independent analysis of the data generated by the responses.

To ensure that all responses met the public consultation validation criteria, and to protect the privacy of respondents as per the *Privacy and Data Protection Act 2014* and *Health Records Act 2001*, data cleansing was completed by SCV.

Data cleansing included the removal of any duplicate responses, based on previously agreed set of rules. Multiple entries from the same person were assessed against guidance outlined in the frequently asked questions on the survey platform. For example, multiple responses from one respondent but relating to different children in their care were allowed. Practitioner survey streams requiring an AHPRA registration number were cross checked with registration data to confirm validity.

All data sets were de-identified ahead of being transferred to EY Sweeney via a secure file transfer portal.

Post data cleansing, a total of 29,054 (98%) valid survey responses remained. Figure 1 below shows the total number of responses and the number of responses removed based on the defined data cleansing methodology.

| | Total responses received | Number of duplicate responses for removal (SCV) | Responses with invalid AHPRA details for removal (SCV) | Responses with invalid postcode for removal (EY)* | Total number of responses for analysis | Total number of quantitative responses processed | Total number of qualitative responses processed |
|--|-----------------------------|--|---|---|--|---|--|
| Public | | | | | | | |
| 1. Member of the public who has accessed care in the past 10 years | 22,045 | 42 | | 179 | 21,824 | 21,824 | 2,724 |
| 2. Member of the public who has not accessed care in the past 10 years | 4,558 | 25 | | 38 | 4,495 | | 541 |
| Total public Practitioner | 26,603 | 67 | N/A | 217 | 26,319 | 21,824 | 3,265 |
| 3. Practitioner who has provided care in the past 3 years | 2,542 | 172 | 46 | 9 | 2,315 | 2,315 | 2,315 |
| Practitioner who has not provided spinal care. However, has provided care for a child who has received spinal care. | 88 | 0 | 4 | 0 | 84 | 84 | 84 |
| 5. Practitioner who has not provided spinal care in the past three years | 100 | 4 | 4 | 0 | 92 | | 92 |
| 6. Practitioner would prefer not to provide AHPRA number | 266 | 17 | | 5 | 244 | | 244 |
| Total practitioner Totals | 2.996 29,599 | 193 260 (29,339) | 54 54 (29,285) | 14 231 (29,054) | 2,735 29,054 | 2,399 24,223 | 2,735 6,000 |

Figure 1. Survey response number by survey stream and removal post data validation

EY Sweeney developed a coding methodology for the qualitative survey data. The methodology applied is outlined below:

- In addition to analysis of the quantitative responses for all 24,223 valid surveys, EY coded the qualitative responses for 6000 survey participants. This was considered sufficient to reach saturation of content themes without risk of the analysis being unreliable.
- To ensure that coverage of all six survey pathways was achieved, it was agreed to divide the selection of the 6000 surveys for coding of qualitative responses. All 2735 of 'Practitioner' survey responses across the four pathways were included and 3265 from the two pathways for 'General Public' respondents.
- A sample 3265 (or 10%) of the General Public responses yields an estimated margin-of-error of ±1.7% with a population of 26,319, at a 95% confidence interval. Increasing the coding beyond this number of responses was considered to have minimal, if any, effect on the accuracy of findings.
- Although EY recognises that text analysis software exists to facilitate automated coding of opentext responses, and thus not require sampling, it was their professional advice that the risk of miscategorising of responses through such an approach was too high. Accordingly, EY manually read and coded sufficient responses to reach thematic saturation and so extract the key messages.
- To avoid unintended bias, 3265 General Public submissions were drawn randomly from the data set provided by SCV for coding.

Where the panel felt that further clinical review of responses was required, clinicians from within SCV completed this review. However, the survey was designed to capture opinion and personal experience and was not developed to capture detailed clinical information.

SUMMARY OF PUBLIC RESPONSES

The full EY Sweeney report is provided in Appendix B. Detailed here are summary findings.

Two survey pathways were made available as a part of the public consultation:

- Member of the public who has accessed spinal care for a child under 12 in the past 10 years
- Member of the public who has not accessed spinal care for a child under 12 in the past 10 years

The distribution of responses from across Australia are shown in Figure 2 below.

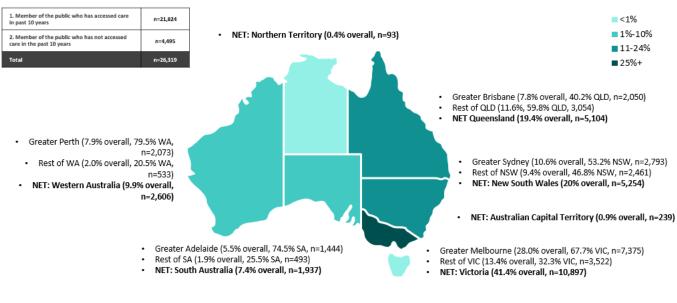


Figure 2. Location of responses from all general public surveys

NET: Tasmania (0.7% overall, n=189)

The submissions from public respondents who had accessed chiropractic spinal care for a child were overwhelmingly positive. Of the 21,824 respondents, 21,750 (99.7%) were supportive of the care received.

Age of children

- A little over half of the respondents, 54.5% (11,894), who had accessed care in the past 10 years reported that the care was provided to a child aged 0–3 months.
- Three quarters 73.1% (15,953)– of respondents indicated that the care was provided was for a child aged 2 years or younger.
- Half of the respondents (10,934) indicated that they accessed spinal care for a child over a continuous period (across multiple age brackets).

Conditions for which care was being sought

• For members of the public who have accessed care in the past 10 years, the main reasons for seeking chiropractic spinal care were posture concerns (31.7%), colic (28.7%), neck pain (23.5%), difficulties with breastfeeding (22.6%), back pain (21.9%), headache (14.9%), and other (48.8%). Other included general health and wellbeing/preventative care (17.4%) and sleep issues (4.1%).

Other care providers

- Of those who accessed spinal care for a child, 68.9% (12,142 from a data set of 17,622 responses) reported that they had also consulted a General Practitioner about the problem.
- Two in five, 43.9% (7,736 from a data set of 17,622 responses), respondents reported that they also consulted a Maternal and Child Health Nurse.

Parent/guardian reported outcomes

- 63.0% (1400 of 2223) of respondents reported that the chiropractic care was effective in treating children under 12 years of age.
- 87.3% (19,052 of 21,824 responses) indicated that the child was 'much improved' after treatment. A further 11.1% (2,422 of 21,824 responses) stated that the child was 'somewhat improved'.
- 45.1% (705 of 1,563 responses) of respondents who accessed care reported that they felt the chiropractor had adequately explained the treatments and that they had felt informed during the process.
- 23.0% (359 of 1563 responses) stated that they valued the two-way communication when interacting with the chiropractor and felt that they were listened to.
- 99.1% (21,628 of 21,824) of respondents indicated that they were either 'satisfied' or 'very satisfied' with information provided by the chiropractor about the benefits of treatment.
- Similarly, 95.8% (20,907 of 21,824) of respondents indicated that they were 'satisfied' or 'very satisfied' with information provided about the risks of the treatment.

When members of the public who had accessed chiropractic care for their child responded about why this review was important to them, it was very clear that they strongly valued the freedom of parental choice when it came to choosing the care they believed most suited to their family.

- 31.3% (696 out of 2223) emphasised that a parent/guardian should have the right to choose the care they feel is most appropriate for their child.
- 26.6% (591 out of 2223) expressed the view that chiropractic care should not be banned.

There was a very small minority of respondents – 0.3% (74 of 21,824 responses) – within the General Public group who reported negative experiences. The panel felt that it was important to review each of those 74 responses to screen for evidence of any potential harm. These were reviewed in detail by a senior clinician within SCV. There were no responses that were suggestive of any significant adverse effects following chiropractic care.

Instead, the negative experiences related to concerns about the cost of treatment with no resultant improvement in the condition being treated, excessive use of X-rays, or practitioner pressure to avoid medications or advice previously provided by other health practitioners.

¹⁸ Safer Care Victoria Chiropractic spinal manipulation of children under 12

SUMMARY OF PRACTITIONER RESPONSES

The full EY Sweeney report is provided in Appendix B. Detailed here are summary findings.

Four survey pathways were made available to practitioners:

- Practitioner who has provided spinal care for a child under 12 in the past three years
- Practitioner who has not provided spinal care for a child under 12 in the past three years. However, has provided care for a child who has received spinal care from another practitioner
- Practitioner who has not provided spinal care for a child under 12 in the past three years
- Practitioner who would prefer not to provide their Australian Health Practitioner Regulation Agency (AHPRA) number.

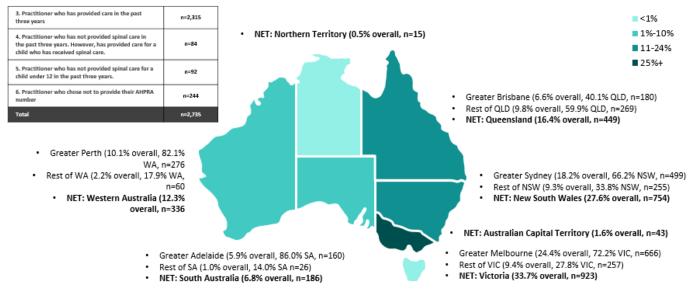


Figure 3. Location of responses from all practitioner surveys

NET: Tasmania (1.1% overall, n=29)

The overwhelming majority – 99.5% (2303 of 2315) – of practitioners who responded as having provided spinal care to a child under 12 within the past three years were registered chiropractors.

Of the practitioner respondents who have provided care (essentially chiropractors), 80.8% (1871 of 2315) reported treating children aged 0–3 months and 88.5% (2049 of 2315) reported treating children aged 0–24 months.

Practitioner reported outcomes

- Drawn from all 2315 responses from practitioners who have provided care, the top five benefits reported, in order of most prevalent, were: relief from pain, better sleep quality, more relaxed or settled child, able to feed and latch better, and improved mobility or range of motion.
- In contrast to those practitioners who had provided spinal care, almost half 47.6% (40 of 84) of the practitioners who had provided care to a child who had previously received spinal care from another practitioner, reported that the spinal care had had no benefits.

Reports of adverse effects

- 63.0% (1458 of 2315) of practitioners providing care reported that no adverse effects related to chiropractic spinal care had been observed or reported.
- 13.0% (301 of 2315) of responses indicated that mild short-term soreness had been observed or reported.
- Thirteen practitioners who responded as having provided care to a child who had previously received spinal care from another practitioner noted concern about the risk of delayed access to what the responding practitioner viewed as being appropriate care as a result of seeking spinal care.

Freedom of choice

• A small proportion – 7.7% (124 of 1606 responses) – of the practitioners providing care mentioned the importance of the rights of parents/guardians to choose care for their child.

The concept of the zone of parental/guardian discretion was considered during panel deliberations. This refers to the zone of parental/guardian choices; to either choose to refuse treatment or choose treatment that may be at odds with what their medical practitioner advises.

The choice for a parent/guardian to have a HVLA spinal manipulation technique applied to their child was tested by the panel with specific consideration to both potential harm and effectiveness. Several panel members felt that as long as the parent/guardian had clear decision-making capacity and authority, was provided with sufficient information and opportunity to understand the evidence underlying the risks, benefits and alternatives that may be available, they should be allowed to make this choice.

The full consultation summary report prepared by EY Sweeney can be found in **Appendix B** of this report.

SUBMISSIONS FROM PROFESSIONAL AND LEARNED ORGANISATIONS

In addition to the online survey, SCV invited professional and learned organisations with an interest in this review to make a written submission for the panel to consider. Nineteen submissions were received from organisations.

It is worth noting that the organisation submissions primarily related to chiropractic spinal care of children in general rather than to only the specific high velocity, low amplitude technique. The responses received provided representative perspectives from across all professions permitted to perform spinal manipulation as defined in Section 123 of National Law.

The panel reviewed all submissions. Three key themes were apparent:

- evidence
- education
- safety/harm.

As the statutory regulator for the chiropractic profession, the Board provided an outline of its statutory functions and responsibilities. The Board has demonstrated a willingness to respond, with the provision of strengthened guidance to chiropractors, when issues of concern are raised.

Evidence

Irrespective of the varying views noted by membership organisations and associations representative of chiropractic and other relevant professions, it was widely acknowledged that there is an urgent need to improve the evidence base for chiropractic practices and to develop best-practice guidelines. Specifically, it was widely agreed that there was insufficient evidence to appropriately guide clinical care.

Below is an excerpt from the submission made by the Australian Chiropractors Association, reportedly the largest chiropractic body in Australia, representing more than 3000 members:

In keeping with the National Scheme and to ensure public benefit, the Australian Chiropractors Association (ACA) proposes the following:

- That the profession conducts a trial of monitoring of care including outcomes of children under 12 years of age
- That the profession continues to further refine industry-led standards and clinical guidelines informed by best practice. This would include continuing professional development and consensus approaches to care including inter-professional understanding and action
- That the profession continues to further commit to expanding knowledge translation from research into clinical practice within the industry
- That the profession and health research agencies increase support for further research into chiropractors and their role in the healthcare of children.⁹

⁹ World Federation of Chiropractic: Australian Chiropractors Association Publishes Submission to Safer Care Victoria Independent Review into Chiropractic Spine Care For Children (https://www.wfc.org/website/index.php?option=com_content&view=category&layout=blog&id=56<emid=164&lang=en)

Education

There is currently no requirement for specialist training in paediatric chiropractic care. The Council on Chiropractic Education Australasia reviews and provides accreditation of pre-registration chiropractic education. The chiropractic profession does not have agreed and accredited specialist pathways, as exist in the medical profession.

However, while not mandatory for practice, advanced postgraduate training courses do exist and are generally considered useful in enhancing the knowledge and skills of the chiropractor workforce in specific interest areas, such as in paediatric care. Such practitioner development and training is currently offered by several different bodies. There does not appear to be any formal accreditation process or best-practice guidelines to ensure consistency across the post registration training offered.

The Council on Chiropractic Education Australasia submission states: "All accredited chiropractic programs include education in such areas as the health, developmental stages, common conditions and treatment, co management and referral options for children under (and over) the age of 12 years."

Submissions received from three tertiary institutions referenced a desire for further research to support development of industry-led standards and guidelines. It was recommended within two of those submissions that once guidelines are developed, standardised post-graduate paediatric training for the chiropractic profession is likely to facilitate improved health outcomes.

The views expressed by the tertiary institutions was echoed in the position presented by Chiropractic Australia, a membership-based organisation supporting the profession.

Chiropractic Australia's submission to this review states: "For those chiropractors who wish to offer a more focused paediatric practice, that is for those who wish to practice paediatric chiropractic as a special interest, we believe that additional accreditation and training standards should be in place and that training for endorsed paediatric practice must be undertaken under the auspices of universities."

Safety/harm

Submissions made by bodies representative of the medical or physiotherapy professions raised concerns related to the potential harm of chiropractic spinal manipulation on children under 12 years. In particular, there was specific concern about potential risks of harm associated with spinal manipulation of very young children, i.e. those under 2 years of age.

However, no specific or confirmed instances of proven harm were presented in any submission. Nonetheless, it was the professional view of those groups that in the absence of evidence of benefit, the risks of harm were sufficient to recommend banning chiropractic spinal manipulation of children.

Systematic review of literature for evidence of effectiveness and safety

In assessing the diverse views presented within the submissions, the panel agreed on the need for investment in properly conducted research, preferably in Australia, and the value that such research would provide the profession in quantifying both effectiveness and safety.

During the first panel meeting on 8 April 2019, it was agreed that Cochrane Australia would be engaged to undertake an appraisal of the evidence for both the safety and effectiveness of spinal manipulation on children under 12 years of age.

Spinal manipulation was defined by the experts on the panel as being **any technique delivered by any** health professional that involves a high velocity, low amplitude thrust beyond the physiological range of motion, impacting the spine, within the limits of anatomical integrity.

The literature search captured studies referring to children under 12 years of age, including babies and infants, treated with spinal manipulation from any healthcare professional for any condition or indication.

If studies included adolescents or adults, in addition to children, and it was impossible to extract data separately for children, the studies were included provided most participants were under 12 years or the mean age of participants was less than 12.

Cochrane identified existing, high-quality systematic reviews that had assessed the evidence for spinal manipulation on children. To avoid unnecessary duplication, Cochrane identified the subset of evidence on the effectiveness and safety of spinal manipulation on children from these existing reviews, and included relevant studies published before or after their completed search dates.

The full systematic review report prepared by Cochrane Australia can be found in **Appendix C** of this report.

EFFECTIVENESS REVIEW

Thirteen studies (including 11 randomised trials) were considered in scope for the effectiveness review. There were no Australian-based studies. The majority of studies included were undertaken in the USA or Europe. Nine of the included studies were based on chiropractic practitioners performing spinal manipulation as defined. The conditions covered in those studies included colic (three studies), enuresis, back/neck pain, headache, asthma (two studies), otitis media, cerebral palsy, hyperactivity (two studies) and torticollis.

Overall, there was very little evidence to support the use of spinal manipulation for any of the conditions studied. For the majority of the conditions, the evidence showed there was no benefit. However, for two conditions – infant colic and enuresis (bed wetting) – there was uncertainty.

The following is an excerpt from the Cochrane Systematic Review report:

Based on meta-analysis of three studies, Cochrane found low certainty evidence that, in infants with colic, mean crying time may be reduced among infants who received spinal manipulation compared to a control (sham, no treatment, active comparator) (0.71 hours (43 minutes) per day lower, 95% CI 1.87 (112 minutes) lower to 0.46 (28 minutes) higher; 3 trials, 156 infants). However, the confidence interval is wide and includes a possible increase in crying time.

Cochrane also found low certainty evidence that the mean number of wet nights may be reduced among children with enuresis who received spinal manipulative therapy compared to sham spinal manipulative therapy (1.6 fewer wet nights per fortnight, 95% CI 3.2 fewer to 0 more; 1 trial, 57 participants). However, the confidence interval is wide and includes the possibility of no effect. For other conditions there was either no evidence of effect, or no data available from which to draw a conclusion.¹⁰

When presented with the findings from Cochrane's systematic review, the panel discussed the absence of strong evidence for chiropractic spinal manipulation. The consumer representatives were particularly surprised at the lack of evidence. The panel also requested advice from Cochrane on the design of potential future research.

Cochrane shared the following suggestions as key considerations when designing studies:

- Providing detail and clarity of the intervention being studied or applied
- Ensuring studies are adequately powered (appropriate sample size)
- Developing core outcome measures, that can preferably be compared against other or future studies.

¹⁰ Cochrane Australia: Systematic Review of Spinal Manipulation in Children, August 2019. See Appendix B

SAFETY REVIEW

Interpretation of the safety findings was informed by the acknowledgement that best practice care requires a modification of force based on the age and developmental stage of a child. The panel advised SCV that Australian chiropractors are trained with that specific awareness and incorporate it into their daily practice.

Based on the parameters defined by the panel, Cochrane identified 10 studies for inclusion in the safety component of the literature review. Studies were included from around the world based on intervention description, agnostic of practitioner type.

Across all 10 studies there was a total of 159 adverse effects noted. Only one study had been based in Australia. It reported two adverse events from a treatment population of 171.

The following is an excerpt from the Cochrane Systematic Review report:

Six of these studies aimed to determine the rates of adverse events occurring across populations of infants and children undergoing spinal manipulative therapy. These studies reported rates spanning one minor treatment aggravation per 1812 consultations to one cerebrovascular incident in 20,000 visits. Two related studies investigated physiological responses to spinal manipulation in children and reported apnoea and skin flushing in 50 of 199 treated infants; and in a separate study, severe but short-lasting bradycardia in almost 50% of infants less than three months old, and in 87 of 695 children over four months.

Four studies described five individual cases of adverse effects from spinal manipulative therapy in infants or children. Of these, three were classified as severe and two as moderate. Of the three reports of a serious adverse event, one resulted in death. The technique employed in this case was described as the Vojta technique and involved forced active rotation and head retraction performed by a physiotherapist (case report from Germany in 2001). Other serious adverse events were loss of consciousness with recovery and hospitalisation for drowsiness and weakness. Though the prevalence of adverse outcomes is very low, the risk cannot be ignored. Any risk associated with care provided must be considered on balance with potential benefits.¹¹

In summary, the review of the literature revealed that the potential risk of harm from spinal manipulation in children was rare and, when it did occur, was typically minor in severity. However, as reported by Cochrane, "consistent with the findings of other systematic reviews, due to the paucity of studies and the lack of reported information on the specific treatment techniques employed, it is difficult to draw conclusions about the safety and effectiveness of spinal manipulation in children."

¹¹ Cochrane Australia: Systematic Review of Spinal Manipulation in Children, August 2019. See Appendix B

ADDITIONAL EVIDENCE COLLECTED

In addition to the systematic review of literature, SCV also requested information from AHPRA, the Health Complaints Commissioner (Victoria), the Office of the Health Ombudsman (QLD), and relevant profession-based councils in New South Wales.

Notifications and complaints data

AHPRA undertook a search of available information in its notifications database. The data reflected notifications that AHPRA had received relating to chiropractic spinal care for children under 12 over the past 10 years.

Below is a summary of the notifications data:

- Nineteen notifications about 18 practitioners
- Four notifications remain open
- One matter was retained by the health complaints entity to manage (not referred to AHPRA)
- Six notifications resulted in no further action
- Eight matters were acted on by the Board.

Of the 15 investigations completed to date, the Chiropractic Board of Australia took further action in 53.3% of cases. Actions taken included issuing a caution, placing conditions on a practitioner's registration, and the practitioner providing an undertaking to the Board.

AHPRA does not manage all notifications or complaints made about health practitioners in Australia. In NSW, notifications are managed by 15 professional councils (supported by the Health Professional Councils Authority) and the Health Care Complaints Commission (HCCC).

The Health Care Complaints Commission identified three cases related to chiropractic spinal manipulation of a child under 12 years. There was a discrepancy noted between the data held by the Chiropractic Council of NSW and the HCCC. The discrepancy has been actioned for investigation.

In Queensland, the Office of the Health Ombudsman (OHO) receives all complaints about health practitioners and determines which of those complaints are referred to a National Board/AHPRA to manage. The Office of the Health Ombudsman reported that since its inception on 1 July 2014 it has not received any complaints relating to spinal manipulation of children under 12 years.

The Victorian Health Complaints Commissioner (HCC) reported no complaints against a chiropractor related to the treatment of a child.

The details of complaints and notifications were considered by the panel. There were no complaints or notifications that related to significant harm to a child as a result of chiropractic spinal manipulation.

The only issue that was of concern to the panel was the discrepancy between data sets. Accurate reporting on a national level is wholly reliant on consistency in the capture, coding and management of data. The relevant bodies are exploring the apparent data inconsistencies.

²⁶ Safer Care Victoria Chiropractic spinal manipulation of children under 12

Insurance claims

SCV requested de-identified data from the principal insurance agencies that provide insurance for chiropractors. Information was sought regarding any claims made in relation to chiropractic spinal manipulation of a child under 12 years.

No cases were reported where an insurance agent has had to defend or settle such a claim.

Acknowledgements

This review would not have been possible without the assistance of the advisory panel members:

| Professor Euan Wallace AM | Panel Chair, Chief Executive Officer, Safer Care Victoria |
|--|--|
| Dr Alison Wray | Paediatric Neurosurgeon, Royal Children's Hospital |
| Professor Andrew Wilson | Chief Medical Officer, Safer Care Victoria |
| David Harding | Physiotherapist, Paediatric Orthopaedic Clinic, Monash Children's Hospital |
| Adj. Associate Professor Donna Markham | Chief Allied Health Officer, Safer Care Victoria |
| Emma Gierschick | Consumer representative |
| Dr Genevieve Keating | Chiropractor, Educator and Director, Dynamic Neuro- development |
| Professor Katrina Williams | Professor of Paediatrics and Head of Department, Monash University and Paediatrician, Developmental Paediatrics, Monash Health |
| Keree Bradshaw | Consumer representative |
| Adj. Associate Professor Matthew Fisher PhD | Chief Executive Officer, Australian Chiropractors Association |
| Mr Michael B. Johnson | Paediatric Orthopaedic Surgeon, Royal Children's Hospital |
| Professor Terry Haines | Professor and Head of School, School of Primary and Allied Health Care, Monash University |
| Dr Wayne Minter AM | Chair, Chiropractic Board of Australia |

We thank them for their contributions.

We would also like to acknowledge the many organisations and individuals for their contributions to the review – we appreciate their time and commitment to sharing their experience and views.

Appendix

APPENDIX A

Terms of reference

APPENDIX B

EY Sweeney: Response analysis for chiropractic spinal care for children under 12 years public consultation

APPENDIX C

Cochrane Australia: Systematic review of Spinal Manipulation in Children



Terms of Reference

REVIEW OF CHIROPRACTIC SPINAL MANIPULATION ON CHILDREN UNDER 12

Background and statement of purpose

On 8 March 2019, the Commonwealth of Australian Governments (COAG) Health Council (CHC) noted community concerns about unsafe spinal manipulation on children performed by chiropractors and agreed that public protection was paramount in resolving this issue.

The Victorian Minister for Health, Jenny Mikakos MP, has asked Safer Care Victoria (SCV) to lead an independent review of the practice of spinal manipulation on children under 12 years, and for the findings of that review to be provided to her for reporting to the COAG Health Council, including any need for changes to the national law.

1. AIMS OF THE REVIEW

To examine and assess the available evidence, including information from consumers, providers, and other stakeholders, for the use of spinal manipulation by chiropractors on children less than 12 years of age.

To provide recommendations regarding this practice to the Victorian Minister for Health.

2. PROPOSED TIMELINE

It is expected that SCV will deliver a final report and recommendations within six months from commencement.

3. REVIEW METHODOLOGY

SCV will establish a panel that will be responsible for reviewing the available evidence and public submissions.

The review will consist of two principal elements:

- (a) A systematic review of the literature.
- (b) A call for public written submissions.

The panel will work collaboratively and use the systematic review and the evidence gathered from written submissions to inform SCV's final report and recommendations.

SCV will deliver the final report and recommendations to the Victorian Minister for Health.

4. PANEL RESPONSIBILITIES

The panel will be a time-limited function of SCV. The Chief Executive Officer (CEO) of SCV will chair the review.

Role of the panel

The panel will advise on the review, enabling SCV to provide recommendations to the Victorian Minister for Health.

Specifically, the panel will:

- work collaboratively to develop and endorse the scope of this review,
- set the parameters for the literature searches and systematic review,
- determine the questions to be asked that will frame the call for public written submissions,
- use all evidence gathered to inform SCV's final recommendations.

Operating principles

Advice provided by the panel should be guided by the following key principles:

- reflects a person-centred approach to care, with an emphasis on supporting and empowering people to achieve their maximum health potential,
- has a key focus on the provision of high-quality health care delivery and improving health outcomes through consideration of a 'system-wide' approach,
- promotes a culture of continuous improvement through evidence-informed decision making
- is inclusive and collaborative in providing advice and respectful of diverse opinions, with all members having an equal voice,
- provides timely, independent and constructive advice based on 'on-the-ground' experience that translates into practical recommendations.

5. PANEL MEMBERSHIP

Panel membership will include experts in healthcare evidence, governance, paediatrics, and in musculoskeletal care, and consumer representation. It is expected that panel membership will include, but not necessarily limited to, consumers, medical practitioners, allied health practitioners, and the relevant regulator agency, Australian Health Practitioner Regulation Agency.

All members will use the breadth and depth of their knowledge, skills and experience to inform the work of the panel.

Proposed membership

- (Chair) CEO, Safer Care Victoria
- Chief Allied Health Officer, Safer Care Victoria
- Chief Medical Officer, Safer Care Victoria
- Consumer representatives
- Paediatric medical practitioners (including expertise in evidence translation)
- Paediatric allied health clinician with expertise in musculoskeletal practice

- Academic Allied Health professional (including expertise in evidence translation)
- Member, Chiropractic Board of Australia
- Member, Australian Chiropractors Association
- Registered Chiropractor with paediatric experience

Panel members will be approved and appointed by CEO Safer Care Victoria.

With the approval of the CEO of SCV, there will be an ability of the panel to co-opt additional expertise as and when required and to commission a systematic review.

Duration of panel appointment

Members will be appointed for a fixed term to completion of the review. The duration of appointment will be approved by the CEO of SCV on behalf of the Minister for Health. Prior to appointment, prospective panel members will be required to commit to the expected duration of the appointment. Should an appointed member unexpectedly find themselves unable to continue their membership they will be required to provide sufficient notice (2 weeks) to enable replacement of their relevant expertise.

Membership responsibilities

All members are expected to participate in at least 80 per cent of meetings.

Members must familiarise themselves with the issues to be covered for each agenda item, participate constructively in all debates and work together in providing pragmatic advice.

The names of panel members will be made publicly available and listed on the SCV website under the Terms of Reference for this review.

Code of conduct

Members are expected to discharge their duties with care and diligence, and must strive in the course of their work to uphold the operating principles of the Panel, and adhere to the following:

- members should approach deliberations in an impartial manner and should not reflect any organisational, sectional or vested interests.
- all papers produced for the Panel are for the exclusive use of its membership.
- members should not inappropriately use information that is discussed at the Panel meetings.
- members should not disclose publicly any information that is identified as confidential.
- all information that is to be made publicly available relating to Panel matters must be approved by the chair.
- members should disclose any real or perceived conflicts of interest before each meeting.
- members should not seek to gain any advantage through their membership of the Panel.

6. OPERATING PROCEDURES

Meeting frequency

Fortnightly to commence then monthly from approximately June 2019, or as required.

Nine panel meetings have been scheduled for this review, two of which are extended meetings allowing for lengthier analysis and discussion by the panel. Additional meetings may be scheduled if urgent matters arise during this review. The advice of members may be sought outside of scheduled meetings.

Quorum

A quorum (defined as 50 per cent of members plus one) is required for meetings to proceed.

Conflict of interest

All review panel members will be required to complete and submit a 'Declaration of private interests' form prior to the first meeting. A register of these declarations will be held by SCV.

Any relevant information provided on the 'Declaration of private interests' form will be included with panel member details on the website.

Members are required to keep SCV informed of any changes to their interests to ensure that management strategies are put in place as needed.

At the beginning of each review panel meeting, members will be asked to declare any existing or new conflicts of interest as they relate to an agenda item under consideration at that meeting. The secretariat will record all such declaration in the minutes. A review panel member may be asked to absent themselves from the discussion of the relevant agenda item. Should the Chair be required to absent themselves then an acting Chair will be appointed for the relevant agenda item(s).

Confidentiality

In some instances, members may be privy to information that is confidential and not in the public domain. Members will not reveal any confidential information entrusted during their duties. Upon cessation of membership, and thereafter, the member shall not reveal any confidential information, which they obtained while a member of the panel, and may not use, retain or attempt to use or retain, any such information, documents or data.

The Chair of the panel will advise of confidentiality aspects as they arise. Members are also requested to clearly indicate if any information they bring to the panel is confidential. All members acknowledge their responsibility to maintain the confidentiality of associated disclosed material.

All papers produced for the panel are for the exclusive use of its membership, and any information that is to be made publicly available relating to panel matters must be approved by the Chair.

7. MANAGEMENT

Sitting fee and travel reimbursement

Remuneration

Members on the review panel attending meetings as a paid employee of their organisation will not receive sitting fees and travel reimbursement. Remuneration for consumers on the review panel will be in accordance with the Department of Premier and Cabinet's *Appointment and Remuneration Guidelines for Victorian Government Boards* (Guidelines). This panel is classified as a Group C Band 3 body as defined by the guidelines.

| Member | Sessional rate |
|------------------|------------------|
| Eligible members | \$225.00 per day |

Consumers on the review panel are entitled to the reimbursement of reasonable travel and personal expenses that they incur as a result of their duties. Refer to the *Victorian Public Service Personal and Travelling Expenses* Policy for reimbursement terms and conditions. Members on the review panel attending meetings as a paid employee of their organisation will not receive sitting fees and travel reimbursement.

For attendance at meetings of two to four hours, consumers on the review panel will be remunerated at a half-day sessional rate. Meetings of four or more hours will be remunerated at a full-day sessional rate.

Expenses

Consumers on the review panel are entitled to reimbursement of reasonable travel and personal expenses that they incur as a result of their duties. Refer to the *Victorian Public Service Personal and Travelling Expenses* Policy for reimbursement terms and conditions.

In order to claim a reimbursement, members are required to:

- complete and sign the Personal Expense Claim Form
- attach receipt(s) for expenses
- submit the form to the Secretariat either at the meeting, via email or the post.

The Secretariat will submit the form to the Department of Health and Human Services payroll unit for processing and payment into the bank account details that been supplied on the form.

Secretariat support

The secretariat support will be provided by SCV.

Safer Care Victoria

Response analysis for chiropractic spinal care for children under 12 years public consultation

Final report

Project no. Date: 30553 13 August, 2019



Con transferrance

EY Sweeney (a trading name of Ernst & Young) ("EY") was engaged on the instructions of Safer Care Victoria ("Client") to produce this community consultation report ("Project"), in accordance with the terms and conditions found in the "30553 Proposal" dated 28 June 2019.

The results of EY's work, including the assumptions and qualifications made in preparing the report, are set out in EY's report dated 13 August 2019 ("Report"). You should read the Report in its entirety including any disclaimers and attachments. A reference to the Report includes any part of the Report. No further work has been undertaken by EY since the date of the Report to update it.

Unless otherwise agreed in writing with EY, access to the Report is made only on the following basis and in either accessing the Report or obtaining a copy of the Report the recipient agrees to the following terms.

1. Subject to the provisions of this notice, the Report has been prepared for the Client and may not be disclosed to any other party or used by any other party or relied upon by any other party without the prior written consent of EY.

2. EY disclaims all liability in relation to any other party who seeks to rely upon the Report or any of its contents.

3. EY has acted in accordance with the instructions of the Client in conducting its work and preparing the Report, and, in doing so, has prepared the Report for the benefit of the Client, and has considered only the interests of the Client. EY has not been engaged to act, and has not acted, as advisor to any other party. Accordingly, EY makes no representations as to the appropriateness, accuracy or completeness of the Report for any other party's purposes.

4. No reliance may be placed upon the Report or any of its contents by any party other than the Client. Any party receiving a copy of the Report must make and rely on their own enquiries in relation to the issues to which the Report relates, the contents of the Report and all matters arising from or relating to or in any way connected with the Report or its contents.

5. Subject to clause 6 below, the Report is confidential and must be maintained in the strictest confidence and must not be disclosed to any party for any purpose without the prior written consent of EY.

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7. No duty of care is owed by EY to any recipient of the Report in respect of any use that the recipient may make of the Report.

8. EY disclaims all liability, and takes no responsibility, for any document issued by any other party in connection with the Project.

9. A recipient must not name EY in any report or document which will be publically available or lodged or filed with any regulator without EY's prior written consent, which may be granted at EY's absolute discretion.

10. A recipient of the Report:

(a) may not make any claim or demand or bring any action or proceedings against EY or any of its partners, principals, directors, officers or employees or any other Ernst & Young firm which is a member of the global network of Ernst Young firms or any of their partners, principals, directors, officers or employees ("EY Parties") arising from or connected with the contents of the Report or the provision of the Report to the recipient; and

(b) must release and forever discharge the EY Parties from any such claim, demand, action or proceedings.

11. In the event that a recipient discloses the Report to a third party in breach of this notice, it will be liable for all claims, demands, actions, proceedings, costs, expenses, loss, damage and liability made or brought against or incurred by the EY Parties, arising from or connected with such disclosure.

12. In the event that a recipient wishes to rely upon the Report that party must inform EY and, if EY agrees, sign and return to EY a standard form of EY's reliance letter. A copy of the reliance letter can be obtained from EY. The recipient's reliance upon the Report will be governed by the terms of that reliance letter.



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EY Sweeney is accredited under the International Standard, ISO 20252.

All aspects of this study have been completed in accordance with the requirements of that scheme.

Also please note that EY Sweeney's liability is limited by a scheme approved under professional standards legislation. A copy of the scheme can be obtained from us upon request.



About the study

Background

- On 8 March 2019, the Commonwealth of Australian Governments (COAG) Health Council noted community concerns regarding spinal manipulation on children performed by chiropractors.
- The Victorian Minister for Health, Jenny Mikakos MP, asked Safer Care Victoria (SCV) to lead an independent review of the practice of spinal manipulation on children under 12 years and for the findings of that review to be provided for reporting to the COAG Health Council.
- Public consultation to gather opinions and experience of chiropractic spinal care commenced on the 22 May 2019 and closed on 21 June 2019 on Engage Victoria (https://engage.vic.gov.au/chiropractic-spinal-care-

children-review) A large response (29,599 completions) was received.

- Six survey streams were made available as a part of the public consultation.
- 1. Member of the public who has accessed care in past 10 years.
- 2. Member of the public who has not accessed care in the past 10 years.
- 3. Practitioner who has provided care in the past three years.
- 4. Practitioner who has not provided spinal care in the past three years. However, has provided care for a child who has received spinal care.

- 5. Practitioner who has not provided spinal care for a child under 12 in the past three years.
- Practitioner who would prefer not to provide their Australian Health Practitioner Regulation Agency (AHPRA) number.
- The survey questionnaires included a combination of quantitative and qualitative responses to gather the experience and opinion of the Australian public. The survey was designed and deployed by the independent panel established by Safer Care Victoria.
- On 28 June 2019, EY Sweeney was commissioned to provide data analytics support to ensure robust, independent, non-biased analysis of public consultation responses.
- This document reports the findings from this research analysis.





Research methodology - Overview

From a methodological perspective, there were three broad components to completing this study: questionnaire design, survey data collection, and analysis and reporting.

Questionnaire design

The six survey questionnaires that were used to complete this study were developed by the independent panel established by Safer Care Victoria to review the chiropractic practice of spinal manipulation on children under 12.

The panel includes experts in paediatrics and musculoskeletal care, consumers, and representatives from the Chiropractic Board of Australia and Australian Chiropractors Association.

Further details about the independent panel can be found here: <u>https://www.bettersafercare.vic.gov.au/our-</u> work/governance-and-information/independentreview-chiropractic-manipulation.

Survey data collection

The six survey questionnaires were programmed and hosted using the Engage Victoria web-platform, allowing them to be accessed by the public.

Engage Victoria is the Victorian Government's Online Consultation platform. The process of collecting the survey data for this study was managed by Safer Care Victoria and the independent panel.

Further details about Engage Victoria can be found here: https://engage.vic.gov.au/about

Analysis and reporting

EY Sweeney was engaged to conduct an independent analysis of the data collected by the six survey streams and report the findings to the independent review panel.

The following pages describe the data analysis methodology applied to responses collected and which were used to generate the findings described within this report.

Further details about EY Sweeney can be found here: https://eysweeney.com.au/

Detail across the methodology for the data analysis and reporting that was conducted by EY Sweeney follows over the coming pages.



Research methodology - Data analysis

This section outlines the approach to data handling and processing.

1.1 Data cleansing

To ensure that all responses met the public consultation validation criteria, and to protect the privacy of respondents as per the *Privacy* and *Data Protection Act 2014 and Health Records Act 2001*, the following data cleansing was completed by Safer Care Victoria.

Duplicate removal

- A merged version of the complete dataset was checked for duplicate email entries.
- Responses submitted across public and practitioner survey streams were accepted as per the Frequently Asked Questions published on Engage Victoria:

https://engage.vic.gov.au/chiropractic-spinalcare-children-review I am a practitioner and a parent - which survey should I answer? We have options to answer as a member of the public and a practitioner. You are welcome to answer both or either surveys.

- Content for duplicate email submissions in public surveys were reviewed to assess whether multiple entries represented different children or were submitted by different family members.
 - If responses submitted by different family members, both entries were retained.
 - If responses submitted by same person, and different experiences were represented, all entries were retained.
 - If responses submitted by same person, and experiences were identical, only primary entry was retained and subsequent submissions were removed.
- Where practitioners submitted a response in an AHPRA identifiable survey and in the no AHPRA provided survey, the no AHPRA number provided response was removed.
- Where practitioner submitted across all three AHPRA identifiable surveys, the primary response was retained.
- Where practitioner submitted multiple entries within one survey stream, the primary entry was retained.



Australian Health Practitioner Regulation Agency provider number validation

- Practitioner responses were reviewed to identify where AHPRA number was incomplete or had incorrect formatting.
- If practitioner name was identified on the AHPRA register, the AHPRA number was amended and submission included in analysis.
- If an AHPRA number could not be found to match a practitioner name then the submission was removed from the dataset.

De-identification

- All identifiable information collected (name, email, IP address, full AHPRA number) were removed by Safer Care Victoria.
- AHPRA practitioner prefix was retained in data submission to EY.
- EY completed a further data match to valid Australian postcodes and removed responses submitted with non-Australian postcodes.

1.2 Data transfer

- Once the data was prepared, EY provided a link to the firm's secure file transfer service, known as Media Shuttle, which SCV used to transfer the cleaned survey data to EY. Media Shuttle is a product provided by Signiant and used by many of the largest corporations in the world. More details are available on Signiant's website (https://www.signiant.com)
- Confirmation was provided upon receipt of data. All data was stored on EY's secure South Melbourne servers. No data was copied onto personal devices. At the conclusion of the project, all data will be permanently deleted.

1.3 Data security

EY's data security practices are audited every year to ensure they are compliant with the standard set-forth in ISO 20252, which is the most stringent accreditation for market research firms in Australia.

1.4 Data preparation

- Once the data was received, it was passed to EY's team of data analysts who completed two initial tasks:
 - They converted the quantitative data into a SPSS file format, which facilitated the subsequent analyses. SPSS is a software package provided by IBM which facilitates advanced statistical analysis. It is one of the most commonly used file formats for data analysis. More details about IBM SPSS are available on their website (https://www.ibm.com/auen/analytics/spss-statistics-software)
 - They prepared the open-text data in a format that facilitated the coding process.
- When these tasks were completed, EY began coding the open-text data and completing the quantitative analysis.
- The analysis of the qualitative data is explored in more detail in section 2.1.



Data cleansing and processing summary

| | Total responses received | Number of duplicate responses for removal (SCV) | Responses with invalid AHPRA details for removal (SCV) | Responses with invalid postcode for removal (EY)* | Total number of responses for analysis | Total number of quantitative responses processed | Total number of qualitative responses processed |
|--|-----------------------------|--|---|--|--|---|--|
| Public | | | | | | | |
| 1. Member of the public who has accessed care in the past 10 years | 22,045 | 42 | | 179 | 21,824 | 21,824 | 2,724 |
| 2. Member of the public who has not accessed care in the past 10 years | 4,558 | 25 | | 38 | 4,495 | | 541 |
| TOTAL PUBLIC | 26,603 | 67 | N/A | 217 | 26,319 | 21,824 | 3,265 |
| Practitioner | | | | | | | |
| 3. Practitioner who has provided care in the past 3 years | 2,542 | 172 | 46 | 9 | 2,315 | 2,315 | 2,315 |
| 4. Practitioner who has not provided spinal care. However, has provided care for a child who has received spinal care. | 88 | 0 | 4 | 0 | 84 | 84 | 84 |
| 5. Practitioner who has not provided spinal care in the past three years | 100 | 4 | 4 | 0 | 92 | | 92 |
| 6. Practitioner would prefer not to provide AHPRA number | 266 | 17 | | 5 | 244 | | 244 |
| TOTAL PRACTITIONER | 2.996 | 193 | 54 | 14 | 2,735 | 2,399 | 2,735 |
| TOTALS | 29,599 | 260 (29,339) | 54 (29,285) | 231 (29,054) | 29,054 | 24,223 | 6,000 |

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Research methodology - Open text coding

2.1 Allocation of coding resources

EY's coding methodology is as follows.

- In addition analysis of the eight closed question responses for all 24,223 valid survey participants asked closed questions, EY coded the open-ended question responses for 6,000 survey participants. This is a sufficient number of responses to analyse without risk of the analysis being unreliable.
- To ensure that coverage of all six survey pathways is achieved, EY and SCV agreed to divide the selection of the 6,000 surveys for coding of open-ended responses with 2,735 allocated to the four 'Practitioner' surveys and 3,265 allocated to the two 'General Public' surveys.
- This means that all of the Practitioner responses were included in the analysis of open-ended question responses and approximately 10% of the General Public open ended question responses were analysed. As mentioned, all pre-coded question responses were included in the analysis.
- A sample 3,265 (or 10%) of the General Public responses yields an estimated margin-of-error of ±1.7% with a population of 26,319, at a 95%

confidence interval. Due to the law of diminishing returns, increasing the coding above this point would only have a minimal effect on the accuracy of findings (for example, a sample size of 10,000 would only improve the predicted margin-of-error by >1%). However, it would require considerable additional investment in time and funds.

- Although EY recognises that text analysis software exists to facilitate automated coding of open-text responses, and thus not require sampling, it is our professional opinion that the risk of miscategorising of responses through such an approach is too high, given the stringent requirements of this project.
- To avoid bias occurring, 3,265 General Public submissions coded were drawn randomly from the data set provided by SCV.

2.2 Codeframe development

EY's in-house coding team conducted a preliminary review of the open-text responses allocated for coding. As they read through, they noted the themes of sentiment that emerged from the responses. This list of themes formed the codeframe that was used to facilitate the qualitative analysis and reporting.

- A code frame is a list of themes with an identifying code number allocated to each individual theme. In the coding process, a coder will read an open-text response and mark down the themes within it by entering the numbers that correspond to the relevant codes in the codeframe.
- All codeframes were provided to SCV for approval, to ensure that the language used to describe themes is clear and fit for purpose.

2.3 Coding process

As described in section 2.2, the coding process is a manual one.

- A team of EY Coders read through open-text responses and manually typed the numbers (codes) that indicated the relevant themes within the response.
- The coding framework developed also had specific guidance around flagging the following type of responses:
 - Check if references to accessing care are within a 10 year time frame;
 - Check if references to providing care are within a 3 year time frame;



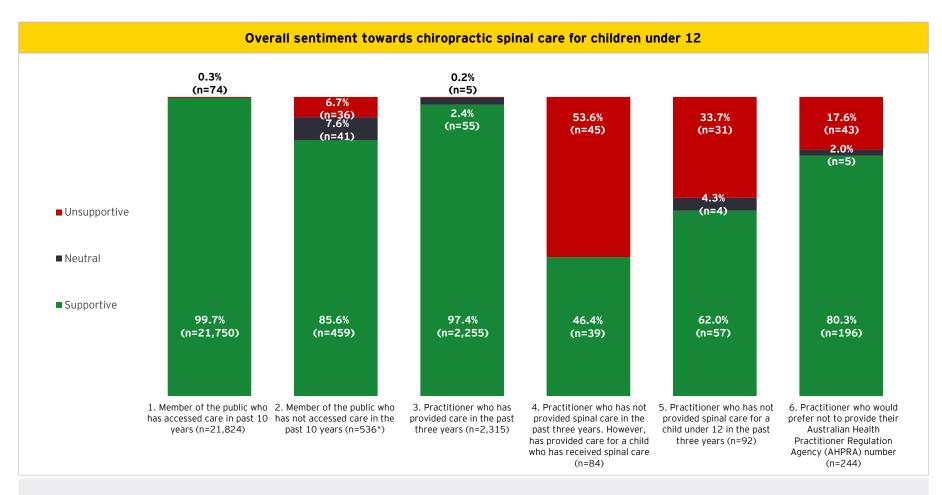
- Indicate sentiment as supportive of chiropractic care or unsupportive of chiropractic care for children;
- Flag where duplication of responses is found across content. None were identified in the coding process;
- Flag comments that outline impact of restriction of care;
- Flag comments that identify safety issues or adverse events relating to chiropractic care. Three responses were identified.
- Through-out the report percentages are rounded to zero decimal places. When adding multiple percentages together, total may be one percentage point different due to round.
- Open-text responses frequently contain more than one key theme, thus proportions reported for coded questions will add to greater than 100%.





Summary of overall sentiment

Summary of sentiment by survey pathway



*Note: Sentiment analysis based on coded responses only



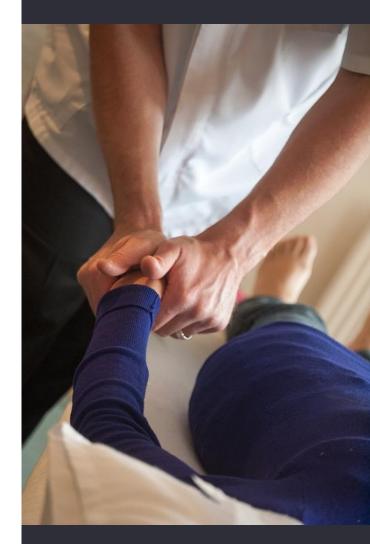
Detailed findings



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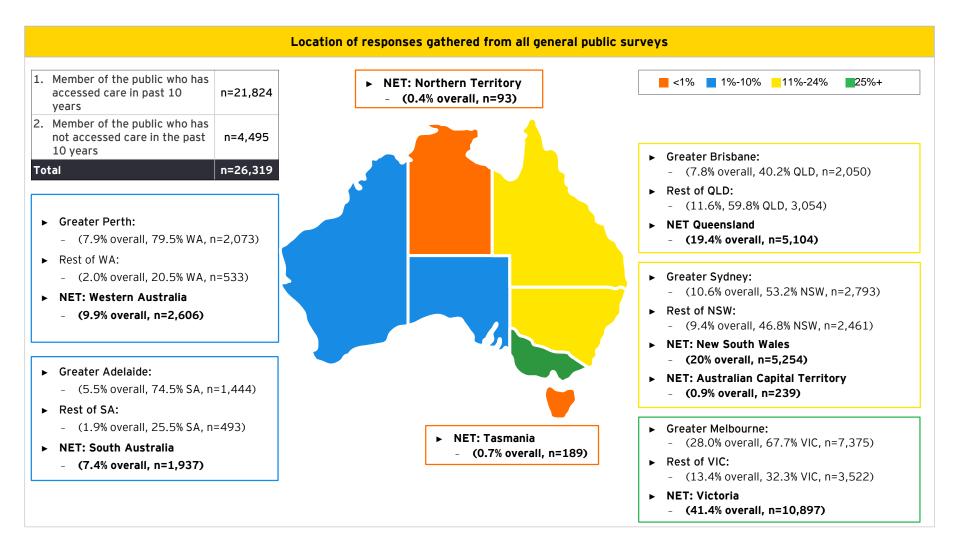
Background

- One component of the consultation was to collect the views of members of the Australian public.
- There were two separate survey streams available to the public:
 - Those who <u>have</u> accessed chiropractic spinal care for a child under 12 in the past 10 years
 - Those who <u>have not</u> accessed chiropractic spinal care for a child under 12 in the past 10 years.
- This section of the report shows the findings for these two survey streams.





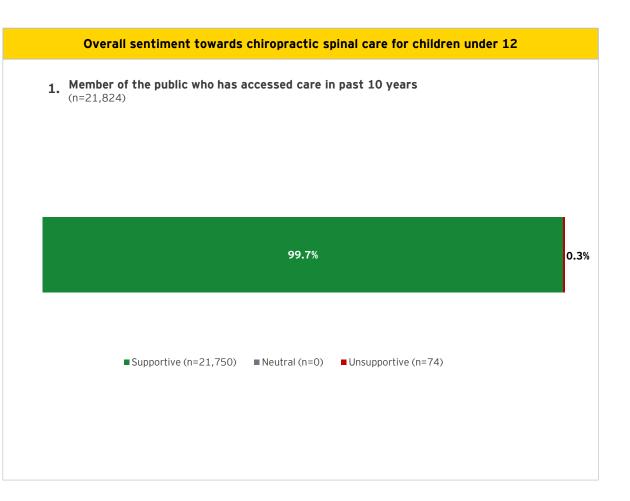
Location of responses





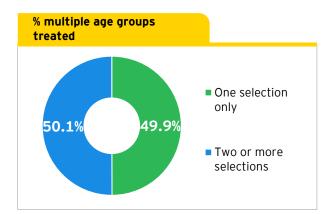


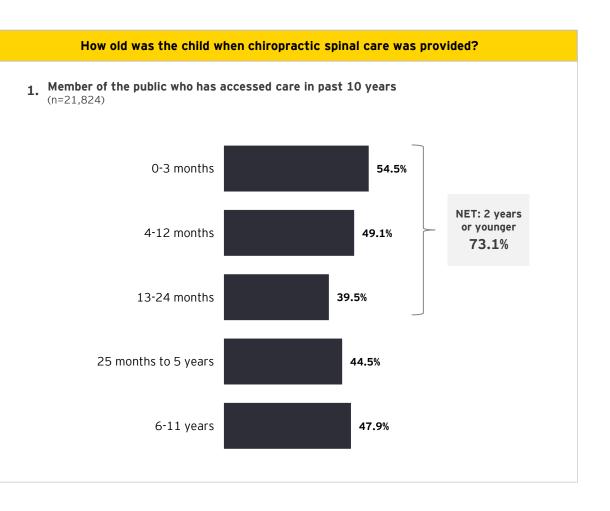
- NOTE: For the members of the general public who have accessed care in the past 10 years sentiment is defined by looking at the results across multiple Likert scale questions. Therefore, all submissions are included in the analysis.
- 99.7% of members of the public, who have accessed spinal care for children in the past 10 years, express a sentiment that is supportive of spinal care for children under 12
- 0.3% of these individuals communicated a sentiment that is unsupportive of spinal care for children under 12, overall.
- Unsupportive submissions were identified as those that answered 'neutral', 'dissatisfied', or 'very dissatisfied' to all questions about satisfaction and those that answered 'no change', 'somewhat worse', or 'much worse' to the question about the child's state following care provided.





- Amongst members of the public, who have accessed care in the past 10 years for children under 12, a majority report that care was provided to a child aged 0-3 months.
- 54.5% of those who accessed care in the past 10 years did so for a child aged between 0-3 months.
- Three quarters (73.1%) of responses indicate that care was for a child aged 2 years or younger.
- Half of the respondents indicate that they received spinal care for children across multiple age brackets.

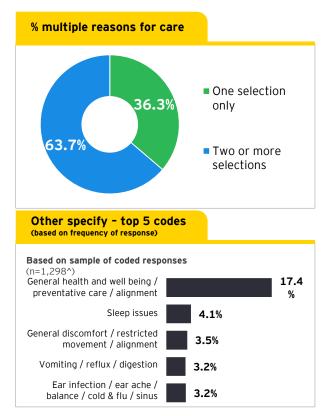


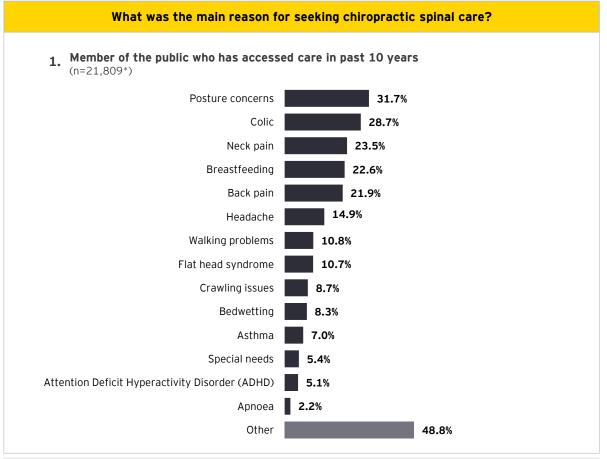


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- Posture concerns are chosen by one-third (31.7%) of responses. This is followed closely by Colic, which is chosen by 28.7%.
- Two thirds (64%) of responses indicated two or more reasons for seeking care.





*Note: 15 submissions did not contain data for this question

^Note: n=1,298 refers to the total number of other responses coded (this was mistakenly referred to as n=1,308 in a draft version of this report).



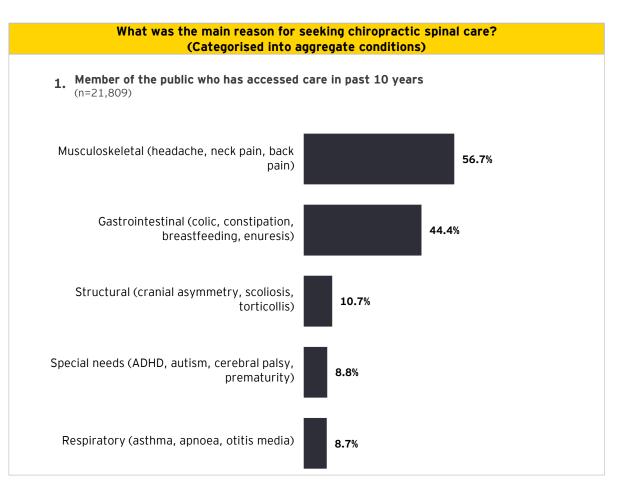
- 79.9% of other specify responses that contained references to "general health and well being / preventative care / alignment" did not contain any additional information.
- Sleep issues were mentioned as an additional reason for seeking care in 3.0% of general health and well being responses.

| What was the main reason for seeking chiropractic spinal care? (General health and well being / preventative care / alignment) | | | | | | |
|---|-------|--|--|--|--|--|
| 1. Member of the public who has accessed care in past 10 years $(n=462^{\wedge})$ | | | | | | |
| General health and well being / preventative care / alignment ONLY | 79.9% | | | | | |
| Sleep issues | 3.0% | | | | | |
| After birth assessment / birth correction | 2.6% | | | | | |
| Treat specific injury (back / groin / car accident / knee / ankle pain) | 2.6% | | | | | |
| Ear infection / ear ache / balance / cold & flu / sinus | 2.8% | | | | | |
| Treatment for traumatic birth / difficult birth / caesarean / premature | 2.4% | | | | | |
| Vomiting / reflux / digestion | 1.7% | | | | | |
| Bowel issues / bladder issues | 1.5% | | | | | |
| Hip pain / clicking hip / scoliosis / knock knees / torticollis | 1.1% | | | | | |
| Mood / anxiety / learning difficulties / intellectual disability | 1.3% | | | | | |
| Tongue and lip tie release / tonsillitis / teeth grinding / jaw pain / ptosis | 0.9% | | | | | |
| General discomfort / restricted movement / alignment | 0.9% | | | | | |

^Note: n=462 refers to the total number of other responses coded as "General health and well being / preventative care / alignment".

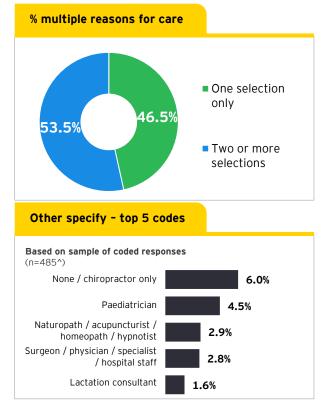


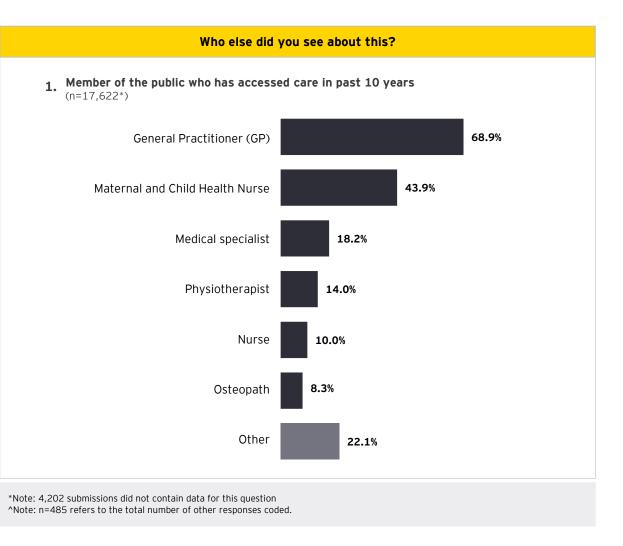
- NOTE: Responses have been categorised into the aggregate conditions found in the practitioner survey.
- 56.7% of members of the general public sought chiropractic care to treat a musculoskeletal concern
- The next most frequently cited reason for seeking chiropractic care was Gastrointestinal aliments, this is included in 44.4% of responses.





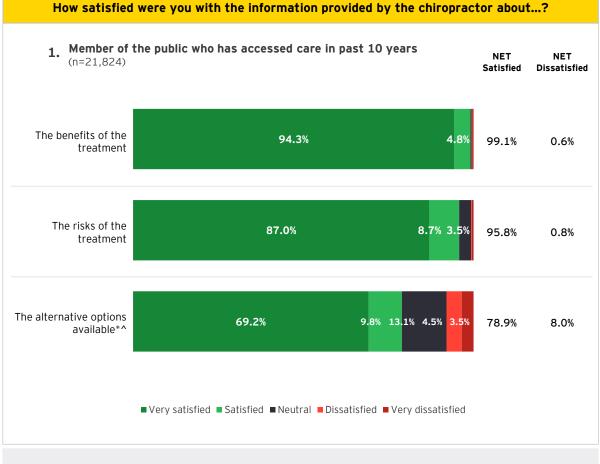
Amongst those who accessed spinal care for a child, 68.9% report that they also consulted a GP. Two in five (43.9%) members of the public, who accessed care, report that they also consulted a Maternal and Child Health Nurse. 53.4% of responses indicate that they consulted two or more other parties, in addition to a chiropractor.







- NOTE: Based on the higher proportion of dissatisfied responses to the alternative options indicated, a review of the qualitative responses indicated that some respondents were dissatisfied with the alternative care options sought (for example, GP response) rather than considering the information about alternative options offered by the chiropractor which was the intention of this question.
- 99.1% of responses indicate that they are either 'satisfied' or 'very satisfied' with information provided by the chiropractor about the benefits of treatment
- Similarly, 95.8% of responses indicate that they are 'satisfied' or 'very satisfied' with information provided about the risks of the treatment.
- ► A lower proportion (78.9%) report that they are satisfied with information provided about alternative options available.



*Note: Percentages shown do not add to 100% due to rounding



- The most commonly mentioned reasons for ratings are that the chiropractor helped cure / relieve aliments
- 34.2% of coded responses from members of the public, who have accessed care in the past 10 years, indicate that the care received helped cure or relieve the child's aliments.
- 29.6% indicate that the chiropractor was informative and knowledgeable.

Please tell us more about your above answers (How satisfied were you with the information provided by the chiropractor about...) 1. Member of the public who has accessed care in past 10 years (n=1,893*) Chiropractor helped cure / relieve child's ailments / 34.2% symptoms 29.6% Chiropractor was informative / knowledgeable 21.8% Went to chiropractor for child development / care Chiropractor did what doctor / GP could not 18.8% 18.1% Chiropractor gave full list of risks and alternatives 18.0% Chiropractic care is beneficial / effective 17.3% Always had good experience with chiropractor Have sought chiropractors for on going treatment 16.8% Provided excellent care / impressed with care 15.1% Chiropractor was very gentle 12.3% Felt there was no risk / treatment was safe 9.2% Chiropractor is gualified / trained / experienced 7.1% Chiropractic care works well alongside other health 6.0% care / is preventative

*Note: Open-text question, only coded responses shown / 831 submissions did not contain data for this question



Sample Verbatim Comments:

Chiropractor helped cure / relieve child's ailments / symptoms

He was very very gentle, did not crack bones which was a big plus for me and my daughter was always so calm and happy after treatments and slept beautifully for the following 3 day[s].

My three children have been adjusted by a number of chiropractors since they were babies. They have all thrived and are rarely sick. It helped with colic when babies and now with all the bumps and bangs that happens with kids.

Chiropractic changed my son's life and got him off medications that changed him for the worse.

Chiropractor was informative / knowledgeable

My chiropractor is amazing and goes above and beyond for me & my family. She's extremely professional in everything she does and has always given me more information than my family GP. Went to chiropractor for child development / care

We went to see a chiro due to our children all having tongue ties released before 6 months of age. My twins were around a month old at the time.

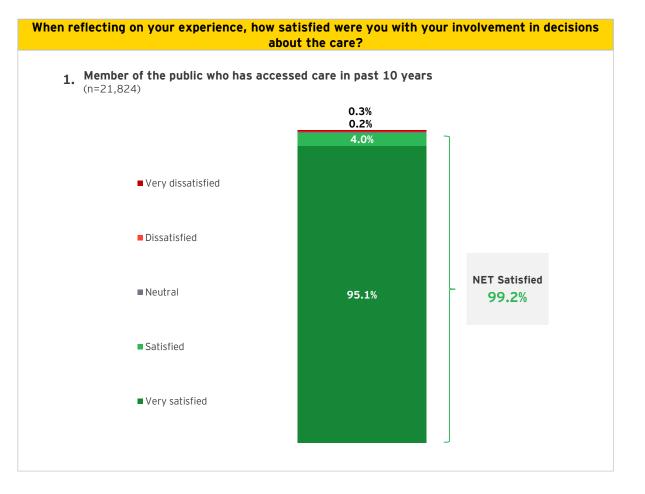
I was very impressed with the amount of information my chiropractor and the clinic provided with me before, during and after the care of my young son.

I have always felt very well informed in regards to care. The information I have received has only made me feel more confident that chiropractic care is right for my family. As they grow, I consider regular chiropractic checks to be part of our family health regime just like regular medical and dental checks, I consider it setting a strong foundation for their future health.

Our chiropractors have looked after our children since birth-initially for check up after birth . now we have a check up for the kids if they have bumps or tumbles .

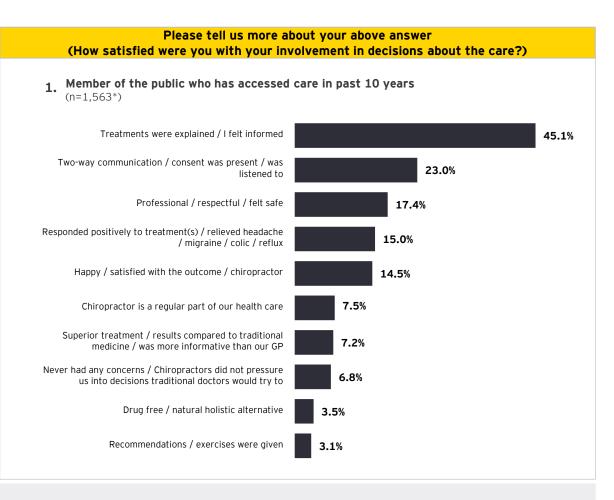


- 99.2% of respondents indicate they are either 'satisfied' or 'very satisfied' with their involvement in decisions about the care provided to their child
- 95.1% of responses report that they are 'very satisfied' with their involvement with the decisions about care.
- A combined 1% report that they are either 'neutral' (n=76), 'dissatisfied' (n=36) or 'very dissatisfied' (n=71).





- Treatment being explained is the most commonly mentioned reason for ratings of satisfaction with involvement in decisions about care
- 45.1% of members of the public, who accessed care, report that the they felt the treatments were explained by the chiropractor and that they felt informed during the process.
- 23.0% state that they experienced two-way communication when interacting with the chiropractor.



*Note: Open-text question, only coded responses shown / 1161 submissions did not contain data for this question



Sample Verbatim Comments:

Treatments were explained / I felt informed

Chiropractor was calm and explained everything as the went through the procedures.

As any actions were taken everything was explained and even some movements done on us as well so we could feel the pressure / action taken.

Before every adjustment, the chiropractor first talks to me and the child, and takes time to "connect" in a friendly way with the child. The chiropractor will then ask me and the child in turn about any concerns, any changes since our last visit, and then physically examine the child.

Two-way communication / consent was present / was listened to

All alternatives were discussed and we had a full assessment and 'chat' about the treatment plan.

66

Professional / respectful / felt safe

My chiropractor always gave me lots of options and great advice that the GP or maternal health nurse did not give. They also really cared for my mental and physical health as well.

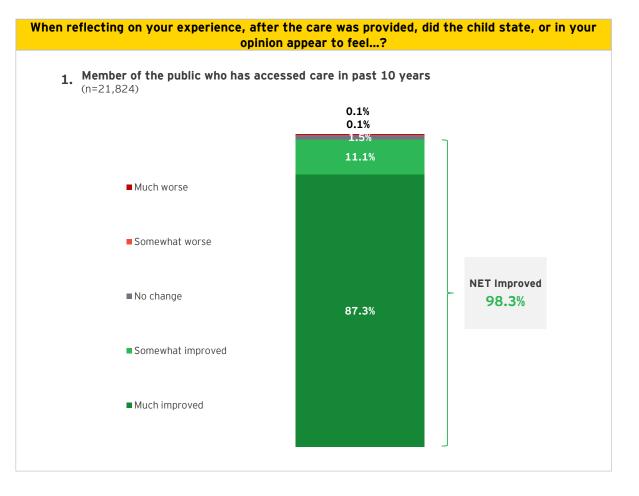
Extremely satisfied. At the beginning of each consult I explained my concerns, they were listened to, I was involved and present for each step and always felt free to voice if I was not comfortable with what was happening.

I was fully involved during the whole process, and the chiropractic explained what he was going to do each step of the way and asked if I was ok with what he was about to do. And asked if I had any further questions for him. As per above, the upfront honesty and openness regarding the treatment was a lot more than we ever received from GP etc. Much more care and time was taken.

We were involved all the way and given options. I felt more cared for than i ever have at a doctor or specialist medical doctor.

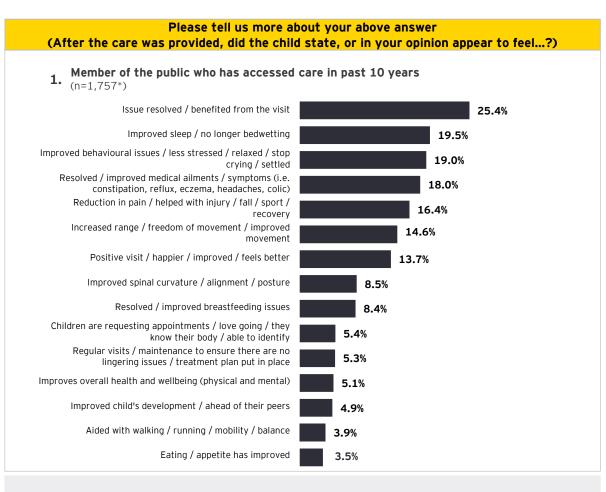


- 98.3% of responses indicated that the child receiving treatment felt either 'somewhat improved' or 'much improved'
- 87.3% indicate that the child was 'much improved' after treatment. A further 11.1% state that the child was 'somewhat improved'.
- 1.5% (n=318) indicate the child experienced no apparent change and less than 0.2% (n=43) indicate the child's condition worsened after treatment.





- Mentions of issues resolving are the most common reasons for citing improvement in a child after spinal care
- 19.5% cite improved sleeping and children no longer bedwetting as benefits of chiropractic care.
- 19.0% also report that behaviour issues or were improved (e.g. child became more relaxed and stopped crying)



*Note: Open-text question, only coded responses shown / 967 submissions did not contain data for this question



Sample Verbatim Comments:

Issue resolved / benefited from the visit

It has been a remarkable recovery and of great interest to all of the doctors involved on my son's care. He was recently discharged by the paediatric gastroenterologist, the ENT surgeon said that surgery wasn't necessary and the sleep doctors remained perplexed by my son's radical recovery of his health problems from chiropractic treatments.

We noticed a change in the child's wellbeing straight away, with symptoms for issues reducing dramatically.

When seeking care for Colic the improvement was immediate. The chiropractor also showed me a simple massage technique to assist with moving the build up of wind. Improved sleep / no longer bedwetting

Slept better, had bowel movements if constipated. Crawling/moving better. More content child.

Improved behavioural issues / less stressed / relaxed / stop crying / settled

His overall wellness improved after each visit; better digestion, more frequent bowel movements, less clicking in his hips, less screaming overall.

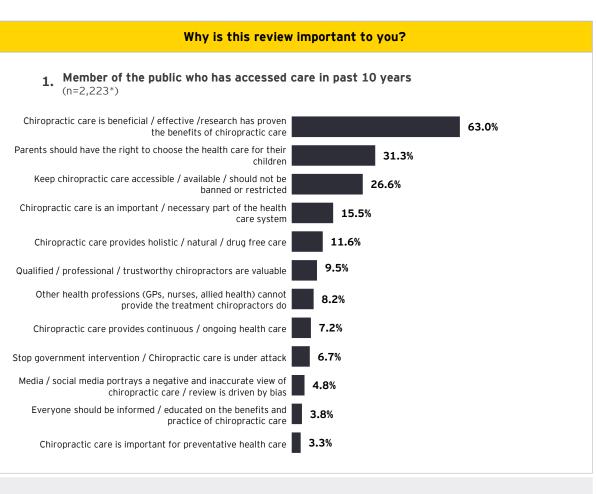
Always has a deep 3 hour nap after his adjustment. I see total peace in my son after an adjustment.

Our baby has had regular chiro treatments since birth and has had no issues with sleep, feeding, settling etc. My children would all improve after a visit. They were less irritable, slept better and were able to manoeuvre themselves more freely!

Each of our boys feels better after adjustments. They always sleep better after an adjustment & mood is improved.



- 63.0% of public responses include a reference to chiropractic care being effective in treating children under 12
- The next two most commonly mentioned reasons for importance of review are: a parent's right to choose care and the view that chiropractic care should not be banned; mentioned by 31.3% and 26.6% of coded submissions, respectively.



*Note: Open-text question, only coded responses shown / 501 submissions did not contain data for this question



Sample Verbatim Comments:

Chiropractic care is beneficial / effective /research has proved the benefits of chiropractic care

I believe spinal health is extremely important to our wellbeing. I myself had miraculous results as a child from Chiropractic care when all Medical intervention had failed me... It is so much easier to correct issues when young than to wait until we have degenerative issues leading to chronic disease.

Because we should not be dictated to about whether we use natural and preventative care for our own families. Chiropractic care is safer than medical care - the research proves this. This is not to say I don't or wouldn't use mainstream medicine because I do when I have to. I believe a integrated approach where we can the use the most appropriate care in the most appropriate situation benefits everyone.

Because I believe it's very important to keep children's chiropractic going. I can't imagine what my options would have been for my daughter if it wasn't available, as I have stated her neck was significantly visibly bent!

Parents should have the right to choose the health care for their children

I would feel saddened and angry if my right to get any of my children checked at a chiropractor was removed, or came with conditions attached. I trust my own judgement about my own children, and I trust my ability to choose an ethical, professional chiropractor who I trust with helping to care for my child.

The decision should not be made for us. I couldn't imagine my children not being able to receive Chiropractic care!!

Because I don't need the government interfering. It's what my child needed at the time and my job as parent was to make that decision...they only thing the government should be doing is making it available to be bulk billed.



Keep chiropractic care accessible / available / should not be banned or restricted

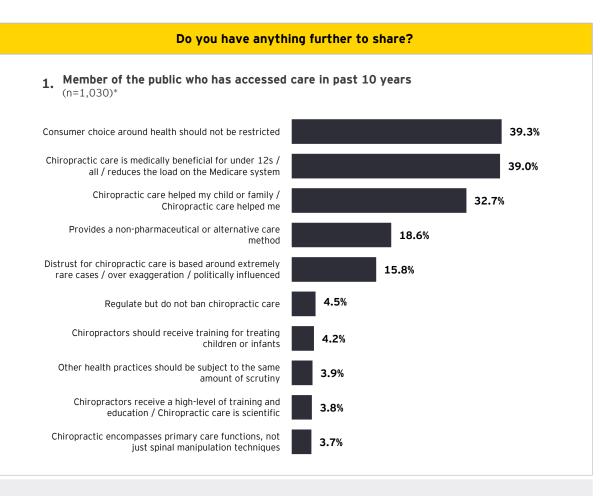
Because it is important that we all have the opportunity to access allied healthcare and treatment for our children. Just because one person didn't seem to be doing the right thing doesn't mean that the whole industry and patients need to suffer, and have our rights/choices taken away.

Given that Chiropractic care is so pivotal to the safe support and management of my children's general healthcare, I would be devastated to be in a position where I would not be able to access this care for my family.

I know there are many wonderful chiropractors who are skilled in working with children and have seen great results. I personally know young children who have been treated and healed by chiropractors for severe problems that no other health practitioner could help with. It would be shameful to deny our children the treatment that could give them the quality life they deserve.



- The importance of consumer choice and the medical benefits of chiropractic care are most commonly mentioned by members of the public who have accessed care. These two statements are included in 39.3% of coded responses, respectively.
- 32.7% of coded responses report that chiropractic care specifically helped them or their family.



*Note: Open-text question, only coded responses shown / 1,694 submissions did not contain data for this question



Sample Verbatim Comments:

Chiropractic care is medically beneficial for under 12s

My experience with Chiropractic care has been fantastic, from the personalised care to the impressive results. If Chiropractic care becomes unavailable for my child in Australia, I will take my child to New Zealand if necessary.

I hate this unsubstantiated scaremongering regarding something that works, can help siblings and parents by having a settled easy baby.

This form of care has been around a long time and has been proven to be helpful and safe compared with many other interventions performed regularly by GP s and other health professionals. I have seen a forceps delivery and had one and the forces on the spine are a lot greater than any Chiropractic treatment.

Consumer choice around health should not be restricted

Please don't take away our choices of providing the best possible health treatment to our kids. My daughter has also had many other issues including colic and sleep. The chiropractic treatment has helped a lot.

I encourage all friends and family to seek chiropractic care for their children as the improvement was incredible. The ongoing support and guidance has proven invaluable to my experience as a first time mum. I believe it is a parents choice as to how they give care to their child and they should be allowed to choose what path to take.

Parents need the right to choose their healthcare for their children. Period. So many doctors have made an incorrect diagnosis for a child, but all GPs wouldn't be banned from practicing on under 12s ? Its madness. Chiropractic care helped my child or family / Chiropractic care helped me

All 3 of my kids have been receiving weekly Chiropractic care since they were 3 months old. They are extremely well developed, very rarely sick and have excellent immune systems. They are strong, confident and healthy kids.

Due to the chiropractic care my son received as a child and still at 19 years of age, he has chosen to pursue this as his career. He has found the benefits to far outweigh any negatives, of which, he has never suffered. We still attend our chiro as a family and look forward to our monthly adjustment.

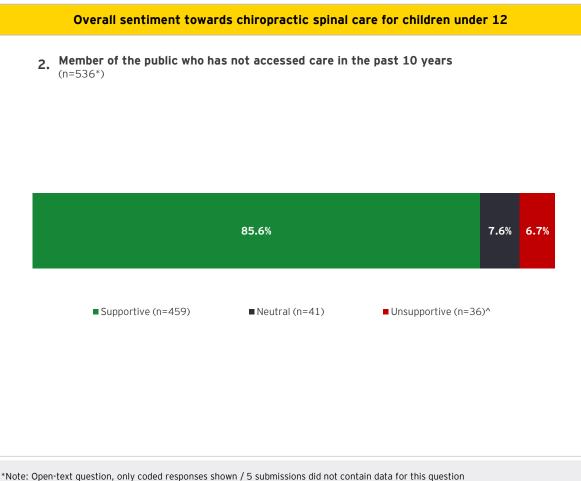
To me and my family chiropractic appointments and treatments have a huge positive effect on our life and make my children happier sleep better get less sick and make their moods so much better.



Stream 2: Member of the public who has not accessed care in the past 10 years

2. Member of the public who has not accessed care in the past 10 years

- NOTE: For the members of the general public who have not accessed care in the past 10 years, sentiment is defined by assessing the responses across open-text questions. Therefore only those submissions that have been coded are included in this analysis.
- 85.6% of coded responses submitted by a member of the public, who has not accessed care in the past 10 years, are supportive of chiropractic spinal care for children, overall.
- 6.7% of the coded responses express a sentiment that is unsupportive of chiropractic spinal care for children.
- 7.6% are neutral or unclear in the positivity or negativity of their sentiment.
- The question deemed as a most accurate proxy for overall supportiveness, amongst this cohort, is 'Please share your views about chiropractic spinal care for children under 12' All supportive, neutral, and unsupportive codes were grouped together and manual check was used to resolve instances where a response included conflicting codes.

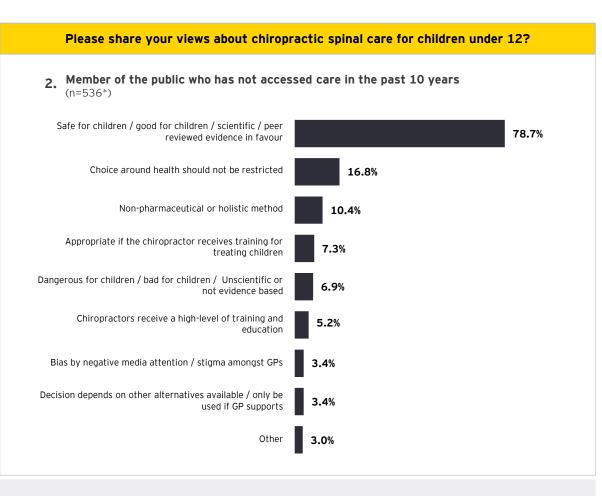


In the draft version of the report, this figure was mistakenly reported as n=37



2. Member of the public who has not accessed care in the past 10 years

- 78.7% of coded responses indicate that spinal care is safe / good for children.
- 16.8% of coded responses express the view that the freedom of choice to access chiropractic care should not be restricted.



*Note: Open-text question, only coded responses shown / 5 submissions did not contain data for this question



Sample Verbatim Comments:

Safe for children / good for children / scientific / peer reviewed evidence in favour

I am pro chiropractic and believe in the professional application of chiropractic adjustments for children, adults and the elderly. The training in chiropractic is second to none. Children SHOULD have the opportunity for great health through chiropractic.

I believe chiropractic care is essential for all children. My son had his first check at 1 week old. I am a great believer in Chiropractic care for all ages. Care of the body starts as a young person and should be continued throughout life. Preventative maintenance is far better than reactive treatment by "doctors" and their multitude of pills that they are more than willing to hand out.

I believe chiropractic spinal care would be safe and beneficial for children under 12 years. It would be especially beneficial if the child has any kind of issue that may originate in the misalignment of the spine. I am sure there are many cases in children that could benefit from chiropractic spinal care.

Choice around health should not be restricted

All families deserve the right to utilise different health practices for different reasons. If we take that choice away from chiropractic, it won't be long before other professions are attacked as well and our freedom to choose becomes more restricted and limited.

Parents should be able to choose if they wish to obtain chiropractic care for their children. There are techniques designed for kids under 12 some of which don't involve manipulation.

It should be the right of parents to be able to choose if they want their child, no matter what age, to be seen or treated by any practitioner, be they doctor, physiotherapist, chiropractor, dentist, or whomever they wish to seek the advice or services of, especially when they are qualified to do the job they are doing!

Non-pharmaceutical or holistic method

Isn't this better than prolonged drug use to help with pain. The drug therapy yes may dull the pain but doesn't fix the issue. It could be something like TMJD caused during the birth process, fixed quickly so the baby can be comfortable and the parents don't worry when the child isn't growing properly. I don't understand why this wonderful therapy would be made unavailable to people who believe and know it helps them.

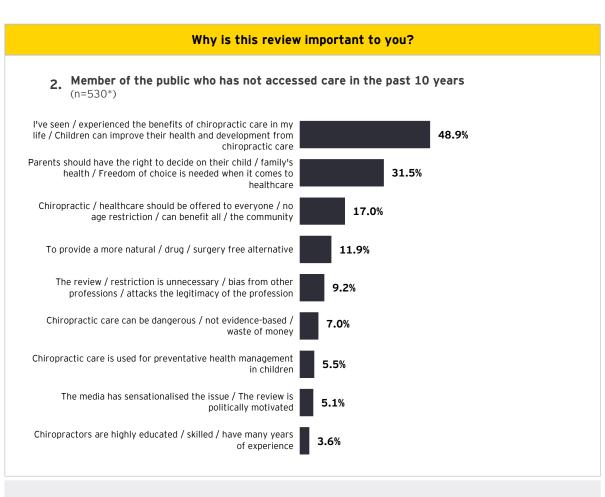
Let's be frank. The allopathic system of medicine has spent huge amounts of effort to marginalise all forms of treatment that exists outside of their cut, burn, poison model.

As an adult that receives chiropractic treatments I believe that these treatments are of great value for children as well. It is an opportunity for ailments to be treated naturally which should always be the first port of call in any treatment for children especially.



2. Member of the public who has not accessed care in the past 10 years

- When asked about the importance of the review, the top reason cited having seen or experienced the benefits of chiropractic care. This was mentioned by 48.9% of coded responses.
- Another common theme is that individuals should have the freedom to choose care for themselves or their family, this is mentioned in 31.5% of coded responses.



*Note: Open-text question, only coded responses shown / 11 submissions did not contain data for this question



Sample Verbatim Comments:

I've seen / experienced the benefits of chiropractic care in my life

Many children are helped by receiving chiropractic care and no child that I know of has ever been injured. I think chiropractors do an amazing and very important job in preventing and relieving pain and children will suffer if this care is no longer available.

Chiropractic care works, it is a gentle holistic approach to overall care that avoids drugs and possibly surgery for issues that were traditionally treated with either drugs and/or surgery.

I think it is important for all children, especially my grandkids to be able to access chiropractic care. My grandkids currently do see a chiropractor and have found it to be very helpful.

Parents should have the right to decide on their child / family's health

We should all have the right to choose who and where we can take our families for whatever health concerns we may have. Chiro

Chiropractic / healthcare should be offered to everyone

All persons young and old need to have access to appropriate care. One size doesn't fit all. Personally I prefer chiropractic care to attending upon a physiotherapist as I get better results quickly and are sustained longer.

What has happened to freedom of rights. Everyone should have the option of treatment, and chiropractors are well trained professionals. One of my grandchildren would be immobile without this form of treatment.

I believe that parents should be able to access chiropractic care for their children if they so desire. I am thankful that I was able to this for my children. I believe that access should be allowed to every living being and to remove an opportunity to an individual based on a minority view is unjust. If somebody doesn't like or believe in chiropractic then they don't have to participate in care, but to legally block a health care provision is barbaric.

I don't think a review is required. Over reaction to a few instances is 'nanny state' thinking. Why should under 12s miss out on a well aligned skeletal structure which provides sound sleep, normal growth, and a high functioning nervous system?





Practitioner surveys

DETAILED FINDINGS

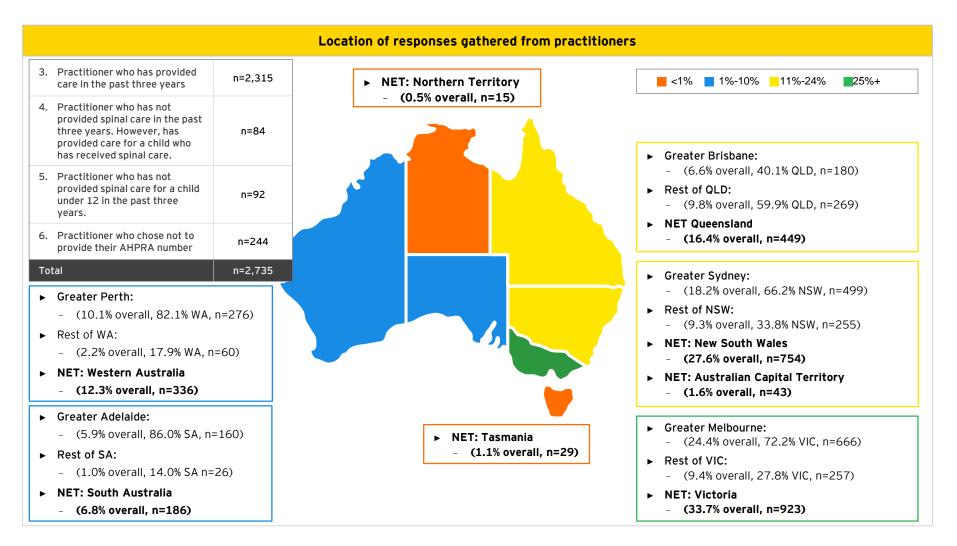
Background

- The second component of the consultation was to collect the views of practitioners in Australia.
- There were four survey streams available to the practitioners:
 - 3) Those <u>who have</u> provided spinal care for a child under 12 in the past three years.
 - 4) Those who <u>have not</u> provided spinal care for a child under 12, but have provided care in the past three years for a child <u>who received spinal care</u> <u>from another practitioner</u>.
 - 5) Those <u>who have not</u> provided spinal care for a child under 12 in the past three years.
 - 6) Those who would prefer not to provide Australian Health Practitioner Regulation Agency (AHPRA) numbers.
- This section of the report shows the findings for these four survey streams.



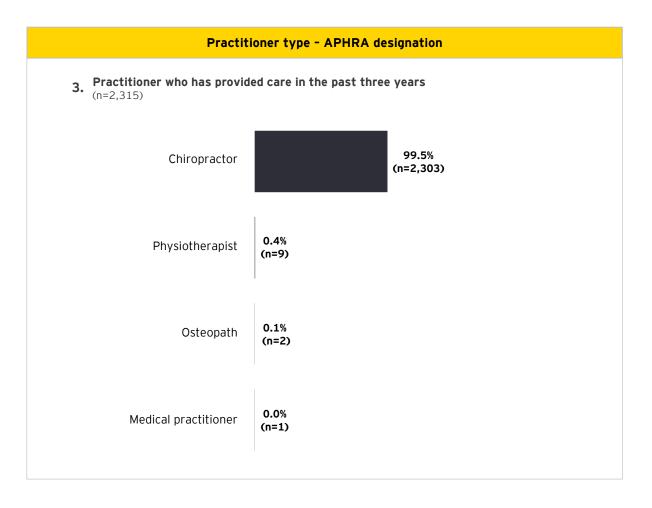


Practitioner surveys - all responses



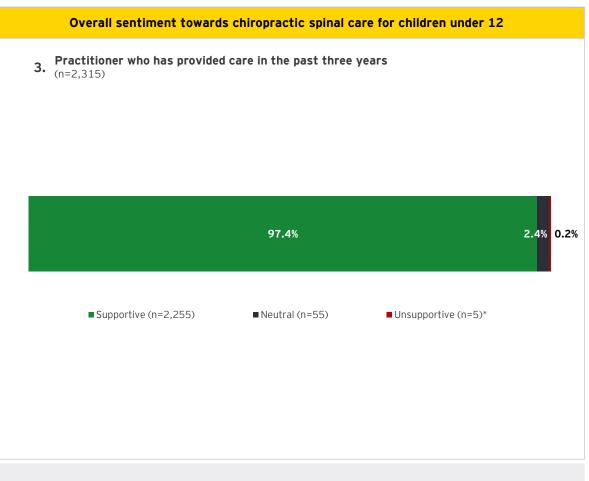


 99.5% of practitioners that have provided care in the past three years are chiropractors.





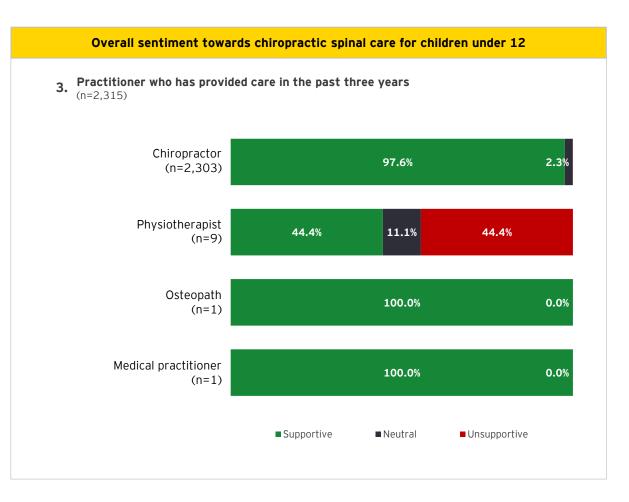
- NOTE: For practitioners who have provided care in the past three years sentiment is defined by assessing the responses across open-text questions. Therefore all submissions are included in the analysis.
- 97.4% of practitioners who have provided chiropractic spinal care for children under 12 express a sentiment that is supportive of chiropractic spinal care for children under 12
- The remaining 2.6% of these practitioner responses are neutral or unclear in their overall sentiment towards chiropractic spinal care for children under 12.
- Six individuals expressed a view that is unsupportive of chiropractic care.
- The question deemed as a most accurate proxy for overall supportiveness, amongst this cohort, is 'Why is this review important to you?' All supportive, neutral, and unsupportive codes were grouped together and manual check was used to resolve instances where a response included conflicting codes.



*In the draft version of the report, this figure was mistakenly reported as n=6

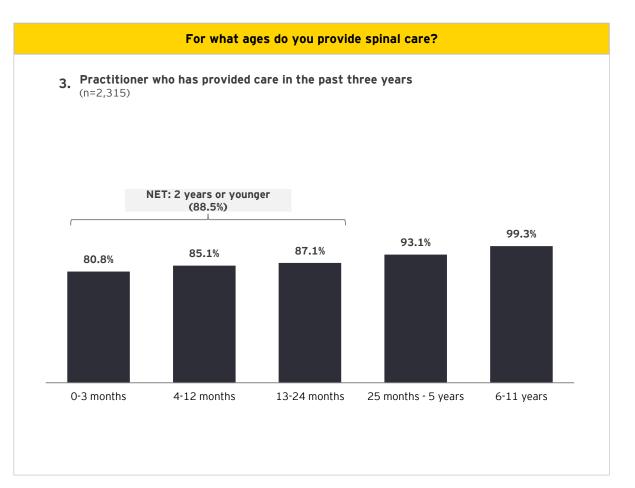


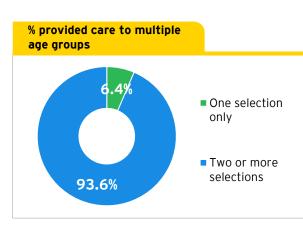
 97.6% of chiropractors express a sentiment that is supportive of chiropractic spinal care for children under 12.





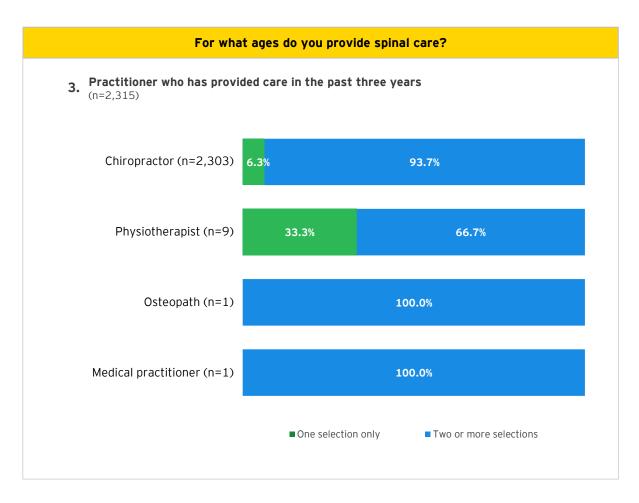
- Amongst practitioners who provide care, 80.8% report treating children aged 0-3 months
- 93.6% of practitioners who provide care report that they treat children from multiple age groups.





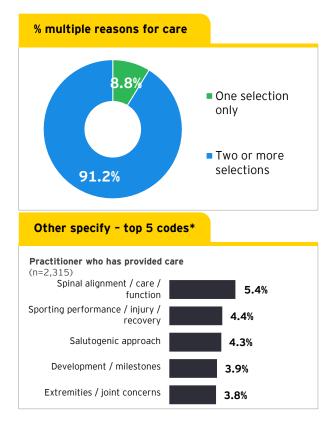


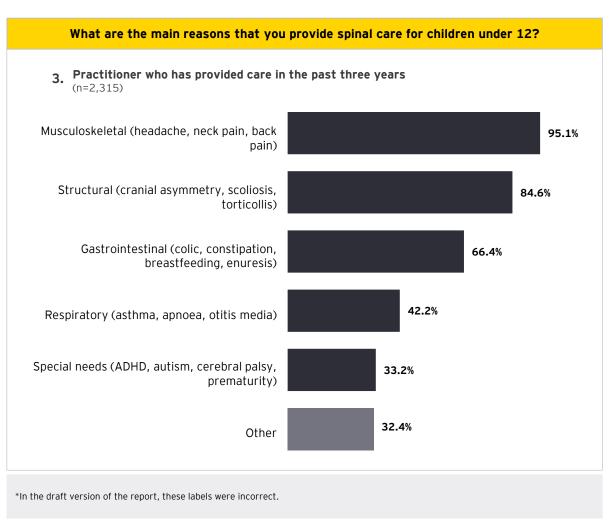
 93.7% of chiropractors who provide care report that they treat children from multiple age groups.





- Amongst practitioners who have provided care, 95.1% report that they have treated children under 12 for musculoskeletal reasons
- 91% of practitioners indicate that they have provided care for two or more reasons.

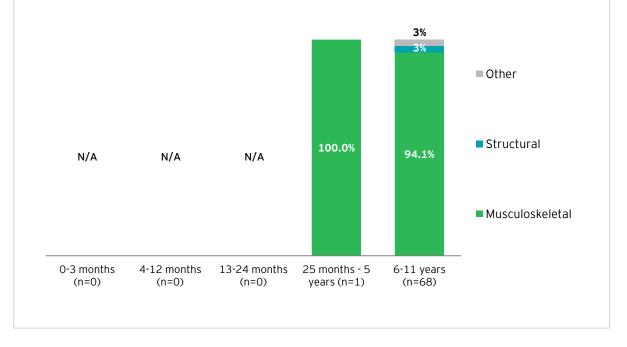




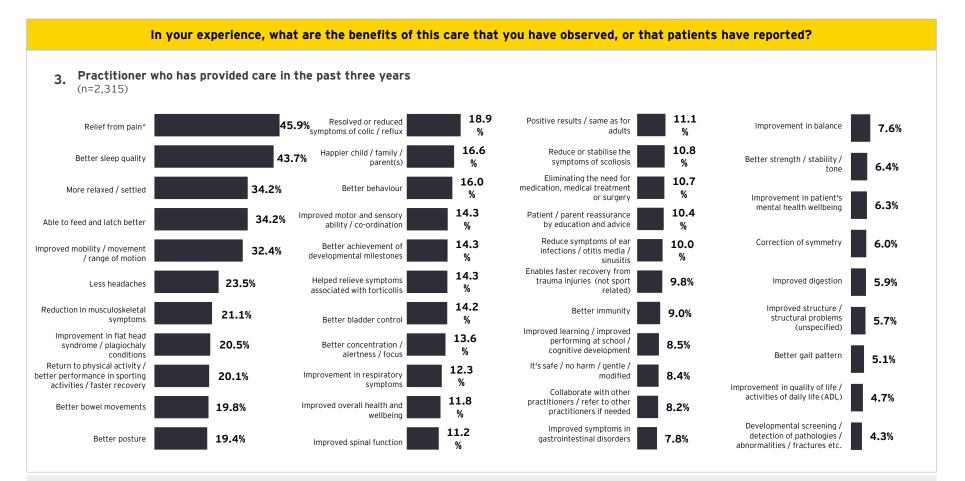
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- Of the n=69 practitioners who provided care to a single age group, for a single reason, n=68 provided care to a child aged between 6-11 years.
- N=65 of the practitioners who provided care to a single age group, for a single reason, provided treatment for a musculoskeletal issue.
- For what ages do you provide spinal care? & What are the main reasons that you provide spinal care for children under 12? (Single age group and single reason selected)
 - 3. Practitioner who has provided care to one age group for one reason in the past three years $(n\!=\!69)$



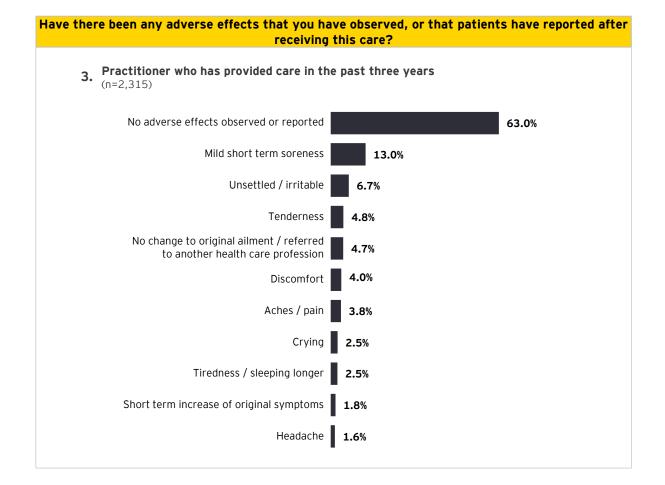




*In the draft version of the report, this code was mistakenly excluded



- 63.0% of practitioners report that no adverse effects relating to chiropractic care have been observed or reported
- 13.0% of responses indicate that mild shortterm soreness has been observed or reported.





Sample Verbatim Comments:

No adverse effects observed or reported

After nearly 5 years of practice, and working with children of all ages over that time, I have never once had a parent or child report any adverse affects to chiropractic care.

No. I use a graded approach to the amount of force or pressure needed with these treatments and am guided by the patient's comfort level, never going beyond it. Children are generally much more flexible than adults so it is unusual to see any post treatment strain or pain attributable to the treatment in the absence of pathology.

In my experience I have not observed any adverse events, nor have the patients/parents reported any after receiving spinal care.

Mild short term soreness

Temporary soreness is the only adverse events I have observed and that the patients/parents have reported.

Common side effects from spinal manipulations have included short term post-treatment soreness associated with mild sprain/strain type injuries. This is a very common outcome associated with spinal manipulation, and all patients are advised of this possible outcome before commencing any form of spinal care.

The only adverse effect that I have come across is mild soreness during and immediately after chiropractic care for a very short period of time. And within 5 minutes to 24 hours those symptoms are gone. Occasionally a few hours of irritability the first time they have their spine adjusted (using non

HVLA).

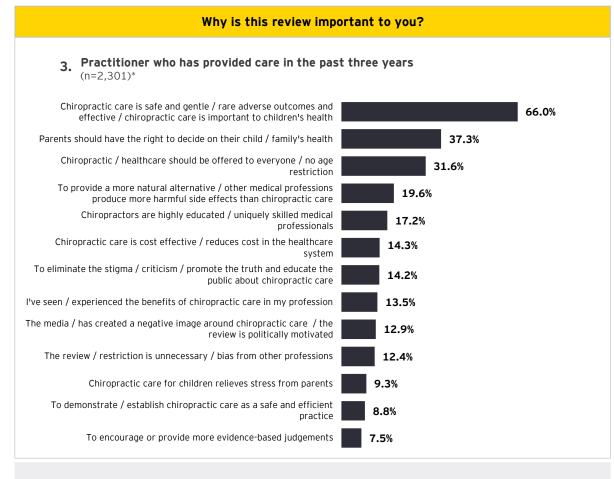
Unsettled / irritable

A few babies have been a bit grumbly and unsettled following adjustments, but no adverse events have been reported to me after more than 30 years of adjusting babies and children.

Occasionally, infants I have treated have been more irritable on the day of treatment, but this settles within a day or two. This seems to be more common after their very first treatment. More often than not, however, parents have reported that their baby is more settled and with improved symmetry in their spinal movements.



- Two thirds (66.0%) of responses state that chiropractic care is safe and effective.
- 37.3% of responses from this survey cohort indicate that the review is important because parents should have the right to decide on care that is provided to their children.



*Note: 14 submissions did not contain data for this question

Sample Verbatim Comments:

Chiropractic care is safe and gentle

I see the benefits to children every day it is awful to think that parents would not be able to make the free choice to provide natural healthcare that is effective and much valued to their children. If chiropractic supports healing that is even partially related to some of the health improvements I have mentioned above, doesn't that mean that kids cannot be said to be really healthy without a healthy spine?

I believe that natural health care has a place in our society. Chiropractic care works very safely and effectively in helping children develop correctly and optimally. Children also experience sprains and strains and the sooner they are corrected, they will have less implications in their adult life.

Seeing the changes in not only the children but the parents themselves when their child is no longer as unsettled is so rewarding and the thought of having to turn away desperate parents from being able to access treatment for their child would be heartbreaking.

Parents should have the right to decide on their child / family's health

Parents should have the freedom to choose which health care practitioners they want for their kids and for what reason. By removing an entire modality of care for children is removing a basic right. Ensuring children have the best start to life is critical and a proactive health care approach is always more effective than allowing issues to develop in teenage years or adulthood. Healthy kids have a better chance of becoming healthy adults.

As a child I have had Chiropractic care, my children receive Chiropractic care and I have personally helped hundreds of parents that came to me often as a last resort get positive results. To take away the ability for people to choose Chiropractic especially when other more conventional treatments have failed would be a huge loss in a country that enjoys such diversity and choices in all other aspects of life.

This review is vital for the freedom of the public to choose their own qualified health practitioner for their families. Chiropractic is a safe, effective and non-invasive therapy that has been used for decades. Chiropractors undergo stringent training in universities, completing a Bachelor degree and a Masters degree.

Chiropractic / healthcare should be offered to everyone / no age restriction

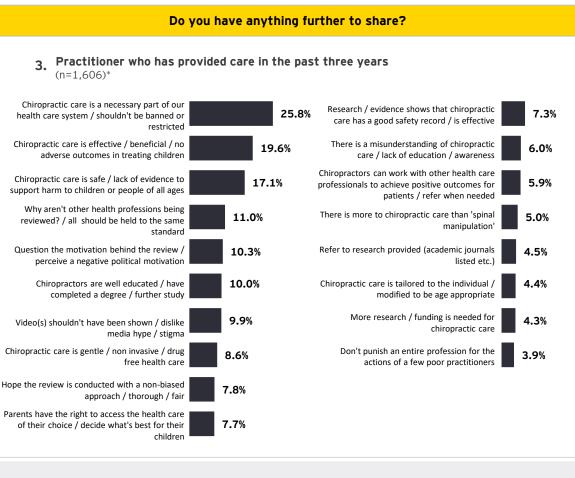
This is extremely important to me as I believe everybody from birth through to the elderly can benefit from Chiropractic care.

As a Chiropractor I care for patients who have a wide array of history, they come to me as a Chiropractor to approach their case the best I possibly can. This review is important to me because the ability to look after the whole community is important to me, I know professionally as a Chiropractor and personally as a paediatric Chiropractic patient when I was 0-12 the importance of receiving Chiropractic care from the ages of 0-12.

The confidence parents, patients and children have in my skill set alone is more than enough to provide a positive, safe and effective health care approach to keep my community happier and healthier. It would be unfair and unjust to deny people the freedom of taking their children to a highly skilled, highly educated practitioner (chiropractor) if they wish to seek us out to maintain their health and well-being.



- 25.8% of responses indicate that chiropractic care is a necessary part of the Australian healthcare system.
- 19.6% of these additional comments indicate that chiropractic care is effective and safe for children.



*Note: 709 submissions did not contain data for this question



Sample Verbatim Comments:

Chiropractic care is a necessary part of our health care system / shouldn't be banned or restricted

So much care that is provided to children is already very low velocity, very gentle care, that is so beneficial to their both short term and long term health e.g. acute cervical torticollis versus management of a scoliosis or plagiocephaly. There is no need to make a blanket ban that will prevent this segment of the population from receiving treatment. It would be so wrong.

I strongly believe that chiropractic care should remain available to all members of the public regardless of age when it is preformed by a skilled professional who modifies the technique to be age appropriate.

Please do not restrict the practice of safe gentle chiropractic care to children, so many would be left needlessly suffering and many others would be left without the extra body awareness and respect that visiting a chiropractor teaches.

Chiropractic care is effective / beneficial / no adverse outcomes in treating children

Anyone who has birthed a baby or had first hand experience witnessing a birth knows the pressure on both mother and baby. The sooner misalignments are gently corrected the less detrimental impact on the brain, nerve system and skeletal structure. It would have been impossible to remould my daughter's skull if she had been left to age 12 when bones are solid. Her vital development and learning years would have been very challenging.

People in our community really support what we do in our office and many people including people under 12 have received huge benefits from the work that we do. As a chiropractor I always ensure the force of an adjustment is appropriate for the age and condition of the patient and this is very gentle yet effective. It would be devastating to see people have their right to choose their healthcare practitioner taken away from them.

If more children receive chiropractic care and have the healing capacity of my body imagine how healthy our population could be in the future. It would also significantly decrease the financial burden on our government through pharmaceutical and surgical costs. Chiropractic care is safe / lack of evidence to support harm to children or people of all ages

Chiropractic care is safe, affordable, and low intervention care that benefits many children, its important that this goes on being available to families.

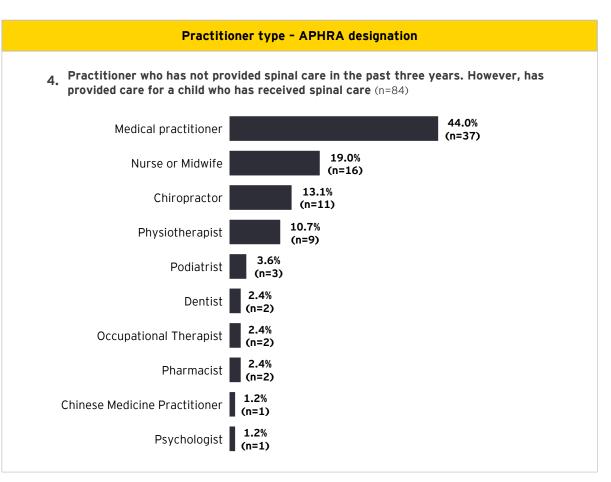
When we talk about manipulation of a baby's spine we are talking about extremely refined, very specific, very gentle manoeuvres. These skilful adjustments are so non-invasive that their potential for injury is almost non-existent. We respect the seriousness of safety and this always comes first in the treatment of any patient; that is why chiropractic adjusting of the infant spine is done with such care and attention rendering it so effective and so safe.

To take away peoples right to chose their own health care provider or that of their children, with no evidence of harm or dangerous practices is unjust and wrong. Chiropractic care has an exemplary safety record and achieves fantastic outcomes without the risks of more invasive treatments or side effects from medications. These practices have their place of course, but chiropractic should always be considered as a safe and effective option.



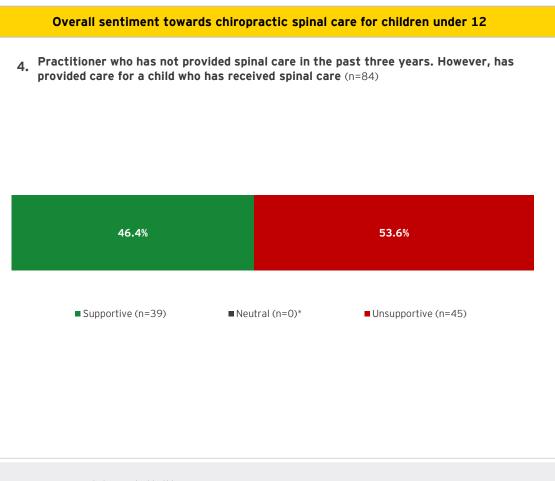


44.0% of practitioners that have not provided care in the past three years, have provided care for a child who has received spinal care are medical practitioners.





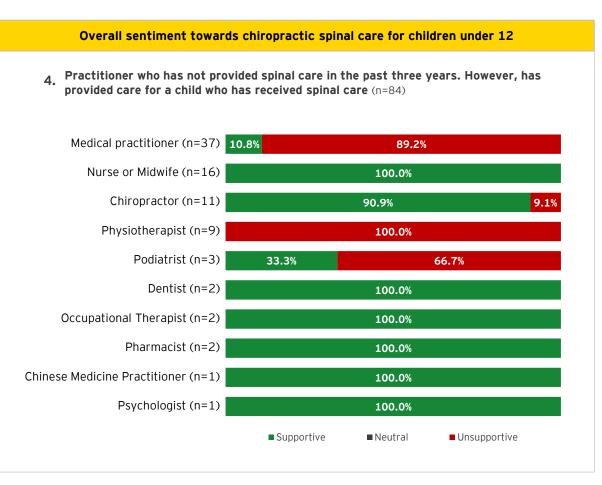
- NOTE: For practitioners who have provided care to children, who received spinal care sentiment is defined by assessing the responses across open-text questions. Therefore all submissions are included in the analysis.
- 53.6% of practitioners, who provided care to a child that had received spinal care, express a sentiment that is unsupportive of chiropractic spinal care for children under 12.
- 46.4% of the responses collected from this cohort express a view that is supportive of chiropractic care for children, no responses were deemed neutral or unclear.
- The question deemed as a most accurate proxy for overall supportiveness, amongst this cohort, is 'Why is this review important to you?' All supportive, neutral, and unsupportive codes were grouped together and manual check was used to resolve instances where a response included conflicting codes.



*No responses were recorded as neutral in this survey

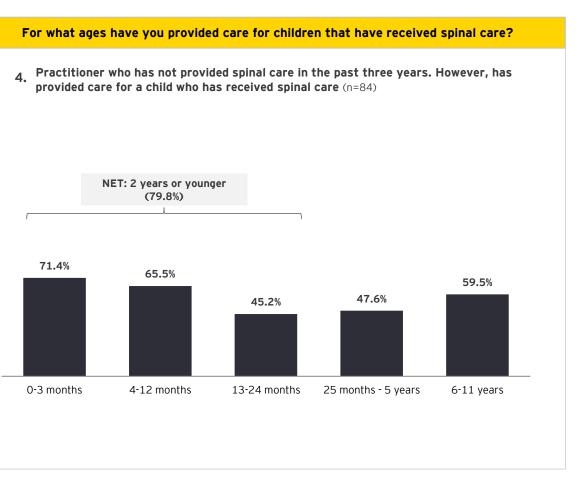


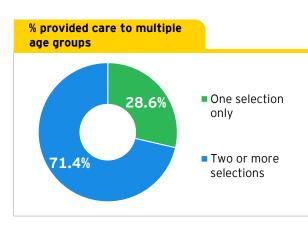
 89.2% of medical practitioners, who provided care to a child that had received spinal care, express a sentiment that is unsupportive of chiropractic spinal care for children under 12.





- Amongst practitioners who provide care, 79.8% report treating children aged up to 2 years old
- 71.4% of practitioners who provide care report that they treat children from multiple age groups.

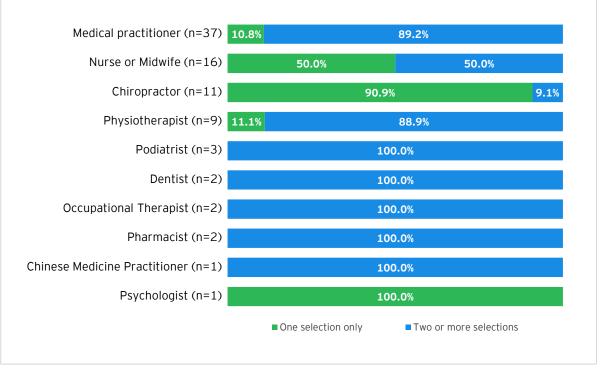






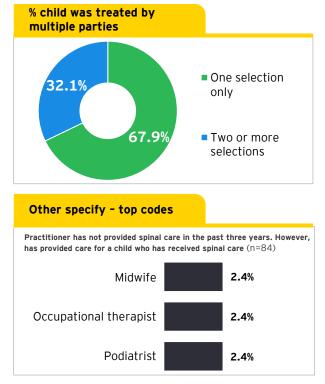
 89.2% of medical practitioners, who provided care to a child that had received spinal care, report treating children from multiple age groups. For what ages have you provided care for children that have received spinal care? (% provided care to multiple age groups)

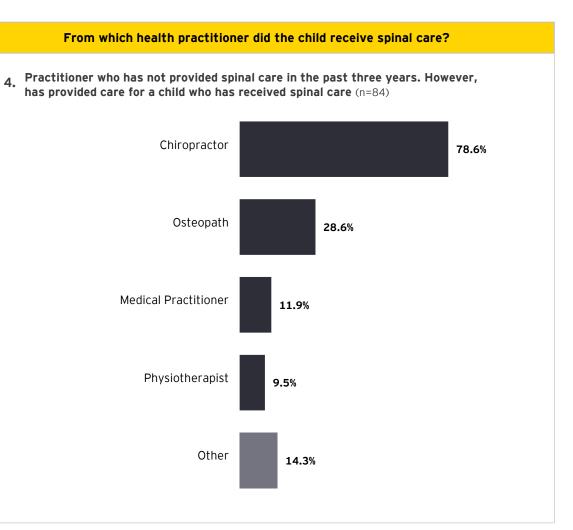
4. Practitioner who has not provided spinal care in the past three years. However, has provided care for a child who has received spinal care (n=84)





- Amongst practitioners who provided care to a child who received care from another party, 78.6% report that child received spinal care from a chiropractor
- 32.1% of practitioners, who provided care to a child who had received spinal care from another party, state that the child received care from multiple health practitioners.





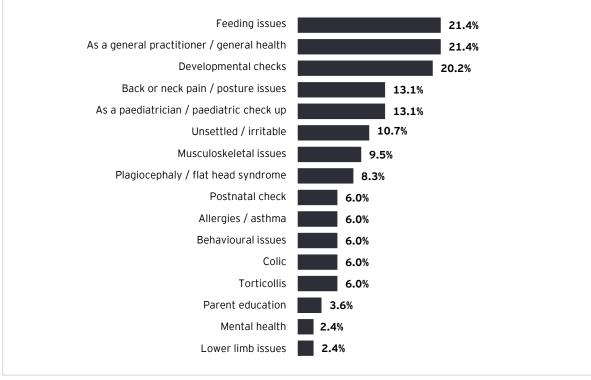
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- Feeding issues and general health checks are the most frequently cited reasons for providing care
- These reasons are both cited by 21.4% of practitioners, who treated children that had also received spinal care.
- Developmental checks are also a prevalent reason for care, being mentioned by 20.2% of respondents.



4. Practitioner who has not provided spinal care in the past three years. However, has provided care for a child who has received spinal care (n=84)





Sample Verbatim Comments:

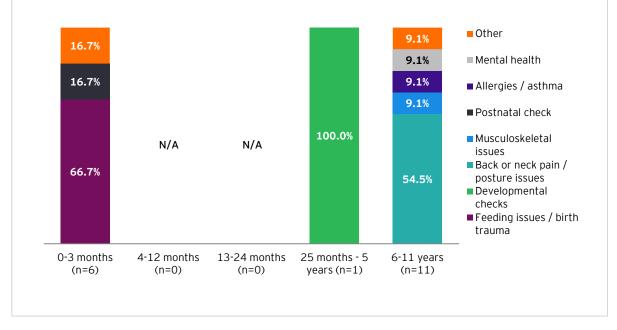
| Feeding issues | As a general practitioner / general health | Developmental checks |
|---|--|--|
| I am a Midwife and a Lactation consultant and was seeing the newborn babies for breastfeeding issues. | I am a GP and saw these children for routine well-checks and mild acute illnesses. | I work with babies and children with queries regarding their development / an identified disability /queries regarding their body shape or position e.g. query torticollis in babies, scoliosis generally presents older unless congenital |
| Unable to successfully breastfeed, due to the process of birth and in utero conditions. | As a general practitioner- care for vaccinations and check-ups, new born reviews, viral Illnesses. | I am a general paediatrician and children with scoliosis and other spinal anomalies often have complex medical and developmental issues. |
| Concerns regarding unsettled behaviour in babies (cry/fuss problems) and difficulty breastfeeding. | I am a general practitioner providing normal family medicine and often see children who have had spinal care in the course of my work. | Developmental delay (infants), musculoskeletal injury/pain (pre-school to school aged children) or pre-pointe screenings for 11-12 year old girls. |



- Of the n=18 practitioners who provided care to a single age group, for a single reason, n=11 provided care to a child aged between 6-11 years.
- Amongst those who treated children aged 6-11 years only, 54.5% treated them for back or neck pain / posture issues.
- For what ages do you provide spinal care? & What are the main reasons that you provide spinal care for children under 12? (Single age group and single reason selected)

Practitioner who has not provided spinal care in the past three years. However, has 4. provided care for a child who has received spinal care for one age group and one reason

4. provided care for a child who has received spinal care for one age group and one reason only (n=18)

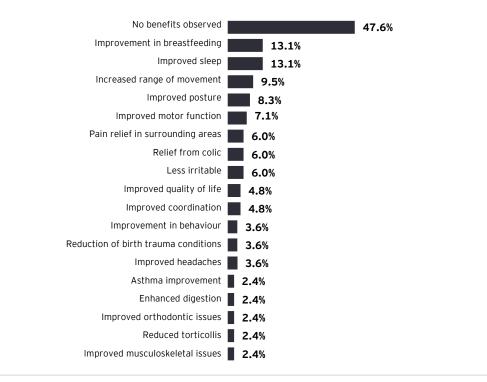




- 47.6% of practitioners who treated children, who also received spinal care, report that there were no benefits observed
- ► 13.1% indicate that they have observed improvements in breast feeding and sleep.
- 9.5% state that they are aware of cases where spinal care for children has resulted in an increased range of movement.

In your experience, what are the benefits that you have observed or that have been reported to you related to children receiving spinal care?

4. Practitioner who has not provided spinal care in the past three years. However, has provided care for a child who has received spinal care (n=84)



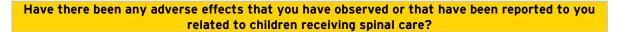


| No benefits observed | Improvement in breastfeeding | Improved sleep |
|--|--|---|
| I have not observed any benefits in a child related to the child receiving spinal care. | Babies that are doing damage while sucking can often benefit from gentle physical work if adjustment of feeding position does not succeed in limiting the nipple damage. | Improved sleep and settling. |
| I have not observed or had described to me any benefits for children receiving spinal care. | Babies with breastfeeding difficulties improving. | Specifically, many children have presented with significant positive changes in their level of calmness, their ability to settle at night for improved sleep routines, and improvements in gross motor coordination as their sensory perception of body in space has been improved with greater spinal alignment. |
| Nil. There are no benefits. It is a dangerous practice by practitioners who refuse to use evidence based practice. The parents of the children I assessed were given incorrect information regarding the benefits of chiropractic care that was not supported by basic science let alone medical literature. | The benefits I have observed are an amazing improvement in ; breast feeding, particularly babies that have only been able to breast feed comfortably from one breast (or when lying only on one side), feeding and sleeping patterns, and the change in a babies gape when attaching to the breast, that improves after a tongue tie release with ongoing chiropractic care. | Parents report children are happier and sleep better. |

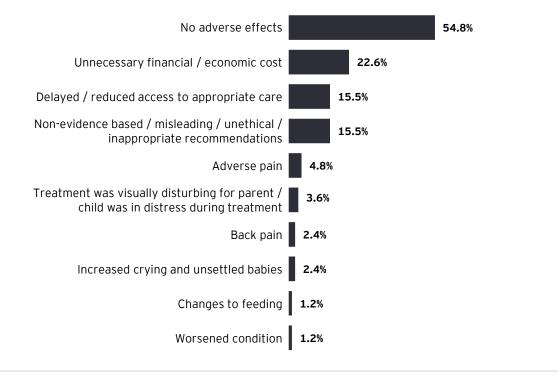


4. Practitioner who has not provided spinal care in the past three years. However, has provided care for a child who has received spinal care.

- 54.8% of practitioners, who treated patients who also received spinal care, state that no adverse effects were observed or reported
- 22.6% of responses report that they observed an unnecessary financial / economic cost being incurred.
- 15.5% of responses from this survey cohort indicate that spinal care for children delays or reduces access to appropriate care.



4. Practitioner who has not provided spinal care in the past three years. However, has provided care for a child who has received spinal care (n=84)





No adverse effects

None have ever been reported to me, nor have a personally observed any adverse effects.

I am not aware of any adverse effects. I refer only to practitioners who are experienced in working in this area.

None that I am specifically aware of, or have observed, in relation to chiropractic care.

Unnecessary financial / economic cost

It is a significant financial burden on parents who believe that the chiropractor is preventing illness or keeping their child healthy when there is 1) no evidence that chiropractic does this, 2) plenty of good-quality evidence that chiropractic achieves nothing for the vast majority of patients and certainly nothing for children, and 3) no sound scientific or anatomical basis for the theories underpinning chiropractic.

I am also able to cite multiple examples of healthy infants whose parents have been advised to subject them to ongoing spinal treatments for 'birth trauma' (even in the absence of birth complications), 'flat heads' (which self resolve in the vast majority of cases once children are mobile), and for 'preventative care'. These treatments come at a significant out of pocket cost to families.

A number of families are also receiving fearmongering advice regarding other issues, such as anti-vaccination information, tongue ties and false and sometimes dangerous nutritional information, from their spinal practitioners locally. They are also sold expensive and unnecessary supplements. ⊘elayed / reduced access to appropriate care

Observed: delayed diagnosis and treatment of scoliosis.

Chiropractor clinics actively showing videos in waiting room dissuading mothers from having regular antenatal screening ultrasounds, I had to talk a pregnant lady back into having her morphology ultrasound after this false information was given to her.

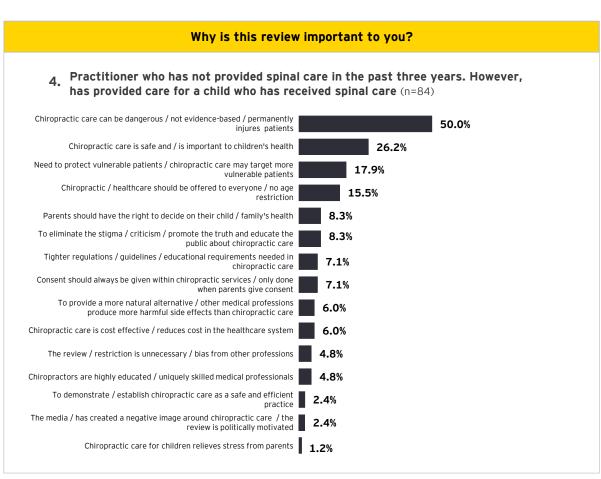
Fortunately, I am yet to personally have to manage direct physical adverse effects of this treatment. What I have experienced, however, is the infants involved, have generally had unnecessary and unhelpful treatment which has delayed their parents seeking appropriate treatment. Furthermore, this treatment generally feeds the anxiety of their parents.





4. Practitioner who has not provided spinal care in the past three years. However, has provided care for a child who has received spinal care.

- 50.0% of practitioner responses indicate that this review is important because chiropractic care can be dangerous / not evidence based
- Conversely, 26.2% responses state that the review is important because chiropractic care is safe / important to children's health.



Chiropractic care can be dangerous / not evidence-based

I feel that vulnerable families are paying large amounts of money to chiropractors/osteopaths who are performing treatments which are not evidence based and may actually harm their child.

As a paediatric trainee, it outrages me that chiropractors can provide medical treatments that are not evidenced based, or even scientifically based. They are dangerous in their management, and vulnerable desperate parents who want the best for their children are being mislead.

I believe allowing chiropractors to masquerade as health practitioners under the same regulatory body as myself and my colleagues is misleading to the community.

Chiropractic care is safe and / is important to children's health

I have seen amazing things happen for infants and parents after chiropractic care. As a midwife, I choose to use these services for my own health and that of my children. My daughter received chiropractic care from 6 days old.

Chiro's, osteo's and physiotherapists all offer options for parents and babies, these options are difficult to do randomised control research on but the families that I see benefit from these therapies. They are gentle, far more gentle than a ventouse/forceps delivery.

Where medicine is able to provide limited results for issues such as infant colic, families at present, have access to Chiropractic and Osteopathic care to turn to. Need to protect vulnerable patients

I am concerned that a vulnerable patient group needs to be protected from the predatory behaviour of unscrupulous practitioners.

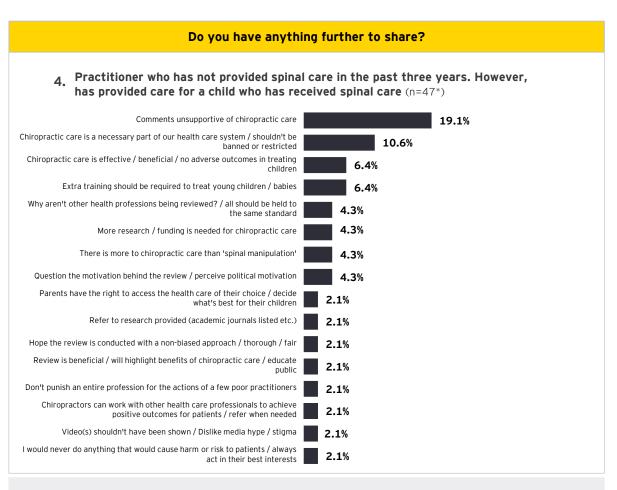
Because people spend money and time on these treatments which can cause psychological harm and which can delay access to standard medical care.

I also feel that it is morally unconscionable to be purporting to provide "treatment" that is costly and ineffective to vulnerable, worried parents who can be easily taken advantage of.



4. Practitioner who has not provided spinal care in the past three years. However, has provided care for a child who has received spinal care.

- The most common additional comments were reiterations of the view that chiropractic care can be dangerous / not evidence based
- 19.1% of additional comments state that chiropractic care can be dangerous / not evidence based.
- 10.6% report that chiropractic care is a necessary part of the Australian health care system and should not be banned or restricted.



*Note: 37 submissions did not contain data for this question



Comments unsupportive of chiropractic care

I do not think that chiropractors should ever be treating children of any age, for any condition.

The community need to be made aware of the dangers and insufficient literature related to chiropractic care. Please help educate the community so they seek treatment for ethical, evidenced based, practitioners.

It is very important to recognise that although some families may report symptomatic relief that often this can be easily explained by placebo effect. Although placebo effect in certain circumstances can be important and even helpful - this is more relevant with things like massage, where the therapy is harmless. If a positive placebo effect also carries a risk of death or disability - the risk outweighs the benefit. Chiropractic care is a necessary part of our health care system / shouldn't be banned or restricted

The whole idea is ludicrous and to even consider limiting care to young people is so beyond belief that I can't believe I have to take part in the survey. As a medical doctor I want my patients to access to all aspects of health care and I trust that a good chiropractor is absolutely part of that equation.

Chiropractic care and physiotherapy are both equal in value, and essential professions and all families need to be able to access these services for the best outcomes for their children.

A scientific approach including consultation with university researchers and lecturers is also required before advocating for a change in health policy and provision of clinical guideline; this cannot be a socially motivated decision as any decision will not only effect the public, it will greatly impact many health professionals who service families and young children alongside other patients. Chiropractic care is effective / beneficial / no adverse outcomes in treating children

I would like to see the government invest more money into researching the manual therapies as they do give parents more options to deal with very unsettled babies instead of medicating.

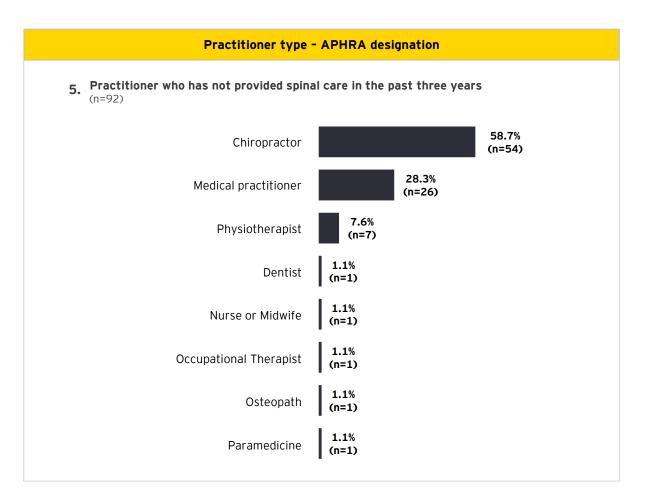
I totally deplore the action of a small group of bigoted biased obsessive people who are mostly not qualified in any health modality.

I have witnessed huge changes in babies post spinal care. In particular better feeding, better sleeping, better post op results after tongue tie release.



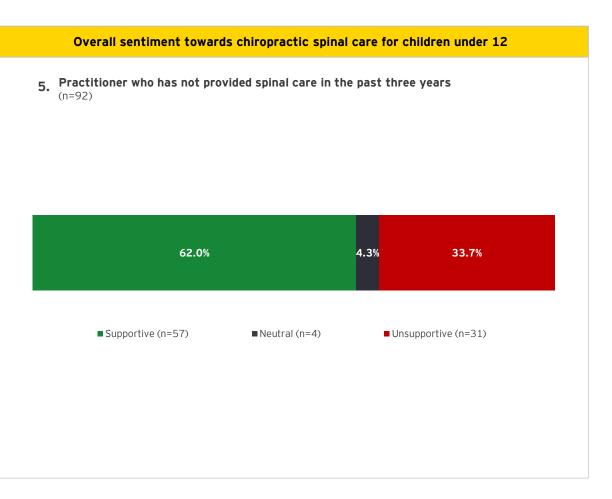
Stream 5: Practitioner who has not provided spinal care for a child under 12 in the past three years

- ► 58.7% of practitioners that have not provided care in the past three years are chiropractors.
- ▶ 28.3% are medical practitioners



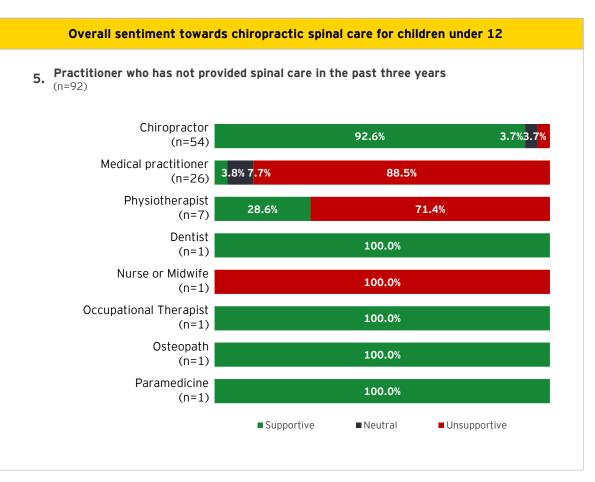


- NOTE: For practitioners who have not provided care in the past three years sentiment is defined by assessing the responses across open-text questions. Therefore all submissions are included in the analysis.
- 62.0% of practitioners who have not provided care for children under 12, in the past three years, express a sentiment that is supportive of chiropractic spinal care for children under 12.
- 33.7% of these responses communicate unsupportive sentiment of chiropractic spinal care for child under 12.
- 4.3% are neutral or unclear in their overall sentiment.
- The question deemed as a most accurate proxy for overall supportiveness, amongst this cohort, is 'Please share your views about chiropractic spinal care for children under 12?' All supportive, neutral, and unsupportive codes were grouped together and manual check was used to resolve instances where a response included conflicting codes.



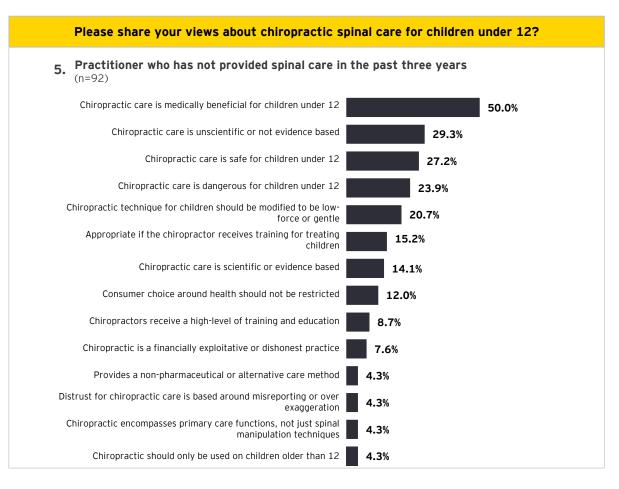


- 92.6% of chiropractors who have not provided care for children under 12, in the past three years, express a sentiment that is supportive of chiropractic spinal care for children under 12.
- 88.5% of medical practitioners express a sentiment that is unsupportive of chiropractic spinal care for children under 12.





- Half of practitioners who have not provided chiropractic care for children under 12 report that they feel such treatments are medically beneficial
- 29.3% of practitioners, who have not provided care, indicate that chiropractic care is unscientific or not evidence based.





Chiropractic care is medically beneficial for children under 12

Musculoskeletal disorders, especially spinal pain, are common and costly problems in Australia. Chiropractors are well placed to offer safe, effective, evidence-based treatment to people of all ages.

Children have health issues just as adults do that may be identified and treated by a Chiropractor. As Chiropractors are primary care health professionals we are trained to identify what is a Chiropractic issue and what needs to be referred to another appropriate profession. As a profession we see many children with great results and very few adverse events as per Parnell Prevost et. al. (2019) study and others show.

Compared to other common interventions, such as OTC paracetamol or ibuprofen, the risk/benefit profile of chiropractic in kids is far better according to the scientific evidence. Just as there are important dosing considerations of medicine use, so too are manual therapies modified for children to ensure their safety.

Chiropractic care is unscientific or not evidence based

It is exploitation of parents' anxiety and fears. The practice does not follow any principles of basic science. Based on an absence of good quality research demonstrating any benefit, it should be prohibited.

I feel it is completely unethical. There is no data showing this is effective or safe in this population.

I have heard people claiming that spinal manipulation will cure asthma/reflux/allergies/poor sleep in babies and that they need re-alignment after "birth trauma". But I haven't seen any science that connects the spine and asthma or reflux for example.

Chiropractic care is safe for children under 12 / safe for all

I believe I have had no side effects from care due to the fact that children and babies require such light and gentle intervention. Not only are child/baby adjustments proportionally gentle due to their size, but minimal intervention is required as a result of their bodies being more receptive and less encumbered by years of adaptive change, (adhesions, scar tissue, neurological patterns etc).

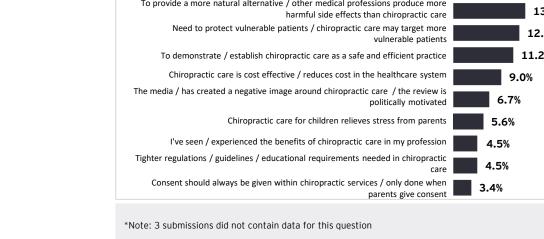
I believe that children under the age of 12 should be able to receive spinal care from Chiropractors. I have seen great improvements in not only pain, but quality of life in younger children over many years of observations while studying. I am yet to treat any children under 12 myself, but believe there is a place for chiropractic treatment in those younger than 12.

Chiropractic spinal care for children under 12 is just as important for those over 12 years of age. Everyone deserves the right to treatment, and should not be determined on age. Whether it is a muscular issue like a hamstring string, or a joint dysfunction children under the age of 12 can benefit greatly from chiropractic spinal care.



- The most commonly cited reason for importance of the review is the belief that chiropractic care is safe / effective / important to children's health. 38.2% of practitioners, who have not provided care in the past three years, state that chiropractic care is safe / effective / important to children's heath.
- 21.3% believe that parents should have the right to decide whether chiropractic spinal care is appropriate for their children.
- ▶ 21.3% indicate that the review is important because chiropractic care is dangerous / not evidence-based.

Why is this review important to you? Practitioner who has not provided spinal care in the past three years 5. (n=89)* Chiropractic care is safe and gentle / rare adverse outcomes and effective / 38.2% chiropractic care is important to children's health Parents should have the right to decide on their child / family's health 21.3% Chiropractic care can be dangerous / not evidence-based / permanently injures 21.3% patients To encourage or provide more evidence-based judgements 20.2% Chiropractic / healthcare should be offered to everyone / no age restriction 18.0% To eliminate the stigma / criticism / promote the truth and educate the public 18.0% about chiropractic care The review / restriction is unnecessary / bias from other professions 15.7% Chiropractors are highly educated / uniquely skilled medical professionals 15.7% To provide a more natural alternative / other medical professions produce more 13.5% harmful side effects than chiropractic care Need to protect vulnerable patients / chiropractic care may target more 12.4% vulnerable patients 11.2% To demonstrate / establish chiropractic care as a safe and efficient practice Chiropractic care is cost effective / reduces cost in the healthcare system 9.0% 6.7% politically motivated Chiropractic care for children relieves stress from parents 5.6% I've seen / experienced the benefits of chiropractic care in my profession 4.5% Tighter regulations / guidelines / educational requirements needed in chiropractic 4.5% care Consent should always be given within chiropractic services / only done when 3.4% parents give consent





Chiropractic care is safe and gentle

I feel chiropractic care is essential for babies that need it and the chance to ensure this care can be provided should not be withdrawn. I feel chiropractic care has a place in a developing child's life to ensure their body can be supported in its development into adulthood.

Chiropractic care is a safe, gentle alternative to costly medications and surgery.

I believe that every parent and child should have a choice in their chosen healthcare modality/practitioner. There are many ethical, science-based Chiropractors within Australia who do great work with many children who benefit from their care. Restricting access to such practitioners will be detrimental to the health and well-being of these children.

Parents should have the right to decide on their child / family's health

Because if these laws are changed, it impedes on many of my colleagues' formal learning and will prevent parents having a legitimate choice in sourcing their health care. I choose to only treat a small, specific demographic who are all older than 12 so there is no personal benefit/deficit to me personally.

The review threatens to remove the choice from the many hundreds of thousands of people who seek manual therapy for their children and the possible flow on health effects and the financial cost implications in the future should this happen. The bias and unfounded negative commentary about Chiropractic from supposedly educated people that are expected to have a considered view is unprofessional at best.

I don't manually manipulate babies or children under 5 personally. Children between 5 and 12 make up a small portion of patronage and I choose management on a case by case basis and do find it useful as mentioned above. The key issue here is the restriction itself. The limiting of the choice of where parents can take children in regards to their health care. It is a loss of sovereignty and starts us down a slippery-slope of further limitation. Chiropractic care can be dangerous / not evidence based

It involves the health of members of the general public who are largely unaware of the risks or lack of efficacy of this procedure.

Because this treatment is dangerous and could permanently damage a child. It is also a waste of the parents' time and money which could have been better spent actually treating whatever the original concern was with evidence based treatment and without causing a delay in seeking appropriate treatment.

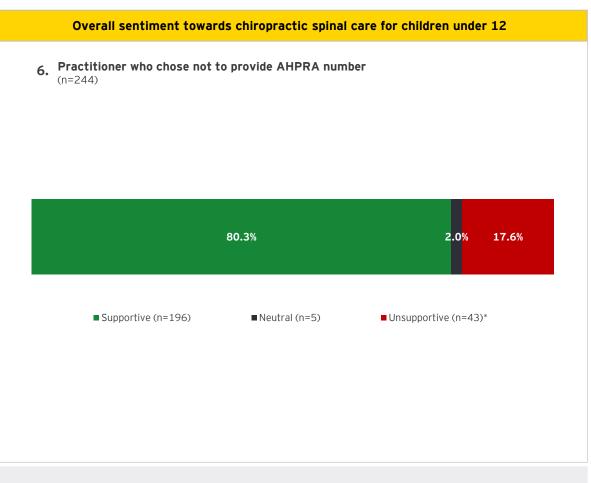
Children with medical problems unrelated to the spine may be treated by chiropractors which has no basis in evidence. This may potentially result in harm mainly through delaying proper medical diagnosis and management.



Stream 6: Practitioner who chose not to provide their AHPRA number

6. Practitioner who chose not to provide AHPRA number

- NOTE: For practitioners who did not provide AHPRA numbers, sentiment is defined by assessing the responses across open-text questions. Therefore all submissions are included in the analysis.
- 79.9% of practitioners, who did not provide AHRPA numbers, express a sentiment that is supportive of chiropractic spinal care for children under 12
- 18.0% of the responses gathered express a view that is unsupportive of chiropractic care for children, while 2.0% are neutral or unclear in their sentiment.
- The question deemed as a most accurate proxy for overall supportiveness, amongst this cohort, is 'Please share your views about chiropractic spinal care for children under 12?' All supportive, neutral, and unsupportive codes were grouped together and manual check was used to resolve instances where a response included conflicting codes.



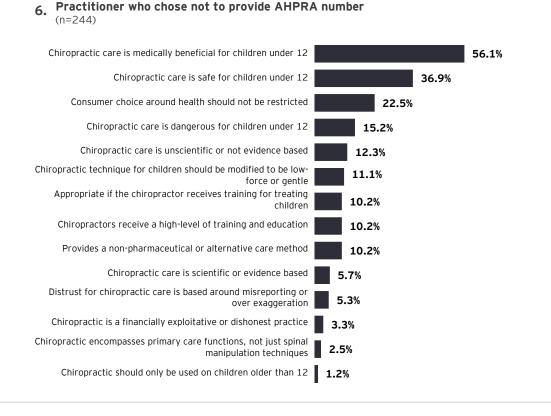
*In the draft version of the report, this figure was mistakenly reported as n=44



6. Practitioner who chose not to provide AHPRA number

- The majority of practitioners who did not provide AHPRA numbers state that chiropractic care is medically beneficial for children under 12
- 56.1% of responses from this survey stream report express the view that chiropractic care is medically beneficial for children under 12.
- 36.9% state that chiropractic care is safe for children under 12 and 22.5% put forward the view that consumer choice around health should not be restricted.

Please share your views about chiropractic spinal care for children under 12





Chiropractic care is medically beneficial for children under 12

As babies this care was life changing. I had a baby who was incredibly distressed and clingy and cried and screamed constantly. It was very tough on my mental health. Multiple trips to the hospital and GP found no answers. We began seeing the chiropractor then and have never looked back. It saved my sanity and had such a profound effect on the distressed state my thenbaby girl was in. I'll never forget it.

Chiropractic care has been proven to benefit the health of children of all ages by providing a drug-free approach to their symptoms. Research has since proven the benefits of chiropractic care and the safety of its treatments.

I am a podiatrist who commonly sees children in my clinic that have immensely benefited from spinal manipulation from a chiropractor, in improving overall health and function. The parents are always extremely happy with the results and only have positive and gentle experiences to share. I feel passionately about allowing parents this choice in health care and would be devastated if this was to be made inaccessible to me when I have children.

Chiropractic care is safe for children under 12

The fact that with chiropractic [medicine's] exceptional safety record that this review is even occurring absolutely baffles me... especially when in comparison to other health care providers and the known risks that they are often associated.

Chiropractic care for all ages, babies to geriatrics is imperative for the proper function and coordination of all living cells and tissues in the body. Optimal nervous system function is essential for all systems and function in the body - particularly babies, as they are constantly growing and dependent on a solid functional nervous system.

Spinal care is never dangerous when properly applied and I am outraged by the false statements that Chiropractic is unsafe for humans of any age.

Consumer choice around health should not be restricted

It is our right as human beings to have choice for how we want to look after our health. Chiropractors have a lot more knowledge for children's health that goes past the scope of just spinal manipulation.

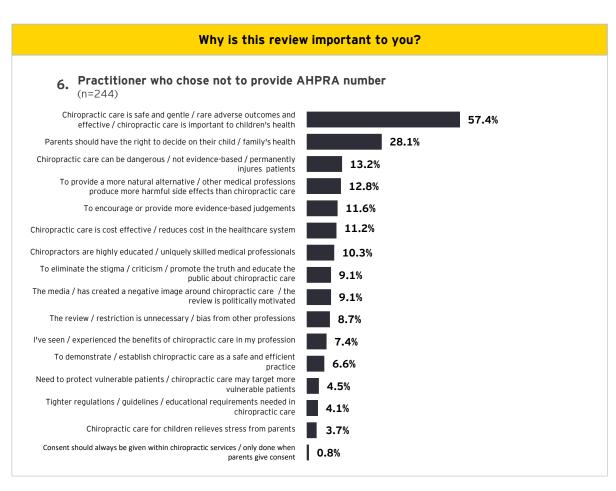
All children and parents should have the right to chose chiropractic care as part of a healthy spinal care plan.

This is a parents right to access the care they believe is best for their children.



6. Practitioner who chose not to provide AHPRA number

- 57.4% of practitioners, who did not provide AHPRA numbers, state the review is important because chiropractic care is safe and beneficial to children
- 28.1% mention that it is their belief that parents should have the right to decide on their child / family's health and that makes this review important to them.





Chiropractic care is safe and gentle / rare adverse outcomes and effective

Chiropractic care can be life changing to children suffering from ongoing issues. I believe that everyone should have access to chiropractic treatments.

To finish, spinal manipulation is safe and highly effective for the overall health of all ages, and to restrict its application for any age is a issue that touches on freedom of choice.

If I was to refuse treatment or the mother was anxious about having a chiropractor treat or be examined by me . That child would have had a lower quality of life, sickness possibly be have growth hindering problems associated with their physical ailments.

Parents should have the right to decide on their child / family's health

It is important because it is about our right to choose which type of health care we want for our family. The research will conclude that it is not a question of public safety. The public are not at a health risk with chiropractic care. If the effectiveness of chiropractic care for treatment for children under 12 is under investigation, a similar investigation should be undergone for the safety and efficacy of health care practitioners across all disciplines.

This review is important to me because I believe this is about choice for people and their children. If you take that away this becomes a police state where people are not allowed to make their own health choices. Having had chiropractic my whole life since I was born I believe everybody deserves that opportunity.

I think it is important that parents have the right to choose the health care they want for their children. I have had many desperate parents come to seek care when nothing else has helped their distressed child with mostly very good outcomes. Some children have not responded as well as others but I have never seen an adverse effect of care for children. Chiropractic care can be dangerous / not evidence-based

Please, please, please do the right thing and set an example to the rest of Australia by banning this form of unnecessary practice on children.

This is a matter of child protection and safety, as well as a safe guard for vulnerable parents who spend large amounts of money on nonevidence based "therapy" without the knowledge of the potential harm that can be caused with only a placebo effect as benefit.

Chiropractors spread false information to people about the benefits of their treatment this becomes dangerous when they are spreading this information to parents, who give consent for the chiropractor to treat their child's spine.





Complete code frames

This section outlines the complete list of themes that were identified in the responses.

To facilitate reporting, these codes were combined where relevant.





General public (have accessed care) codeframe: 'What was the main reason for seeking chiropractic spinal care?'

| | Code | frame | |
|----|---|-------|---|
| 1 | Behavioural issues / Unsettled baby | 18 | Treatment for traumatic birth / difficult birth / caesarean / premature |
| 2 | Sleep issues | 19 | General discomfort / restricted movement / alignment |
| 3 | Bowel issues / bladder issues | 20 | Allergies / food intolerence |
| 4 | Breech birth | 21 | After birth assessment / birth correction |
| 5 | Vomiting / reflux / digestion | 22 | Hip pain / clicking hip / Scoliosis / Knock knees / Torticollis |
| 6 | Feeding concerns / stomach pain | 23 | Forceps delivery |
| 7 | Check-up NFI | 24 | Cerebral palsy / Seizures / Stroke / Nerve damage / Brain damage |
| 8 | General health and well being / preventative care / alignment | 25 | Skin condition |
| 9 | Speech / co-ordination issues | 26 | Other |
| 10 | Excessive crying / screaming | | |
| 11 | Ear infection / ear ache / balance / cold & flu / sinus | | |
| 12 | Saliva control / Respiratory | | |
| 13 | Treat specific injury (Back / Groin / Car Accident / Knee / Ankle pain) | | |
| 14 | Mood / anxiety / learning difficulties / intellectual disability | | |
| 15 | Does not seem to have a child? / copy and pasted response | | |
| 16 | Tongue and lip tie release / tonsillitis / teeth grinding / jaw pain / ptosis | | |
| 17 | Misshapen head / Cranial development | | |



General public (have accessed care) codeframe: 'Who else did you see about this?'

| | Codeframe | | | | |
|----|--|----|-------------|--|--|
| 1 | None | 18 | Dietitian | | |
| 2 | Paediatrician | 19 | Audiologist | | |
| 3 | Podiatrist | | | | |
| 4 | Naturopath / Acupuncturist / Homeopath / Hypnotist | | | | |
| 5 | Surgeon / Physician / Specialist / Hospital staff | | | | |
| 6 | Chiropractor | | | | |
| 7 | Dentist / orthodontist | | | | |
| 8 | Lactation Consultant | | | | |
| 9 | Massage Therapist / Myotherapst / Remedial massage | | | | |
| 10 | Mid Wife | | | | |
| 11 | Psychologist | | | | |
| 12 | Occupational Therapist / Orthotist | | | | |
| 13 | Optometrist | | | | |
| 14 | Speech Therapist / Tongue tie specialist | | | | |
| 15 | Kinesiologist | | | | |
| 16 | Sleep therapist | | | | |
| 17 | Pharmacist | | | | |



General public (have accessed care) codeframe: 'How satisfied were you with the information provided by the chiropractor about... Please tell us more about your above answers?'

| | Codeframe | | | | |
|----|--|----|--|--|--|
| 1 | Chiropractor was informative / knowledgeable | 18 | Go to chiropractor for general health | | |
| 2 | Chiropractor gave more holistic solution | 19 | Professional | | |
| 3 | Chiropractor helped cure / relieve child's ailments / symptoms | 20 | Chiropractic care is beneficial / effective | | |
| 4 | Chiropractor gave full list of risks and alternatives | 21 | Provided excellent care / Impressed with care of chiro | | |
| 5 | Chiropractor did what Doctor / GP could not | 22 | Would have preferred more information given | | |
| 6 | Doctor's are uneducated when it comes to chiropractors/osteo's | 23 | Risks and alternatives were not explained | | |
| 7 | Did not want to medicate child so went to Chiropractor | 24 | No improvement / condition worsened after treatment | | |
| 8 | GP did not listen / Did not feel heard by GP | 25 | Chiropractor is trustworthy | | |
| 9 | Chiropractor was very gentle | 26 | Chiropractor made us feel comfortable | | |
| 10 | Chiropractor very thorough / careful | 27 | Chiropractic care works well alongside other health care | | |
| 11 | Always had good experience with Chiropractor | 28 | Always asks for consent / feel like I have control | | |
| 12 | Saw results quickly | 29 | Open communication / were honest | | |
| 13 | There are no other options / suitable treatments that worked | 30 | Provided follow up to care | | |
| 14 | Felt there was no risk / treatment was safe | 31 | Allow people / parents to have the choice to access chiropractic care without restrictions | | |
| 15 | Have sought chiropractors for on going treatment | 32 | Qualified / trained / experienced | | |
| 16 | Best option | 33 | Chiropractic care is important for preventative health care | | |
| 17 | Go to chiropractor for child development / care | | | | |



General public (have accessed care) codeframe: 'When reflecting on your experience - How satisfied were you with your involvement in decisions about the care? Please tell us more about your above answer?'

| | Code | frame | |
|----|--|-------|--|
| 1 | Referred us to another practitioner / helped us understand the health limits of chiropractic | 18 | Would / have recommend(ed) chiropractic to other parents |
| 2 | Involved / comfortable | 19 | Pressured to sign up to long term treatment |
| 3 | Happy / satisfied with the outcome / chiropractor | 20 | Posed more risk to my child than what I was comfortable with |
| 4 | Informed / treatments were explained | 21 | More specialised care |
| 5 | Two-way communication / consent was present / was listened to | 22 | Preventative care is important |
| 6 | Professional / respectful / felt safe / took care | 23 | Was more informative than our GP |
| 7 | Superior treatment / results compared to traditional medicine | | |
| 8 | Support unrestricted access to chiropractic services | | |
| 9 | Responded positively to treatment(s) | | |
| 10 | Chiropractor is a regular part of our health care | | |
| 11 | It was my choice | | |
| 12 | Drug free / natural holistic alternative | | |
| 13 | Relieved headache / migraine | | |
| 14 | Chiropractors did not pressure us into decisions / traditional doctors would try to | | |
| 15 | Relieved colic / reflux | | |
| 16 | Never had any concerns | | |
| 17 | Recommendations / exercises were given | | |



General public (have accessed care) codeframe: 'Please tell us more about your above answer (After the care was provided, did the child state, or in your opinion appear to feel...)'

| | Codef | irame | |
|----|--|-------|--|
| 1 | 100% improvement / completely /dramatically healed / issue resolved / benefited from the visit (physical benefit) | 18 | Treatment helps prevent illnesses / my child is rarely ill |
| 2 | Positive visit / happier / improved / feels better (emotive response) | 19 | Immediate improvement |
| 3 | Reduction in pain / ache relief / no more discomfort / tension | 20 | Not an immediate fix / gradual / takes more than one session |
| 4 | Increased range / freedom of movement / Improved movement | 21 | Treated / assisted with flat head syndrome / head sticking to one side / aided with head tilt |
| 5 | Improved sleep / no longer bedwetting | 22 | See the chiropractor for a long time / always seen the chiro / part of life |
| 6 | Ignored by health professionals / conventional treatment failed / nothing worked / GP did not elicit the same result / rarely visit the GP | 23 | Regular visits / maintenance to ensure there are no lingering issues / treatment plan put in place |
| 7 | Improved behavioural issues / less stressed / relaxed / stop crying / settled | 24 | Chiropractor provided information / exercises / we know how to better manage aliments / injuries |
| 8 | Improved spinal curvature / alignment / posture | 25 | Assisted with growing pains |
| 9 | Improved overall health | 26 | Aided with walking / running / mobility / balance |
| 10 | Resolved / improved breastfeeding issues | 27 | Helped with injury / fall / sport / recovery |
| 11 | Improved attention / focus / confidence | 28 | Treatment didn't help / couldn't identify a change / hard to tell |
| 12 | Resolved / improved medical ailments / symptoms (i.e. constipation, reflux, eczema, headaches, colic) | 29 | Want everyone to have access to Chiropractic treatments / couldn't imagine not having this treatment |
| 13 | All issues / problems (non-specific) are resolved / improved | 30 | Trust my Chiropractor / qualified / gentle / professional |
| 14 | Improves overall health and wellbeing (physical and mental) | 31 | Treatment did not require medication / drug free solution / didn't require medical intervention |
| 15 | Improved child's development / ahead of their peers | 32 | Boosted / strengthened immune / nervous system |
| 16 | Eating / appetite has improved | | |
| 17 | Children are requesting appointments / love going / they know their body / able to identify | | |



General public (all) codeframe: 'Why is this review important to you?'

| | Code | frame | |
|----|---|-------|--|
| 1 | People should have the right to choose their own health care | 18 | Chiropractic care is under attack |
| 2 | Chiropractic care is beneficial / effective | 19 | Research / evidence has proved the benefits of chiropractic care |
| 3 | Chiropractic care is an important / necessary part of the health care system | 20 | Chiropractic care should be subsidised / cheaper |
| 4 | Chiropractic care is for everyone regardless of age | 21 | Provides effective care for birth trauma conditions |
| 5 | Support / believe in chiropractic care | 22 | Chiropractic care is important for preventative health care |
| 6 | Chiropractic care provides continuous / ongoing health care | 23 | Chiropractors are caring / supportive |
| 7 | Keep chiropractic care accessible / available / should not be banned or restricted | 24 | Chiropractic care is non invasive |
| 8 | Chiropractic care is safe | 25 | Regulation / guidelines should be in place |
| 9 | Good for children's health / wellbeing | 26 | Other medical professions should be under review |
| 10 | Parents should have the right to choose the health care for thir children | 27 | Chiropractors are knowledgeable |
| 11 | Everyone should be informed / educated on the benefits and practice of Chiropractic cae | 28 | Helps with breastfeeding issues |
| 12 | Chiropractic care is gentle | 29 | Chiropractic care works well with other medical practice / have been referred on by chiropractor when needed |
| 13 | Qualified / professional / trustworthy chiropractors are valuable | 30 | Target poor practice instead / don't punish all chiropractors |
| 14 | Media / social media portrays a negative and inaccurate view of chiropractic care | 31 | Review is driven by bias / corruption / agenda of big pharmaceuticals and politics |
| 15 | Other health professions (GPs, nurses, allied health) cannot provide the treatment chiropractors do | 32 | Review is good / support it |
| 16 | Stop government intervention | 33 | Against forcible spinal cracking on children |
| 17 | Chiropractic care provides holistic / natural / drug free care | 34 | Alternative health care as an option |



General public (all) codeframe: 'Do you have anything further to share?'

| | Code | frame | |
|----|--|-------|--|
| 1 | Chiropractic care helped my child or family | 18 | Chiropractic encompasses primary care functions, not just spinal manipulation techniques |
| 2 | Chiropractic care helped me | 19 | Other health practices should be subject to the same amount of scrutiny |
| 3 | Consumer choice around health should not be restricted | 20 | Regulate but do not ban chiropractic care |
| 4 | Chiropractic care is medically beneficial for under 12s | 21 | Reduces the load on the Medicare system |
| 5 | Chiropractic care is beneficial for infant health | 22 | Chiropractors should receive training for treating children or infants |
| 6 | Chiropractic care is safe | 23 | Would still try to access chiropractic care even if it were restricted |
| 7 | Chiropractic care is scientific or evidence based | 24 | The review's funding should be put into more important medical research instead |
| 8 | Provides a non-pharmaceutical or alternative care method | 25 | Chiropractic care is medically beneficial for all ages |
| 9 | Politically influenced review | | |
| 10 | Chiropractors receive a high-level of training and education | | |
| 11 | Distrust for chiropractic care is based around misreporting or over exaggeration | | |
| 12 | Distrust for chiropractic care is based around extremely rare cases of harm | | |
| 13 | Chiropractic care helped my child or family | | |
| 14 | Chiropractic care helped me | | |
| 15 | Consumer choice around health should not be restricted | | |
| 16 | Chiropractic care is medically beneficial for under 12s | | |
| 17 | Chiropractic care is beneficial for infant health | | |



General public codeframe (have not accessed care): 'Please share your views about chiropractic spinal care for children under 12 years?'

| | Code | frame | |
|----|---|-------|--|
| 1 | Safe for all / good for all | 18 | Consumer choice around chiropractic care should be restricted |
| 2 | Dangerous for all / bad for all | 19 | Other health practices should be subject to the same amount of scrutiny |
| 3 | Safe for children / good for children | 20 | Decision depends on other alternatives available / only be used if GP supports |
| 4 | Dangerous for children / bad for children | 21 | Chiropractic should only be used on children older than 6 |
| 5 | Scientific / peer reviewed evidence in favour | 22 | Severe consequences of chiropractic adjustments |
| 6 | Ancetodal evidence evidence in favour | 23 | Bias by negative media attention / stigma amongst GPs |
| 7 | Unscientific or not evidence based | | |
| 8 | Medically beneficial for children | | |
| 9 | Non-pharmaceutical or holistic method | | |
| 10 | Consumer choice around health should not be restricted | | |
| 11 | The child should be consenting to chiropractic care | | |
| 12 | Beneficial for infant health | | |
| 13 | Dangerous for infants | | |
| 14 | Chiropractors receive a high-level of training and education | | |
| 15 | Appropriate if the chiropractor receives training for treating children | | |
| 16 | Should not be subsidised | | |
| 17 | Should be subsidised | | |



General public codeframe (have not accessed care): 'Why is this review important to you?'

| | Code | frame | |
|----|---|-------|--|
| 1 | Children can improve their health and development from chiropractic care/chiropractic is important to children's health | 18 | Consumer choice around chiropractic care should be restricted |
| 2 | Children should have access to health/chiropractic care/the same as adults | 19 | Other health practices should be subject to the same amount of scrutiny |
| 3 | Freedom of choice is needed when it comes to healthcare | 20 | Decision depends on other alternatives available / only be used if GP supports |
| 4 | To provide a more natural/drug/surgery free alternative | 21 | Chiropractic should only be used on children older than 6 |
| 5 | Parents should have the right to decide on their child/family's health | 22 | Severe consequences of chiropractic adjustments |
| 6 | To demonstrate/establish chiropractic care as a safe and efficient practice | 23 | Bias by negative media attention / stigma amongst GPs |
| 7 | Chiropractic/healthcare should be offered to everyone/no age restriction/can benefit all/the community | | |
| 8 | Chiropractic care should be subsidised | | |
| 9 | Chiropractic care can assist in relieving symptoms of musculoskeletal/important in musculoskeletal care | | |
| 10 | To encourage or provide more evidence-based/researched information | | |
| 11 | Chiropractic care is important for the nervous system/neurological functioning in children/everyone | | |
| 12 | To eliminate the stigma/criticism/promote the truth and educate the public about chiropractic care | | |
| 13 | Chiropractic care can be dangerous/not evidence-based/permanently injured patients | | |
| 14 | Chiropractic care is cost effective/reduces cost in the healthcare system | | |
| 15 | I've seen/experienced the benefits of chiropractic care in my life | | |
| 16 | Restricting care is cruel/unfair/wrong/disservice the patients and burdens the healthcare system | | |
| 17 | The review/restriction is unnecessary/bias from other professions/attacks the legitimacy of the profession | | |



Practitioner (all) codeframe: 'Please share your views about chiropractic spinal care for children under 12.'

| | Code | frame | |
|----|---|-------|--|
| 1 | Safe for all patients | 18 | Other health practices should be subject to the same amount of scrutiny |
| 2 | Dangerous for all patients | 19 | Chiropractic technique for children should be modified to be low-force or gentle |
| 3 | Safe for children under 12 | 20 | Distrust for chiropractic care is based around misreporting or overexaggeration |
| 4 | Dangerous for children under 12 | 21 | Chiropractic encompasses primary care functions, not just spinal manipulation techniques |
| 5 | Chiropractic care is scientific or evidence based | | |
| 6 | Chiropractic care is unscientific or not evidence based | | |
| 7 | Medically beneficial for children under 12 | | |
| 8 | Provides a non-pharmaceutical or alternative care method | | |
| 9 | Consumer choice around health should not be restricted | | |
| 10 | The child should be consenting to chiropractic care | | |
| 11 | Chiropractic care is beneficial for infant health | | |
| 12 | Chiropractic care is dangerous for infants | | |
| 13 | Chiropractors receive a high-level of training and education | | |
| 14 | Appropriate if the chiropractor receives training for treating children | | |
| 15 | Chiropractic is a financially exploitative or dishonest practice | | |
| 16 | Chiropractic should only be used on children older than 12 | | |
| 17 | Consumer choice around chiropractic care should be regulated | | |



Practitioner (all) codeframe: 'Why is this review important to you?' (1/2)

| | Codeframe | | | |
|----|---|----|---|--|
| 1 | Children can improve their health and development from chiropractic care/chiropractic is important to children's health | 18 | Chiropractic care is safe and gentle/low insurance premiums/evidence demonstrates the practice as low risk/rare adverse outcomes and effective | |
| 2 | Children should have access to health/chiropractic care/the same as adults | 19 | The media/online video has created a negative image around chiropractic care/taken out of context | |
| 3 | Freedom of choice is needed when it comes to healthcare | 20 | The review is politically motivated/Victorian Health Minister has depicted a negative stigma around chiropractic care | |
| 4 | To provide a more natural/drug/surgery free alternative | 21 | Access to healthcare shouldn't be decided by the Government | |
| 5 | Parents should have the right to decide on their child/family's health | 22 | My children/grandchildren have experienced/benefited from chiropractic care | |
| 6 | To demonstrate/establish chiropractic care as a safe and efficient practice | 23 | Medical decisions/opinions on chiropractic care shouldn't be based on emotions/'knee jerk reactions' | |
| 7 | Chiropractic/healthcare should be offered to everyone/no age restriction/can benefit all/the community | 24 | Tighter regulations/guidelines/educational requirements needed in chiropractic care | |
| 8 | Children can already develop spinal/musculoskeletal issues/chiropractic care can treat children with these issues | 25 | The chiropractic industry shouldn't be tarnished by individual practices/cases | |
| 9 | Chiropractic care can assist in relieving symptoms of musculoskeletal/important in musculoskeletal care | 26 | Chiropractic care for children relieves stress from parents/parents are satisfied with the practice/will be disappointed if chiropractic care is taken away | |
| 10 | To encourage or provide more evidence-based/researched information/anecdotal account | 27 | Patients/parents shouldn't waste large amounts of money on chiropractic care | |
| 11 | To eliminate the stigma/criticism/promote the truth and educate the public about chiropractic care | 28 | Chiropractic care is used for general preventative care/ health management in children | |
| 12 | Chiropractic care can be dangerous/not evidence-based/permanently injured patients | 29 | Children with sport injuries/participate in sports benefit from chiropractic care | |
| 13 | Need to protect vulnerable patients/chiropractic care may target more vulnerable patients | 30 | Chiropractic care helps mothers and their newborns/issues in infancy health (e.g. rough birth/colic/breastfeeding) | |
| 14 | I would like to maintain the ability to provide care for children | 31 | Chiropractors are highly educated/uniquely skilled/have many years of experience /have been around for a long time in the medical field | |
| 15 | I've seen/experienced the benefits of chiropractic care in my profession | 32 | Chiropractic care is dangerous/can permanently damage children | |
| 16 | Restricting care is cruel/unfair/disservice the patients and burdens the healthcare system | 33 | Chiropractic care is a last resort method for parents/used when other medical practices have failed | |
| 17 | The review/restriction is unnecessary/bias from other professions/attacks the legitimacy of the profession | 34 | Chiropractic care is cost effective/reduces cost in the healthcare system | |



Practitioner (all) codeframe: 'Why is this review important to you?' (2/2)

| | Codeframe | | | | |
|----|--|--|--|--|--|
| 36 | Children in today's society can develop spinal/development issues with the use of technology | | | | |
| 37 | Chiropractic care is recognised under the AHPRA governing body | | | | |
| 38 | Chiropractic care needs further support/funding from the Government | | | | |
| 39 | Chiropractic care is referral based/should mostly collaborate with other medical services | | | | |
| 40 | Chiropractors implement age appropriate techniques/care designed for the specific patient | | | | |
| 41 | Consent should always be given within chiropractic services/only done when parents give consent | | | | |
| 42 | Pharmaceutical drugs/other medical professions produce more harmful side effects than chiropractic care | | | | |
| 43 | Medical practices that deal with spinal (physiotherapy, osteopathy, GP) or paediatric care should also be under review /same restrictions applied to all /chiropractors implement the same techniques as other forms of care | | | | |
| 44 | The review will effect/restrict my practice/income/how I care for patients | | | | |



Practitioner (who provided care) codeframe: 'What are the main reasons that you provide spinal care for children under 12?'

| Codeframe | | | | | |
|-----------|--------------------------------------|----|--|--|--|
| 1 | General check up | 18 | Excessive crying | | |
| 2 | Salutogenic approach | 19 | Clicky hips | | |
| 3 | Sleeping difficulties | 20 | Subluxation | | |
| 4 | Sporting performance/injury/recovery | 21 | Problems feeding/latching / tongue tie | | |
| 5 | Other injuries | 22 | Skin conditions | | |
| 6 | Posture | 23 | Reflexes | | |
| 7 | Development / milestones | 24 | Neurological development/disorders | | |
| 8 | Birth trauma / post birth check up | 25 | Poor tone | | |
| 9 | Emotional wellbeing | 26 | Immune/Iymphatic system / allergy/intolerances | | |
| 10 | Improve balance/coordination | 27 | Reading/vision difficulties | | |
| 11 | Growing pains | 28 | Spinal alignment/care/function | | |
| 12 | Failure to thrive | 29 | Nervous system function | | |
| 13 | Learning difficulties | 30 | Concentration | | |
| 14 | Behavioural issues | 31 | Other | | |
| 15 | Extremities/joint concerns | | | | |
| 16 | Biomechanics/gait | | | | |
| 17 | Unsettled/restless baby | | | | |



Practitioner (who provided care) codeframe: 'In your experience, what are the benefits of this care that you have observed, or that patients have reported?' (1/2)

| | Codeframe | | | | |
|----|--|----|--|--|--|
| 1 | Symptoms have reduced or resolved | 18 | Eliminating the need for medication, medical treatment or surgery | | |
| 2 | More relaxed/ settled | 19 | Preventative care/ preventing injuries | | |
| 3 | Better sleep quality | 20 | Improvement in respiratory symptoms/ improvement in asthma symptoms (mobilisation of the rib cage) | | |
| 4 | Resolved or reduced symptoms of colic/ reflux | 21 | Better bladder control/ Reduced or stopped bed wetting (nocturnal enuresis) | | |
| 5 | Relief from or less pain | 22 | Better concentration /alert/ focus | | |
| 6 | Improved mobility/ movement / range of motion(ROM) | 23 | Reduction in Musculoskeletal symptoms | | |
| 7 | Able to feed and latch better | 24 | More energy | | |
| 8 | Improved digestion | 25 | Improved motor and sensory ability/ co-ordination | | |
| 9 | Better immunity | 26 | Less headaches | | |
| 10 | Improved spinal function | 27 | Improved function (unspecified) | | |
| 11 | Improved overall health and wellbeing | 28 | Its safe/ no harm/ gentle/ modified | | |
| 12 | Better posture | 29 | Better flexibility | | |
| 13 | Return to physical activity/ better performance in sporting activities/ faster recovery | 30 | Better strength/ stability/ tone | | |
| 14 | Better bowel movements | 31 | Better gait pattern | | |
| 15 | Improvement in balance | 32 | Better milestone development/ cognitive development/ learning | | |
| 16 | Improvement in quality of life/ activities of daily life (ADL) | 33 | Positive results/ same as for adults | | |
| 17 | Better behaviour | 34 | Improved symptoms in gastrointestinal Disorders | | |

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Practitioner (who provided care) codeframe: 'In your experience, what are the benefits of this care that you have observed, or that patients have reported?' (2/2)

| | Codeframe | | | | |
|----|---|--|--|--|--|
| 35 | Reduction of scoliosis/ reduce or stable the symptoms of scoliosis | | | | |
| 36 | Early assessment and identification of scoliosis | | | | |
| 37 | Help relieve symptoms associated with Torticollis | | | | |
| 38 | Improvement in Flat head syndrome/ plagiochaly conditions (cranial conditions inc. head symmetry) | | | | |
| 39 | Improved structure/ structural problems (unspecified) | | | | |
| 40 | Patient/parent reassurance by education and advice | | | | |
| 41 | Happier child/ family/parent(s) | | | | |
| 42 | Improvement in patient's mental health wellbeing | | | | |
| 43 | Improved socially | | | | |
| 44 | Correction of symmetry | | | | |
| 45 | Reduce symptoms of ear infections/ otitis media/ sinusitis | | | | |
| 46 | Soft tissue issues/ benefits from soft tissue techniques/ activator | | | | |
| 47 | Improved learning/ improved performing at school/ cognitive development | | | | |
| 48 | Quicker recovery from trauma injuries (not sport related) | | | | |
| 49 | Collaborate with other practitioners/ refer to other practitioners if needed | | | | |
| 50 | Developmental screening/ detection of pathologies/ abnormalities/ fractures etc | | | | |
| 51 | More cost effective (for people and on the government) | | | | |



Practitioner (who provided care) codeframe: 'Have there been any adverse effects that you have observed, or that patients have reported after receiving this care?'

| | Codeframe | | | | |
|----|--|----|--|--|--|
| 1 | No adverse effects observed or reported | 18 | Hyperactive / more energetic | | |
| 2 | Mild short term soreness | 19 | Increased hunger | | |
| 3 | Tenderness | 20 | Skin irritation to tapes or creams used | | |
| 4 | Tiredness / sleeping longer | 21 | Vomiting | | |
| 5 | Unsettled / irritable | 22 | Increased temperature / fever | | |
| 6 | Discomfort | 23 | Increased mucus production / sneezing / runny nose | | |
| 7 | Crying | 24 | Inflammation / redness | | |
| 8 | No change to original ailment / referred to another health care profession | 25 | Mild side effects (unspecified) | | |
| 9 | Headache | 26 | Feeding or digestion issues | | |
| 10 | Stiffness | 27 | Treatment takes longer to take effect | | |
| 11 | Aches / pain | | | | |
| 12 | Short term increase of original symptoms | | | | |
| 13 | Bruising | | | | |
| 14 | Increased bowel movement | | | | |
| 15 | Poor sleep | | | | |
| 16 | Light-headed / dizziness | | | | |
| 17 | Frightened / don't like the sound | | | | |



Practitioner (all) codeframe: 'Do you have anything further to share?'

| | Codeframe | | | | |
|----|--|----|---|--|--|
| 1 | Chiropractic care is safe / lack of evidence to support harm to children or people of all ages | 18 | Don't punish an entire profession for the actions of a few poor practitioners | | |
| 2 | Parents have the right to access the health care of their choice / decide what's best for their children | 19 | More research / funding is needed for Chiropractic care | | |
| 3 | Why aren't other health professions being reviewed? / There are other professions providing similar care / should all be held to the same standard | 20 | Extra training should be required to treat young children / babies | | |
| 4 | Review seems to be generated as a result of the publishing on social media / media coverage | 21 | Have had positive feedback / no adverse outcomes in treating children | | |
| 5 | Chiropractic care is a necessary part of our health care system / shouldn't be banned or restricted | 22 | Research / evidence shows that Chiropractic care has a good safety record / is effective | | |
| 6 | Refer to research provided (academic journals listed etc.) | 23 | There is more to Chiropractic care than 'spinal manipulation' | | |
| 7 | There is a misunderstanding of Chiropractic care / lack of education / awareness | 24 | Dislike media hype / stigma / fear mongering against Chiropractic care | | |
| 8 | Chiropractors are well educated / have completed a degree / further study | 25 | Chiropractors can work with other health care professionals to achieve positive outcomes for patients / refer when needed | | |
| 9 | Dislike views / comments of the Health Minister | 26 | Video(s) shouldn't have been shown / stricter marketing guidelines are needed | | |
| 10 | Question the motivation behind the review / political motivation | 27 | Chiropractic care is affordable / cost effective | | |
| 11 | Hope the review is conducted with a non-biased approach / thorough / fair | 28 | Issues should be dealt with internally / through AHPRA not the government | | |
| 12 | Review is unnecessary / waste of time / money | 29 | Care is given with parental consent / make sure parents are comfortable / informed | | |
| 13 | Chiropractic care is effective / beneficial | 30 | I would never do anything that would cause harm or risk to patients / always act in their best interests | | |
| 14 | Chiropractic care is gentle / non invasive | 31 | People who question Chiropractic care should visit a clinic / observe treatments before forming an opinion | | |
| 15 | Chiropractic is a form of natural and drug free health care | 32 | Chiropractors in Australia can't register as specialists / need to be able to specialise paediatric care | | |
| 16 | Chiropractic care is tailored to the individual / modified to be age appropriate | 33 | Survey feedback | | |
| 17 | Review is beneficial / will highlight benefits of Chiropractic care / educate public | 34 | Negative towards chiropractic care | | |



Practitioner (provided care for a child who has received spinal care) codeframe: 'In your experience, what are the benefits that you have observed or that have been reported to you related to children receiving spinal care?'

| | Codeframe | | | | |
|----|--------------------------------------|----|---------------------------------|--|--|
| 1 | Improvement in breastfeeding | 18 | Improved headaches | | |
| 2 | Improvement in behaviour | 19 | Improved musculoskeletal issues | | |
| 3 | Asthma improvement | | | | |
| 4 | Enhanced digestion | | | | |
| 5 | Pain relief in surrounding areas | | | | |
| 6 | Increased range of movement | | | | |
| 7 | Relief from colic | | | | |
| 8 | Improved sleep | | | | |
| 9 | Less irritable | | | | |
| 10 | Improved posture | | | | |
| 11 | Improved orthodontic issues | | | | |
| 12 | Reduction of birth trauma conditions | | | | |
| 13 | No benefits observed | | | | |
| 14 | Improved quality of life | | | | |
| 15 | Reduced torticollis | | | | |
| 16 | Improved motor function | | | | |
| 17 | Improved coordination | | | | |



Practitioner (provided care for a child who has received spinal care) codeframe: 'Have there been any adverse effects that you have observed or that have been reported to you related to children receiving spinal care?'

| | Codeframe | | | |
|----|---|--|--|--|
| 1 | No adverse effects | | | |
| 2 | Delayed / reduced access to appropriate care | | | |
| 3 | Unnecessary financial / economic cost | | | |
| 4 | Back pain | | | |
| 5 | Changes to feeding | | | |
| 6 | Adverse pain | | | |
| 7 | Worsened condition | | | |
| 8 | Non-evidence based / misleading /unethical / inappropriate recommendations | | | |
| 9 | Treatment was visually disturbing for parent / child was in distress during treatment | | | |
| 10 | Increased crying and unsettled babies | | | |



Sentiment analysis

This section outlines the codes that were combined to identify the overall supportiveness or unsupportiveness of responses.



2. Member of the public who has not accessed care in the past 10 years - Sentiment analysis

Supportive codes

- ► Safe for all / good for all
- ► Safe for children / good for children
- ► Scientific / peer reviewed evidence in favour
- ► Anecdotal evidence / evidence in favour
- Medically beneficial for children
- ► Non-pharmaceutical or holistic method
- Consumer choice around health should not be restricted
- ► Chiropractors receive a high-level of training and education
- Should be subsidised
- Other health practices should be subject to the same amount of scrutiny
- ▶ Bias by negative media attention / stigma amongst GPs

Unsupportive codes

- ▶ Dangerous for all / bad for all
- Severe consequences of chiro
- ► Unscientific or not evidence based
- Dangerous for children / bad for children
- Dangerous for infants
- ▶ The child should be consenting to chiropractic care
- Should not be subsidised



3. Practitioner who has provided care in the past three years -Sentiment analysis

| | Supportiv | ve co | odes |
|---|--|-------|--|
| • | Children can improve their health and development from chiropractic care / chiropractic is important to children's health | ۲ | The review / restriction is unnecessary / bias from other professions / attacks the legitimacy of the profession |
| • | Children should have access to health / chiropractic care / the same as adults | ► | Chiropractic care is safe and gentle / low insurance premiums / evidence demonstrates the practice as low risk / rare adverse outcomes and effective |
| • | Freedom of choice is needed when it comes to healthcare | | |
| • | Parents should have the right to decide on their child / family's health | ► | The media / online video has created a negative image around chiropractic care / taken out of context |
| • | Chiropractic / healthcare should be offered to everyone / no age restriction / can benefit all / the community | ۲ | The review is politically motivated / Victorian health minister has depicted a negative stigma around chiropractic care |
| • | Children can already develop spinal / musculoskeletal issues / chiropractic care can treat children with these issues | ► | Access to healthcare shouldn't be decided by the government |
| • | Chiropractic care can assist in relieving symptoms of musculoskeletal / important in | ► | My children / grandchildren have experienced / benefited from chiropractic care |
| | musculoskeletal care | ► | Medical decisions / opinions on chiropractic care shouldn't be based on emotions / 'knee jerk reactions' |
| • | To eliminate the stigma / criticism / promote the truth and educate the public about | | |
| | chiropractic care | ► | The chiropractic industry shouldn't be tarnished by individual practices / cases |
| • | I've seen / experienced the benefits of chiropractic care in my profession | ► | Chiropractic care is used for general preventative care / health management in children |
| • | Restricting care is cruel / unfair / disservice the patients and burdens the healthcare system | ۲ | Chiropractic care helps mothers and their newborns / issues in infancy health (e.g. rough birth / colic / breastfeeding) |
| Þ | The review / restriction is unnecessary / bias from other professions / attacks the legitimacy of the profession | ۲ | Chiropractors are highly educated / uniquely skilled / have many years of experience / have been around for a long time in the medical field |
| • | Chiropractic care is safe and gentle / low insurance premiums / evidence demonstrates the practice as low risk / rare adverse outcomes and effective | ۲ | Chiropractic care is a last resort method for parents / used when other medical practices have failed |
| • | The media / online video has created a negative image around chiropractic care / taken out of context | ۲ | Chiropractic care is cost effective / reduces cost in the healthcare system |



3. Practitioner who has provided care in the past three years -Sentiment analysis

Unsupportive codes

- ▶ To encourage or provide more evidence-based / researched information / anecdotal account
- Chiropractic care can be dangerous / not evidence-based / permanently injured patients
- Need to protect vulnerable patients / chiropractic care may target more vulnerable patients
- ▶ Patients / parents shouldn't waste large amounts of money on chiropractic care
- Chiropractic care is dangerous / can permanently damage children



4. Practitioner who has not provided spinal care in the past three years. However, has provided care for a child who has received spinal care.

Supportive codes

- Children can improve their health and development from chiropractic care / chiropractic is important to children's health
- Children should have access to health / chiropractic care / the same as adults
- Freedom of choice is needed when it comes to healthcare
- ▶ Parents should have the right to decide on their child / family's health
- Chiropractic / healthcare should be offered to everyone / no age restriction / can benefit all / the community
- Children can already develop spinal / musculoskeletal issues / chiropractic care can treat children with these issues
- Chiropractic care can assist in relieving symptoms of musculoskeletal / important in musculoskeletal care
- ► To eliminate the stigma / criticism / promote the truth and educate the public about chiropractic care
- I've seen / experienced the benefits of chiropractic care in my profession
- Restricting care is cruel / unfair / disservice the patients and burdens the healthcare system
- ► The review / restriction is unnecessary / bias from other professions / attacks the legitimacy of the profession
- Chiropractic care is safe and gentle / low insurance premiums / evidence demonstrates the practice as low risk / rare adverse outcomes and effective
- The media / online video has created a negative image around chiropractic care / taken out of context

- ► The review / restriction is unnecessary / bias from other professions / attacks the legitimacy of the profession
- Chiropractic care is safe and gentle / low insurance premiums / evidence demonstrates the practice as low risk / rare adverse outcomes and effective
- The media / online video has created a negative image around chiropractic care / taken out of context
- ► The review is politically motivated / Victorian health minister has depicted a negative stigma around chiropractic care
- ► Access to healthcare shouldn't be decided by the government
- ▶ My children / grandchildren have experienced / benefited from chiropractic care
- Medical decisions / opinions on chiropractic care shouldn't be based on emotions / 'knee jerk reactions'
- ► The chiropractic industry shouldn't be tarnished by individual practices / cases
- Chiropractic care is used for general preventative care / health management in children
- Chiropractic care helps mothers and their newborns / issues in infancy health (e.g. rough birth / colic / breastfeeding)
- Chiropractors are highly educated / uniquely skilled / have many years of experience / have been around for a long time in the medical field
- Chiropractic care is a last resort method for parents / used when other medical practices have failed
- ► Chiropractic care is cost effective / reduces cost in the healthcare system

The same code definitions were used to analysis survey stream 3 and 4



4. Practitioner who has not provided spinal care in the past three years. However, has provided care for a child who has received spinal care.

| | Unsupportive codes |
|---|--|
| Þ | To encourage or provide more evidence-based / researched information / anecdotal account |
| ۲ | Chiropractic care can be dangerous / not evidence-based / permanently injured patients |
| ۲ | Need to protect vulnerable patients / chiropractic care may target more vulnerable patients |
| ► | Patients / parents shouldn't waste large amounts of money on chiropractic care |
| ► | Chiropractic care is dangerous / can permanently damage children |
| | |
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| | |

The same code definitions were used to analysis survey stream 3 and 4



5. Practitioner who has not provided spinal care for a child under 12 in the past three years.

Supportive codes

- ► Safe for all patients
- ► Safe for children under 12
- ► Chiropractic care is scientific or evidence based
- ▶ Medically beneficial for children under 12
- ▶ Provides a non-pharmaceutical or alternative care method
- Consumer choice around health should not be restricted
- ► Chiropractic care is beneficial for infant health
- Chiropractors receive a high-level of training and education
- Appropriate if the chiropractor receives training for treating children
- Distrust for chiropractic care is based around misreporting or over exaggeration
- Chiropractic encompasses primary care functions, not just spinal manipulation techniques

Unsupportive codes

- Dangerous for all patients
- ▶ Dangerous for children under 12
- Chiropractic care is unscientific or not evidence based
- Chiropractic care is dangerous for infants



6. Practitioner who chose not to provide AHPRA number

Supportive codes

- Children can improve their health and development from chiropractic care / chiropractic is important to children's health
- Children should have access to health / chiropractic care / the same as adults
- Freedom of choice is needed when it comes to healthcare
- ► To provide a more natural / drug / surgery free alternative
- Parents should have the right to decide on their child / family's health
- ▶ To demonstrate / establish chiropractic care as a safe and efficient practice
- Chiropractic / healthcare should be offered to everyone / no age restriction / can benefit all / the community
- Children can already develop spinal / musculoskeletal issues / chiropractic care can treat children with these issues
- Chiropractic care can assist in relieving symptoms of musculoskeletal / important in musculoskeletal care
- To eliminate the stigma / criticism / promote the truth and educate the public about chiropractic care
- I've seen / experienced the benefits of chiropractic care in my profession
- Restricting care is cruel / unfair / disservice the patients and burdens the healthcare system
- ► The review / restriction is unnecessary / bias from other professions / attacks the legitimacy of the profession
- Chiropractic care is safe and gentle / low insurance premiums / evidence demonstrates the practice as low risk / rare adverse outcomes and effective

- The media / online video has created a negative image around chiropractic care / taken out of context
- ► The review is politically motivated / Victorian health minister has depicted a negative stigma around chiropractic care
- ► Access to healthcare shouldn't be decided by the government
- ▶ My children / grandchildren have experienced / benefited from chiropractic care
- Medical decisions / opinions on chiropractic care shouldn't be based on emotions / 'knee jerk reactions'
- ▶ The chiropractic industry shouldn't be tarnished by individual practices / cases
- Chiropractic care for children relieves stress from parents / parents are satisfied with the practice / will be disappointed if chiropractic care is taken away
- Chiropractic care is used for general preventative care / health management in children
- > Chiropractic care helps mothers and their newborns / issues in infancy health
- Chiropractors are highly educated / uniquely skilled / have many years of experience / have been around for a long time in the medical field
- Chiropractic care is a last resort method for parents / used when other medical practices have failed
- Chiropractic care is cost effective / reduces cost in the healthcare system
- Pharmaceutical drugs / other medical professions produce more harmful side effects than chiropractic care
- Medical practices that deal with spinal (physiotherapy, osteopathy, GP) or paediatric care should also be under review / same restrictions applied to all / chiropractors implement the same techniques as other forms



6. Practitioner who chose not to provide AHPRA number

Unsupportive codes

- Chiropractic care can be dangerous / not evidence-based / permanently injured patients
- Need to protect vulnerable patients / chiropractic care may target more vulnerable patients
- ▶ Patients / parents shouldn't waste large amounts of money on chiropractic care
- Chiropractic care is dangerous / can permanently damage children





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ED None.

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Systematic Review of Spinal Manipulation in Children

Review prepared by Cochrane Australia for Safer Care Victoria

19 August 2019

Review team

Sally Green, Steve McDonald, Melissa Murano, Miyoung Choi and Sue Brennan

Trusted evidence Informed decisions. Better Evidence.

Executive Summary

Safer Care Victoria commissioned Cochrane Australia to undertake this systematic review of the effectiveness and safety of spinal manipulation in children under 12 years for any condition or symptom. Spinal manipulation is defined as *any technique delivered by any health professional that involves a high velocity, low amplitude thrust beyond the physiological range of motion, impacting the spine, within the limits of anatomical integrity.* Additional consideration was given to the safety and effectiveness of coccygeal manipulation in children.

Existing, high-quality systematic reviews have assessed the evidence for spinal manipulation in children. For timeliness, and to avoid unnecessary duplication, we identified the subset of evidence on the effectiveness and safety of spinal manipulation in children from these existing reviews, and included relevant studies published before or after their completed search dates.

We included 13 studies (11 randomised trials) of the **effectiveness** of SMT across several conditions: colic (three studies), enuresis, back/neck pain, headache, asthma (two studies), otitis media, cerebral palsy, hyperactivity (two studies) and torticollis. Based on meta-analysis of three studies, we found low certainty evidence that, in infants with colic, mean crying time may be reduced among infants who received spinal manipulation compared to a control (sham, no treatment, active comparator) (0.71 hours (43 minutes) per day lower, 95% CI 1.87 (112 minutes) lower to 0.46 (28 minutes) higher; 3 trials, 156 infants). However, the confidence interval is wide and includes a possible increase in crying time.

We found low certainty evidence that the mean number of wet nights may be reduced among children with enuresis who received SMT compared to sham SMT (1.6 fewer wet nights per fortnight, 95% CI 3.2 fewer to 0 more; 1 trial, 57 participants). However, the confidence interval is wide and includes the possibility of no effect. For other conditions there was either no evidence of effect, or no data available from which to draw a conclusion.

For **safety**, we identified ten studies. Six of these studies aimed to determine the rates of adverse events occurring across populations of infants and children undergoing SMT. These studies reported rates spanning one minor treatment aggravation per 1812 consultations to one cerebrovascular incident in 20,000 visits. Two related studies investigated physiological responses to spinal manipulation in children and reported apnoea and skin flushing in 50 of 199 treated infants; and in a separate study, severe but short-lasting bradycardia in almost 50% of infants less than three months old, and in 87 of 695 children over four months.

Four studies described five individual cases of adverse effects from SMT in infants or children. Of these, three were classified as severe and two as moderate. Of the three reports of a serious adverse event, one resulted in death. The technique employed in this case was described as the Vojta technique and involved forced active rotation and head retraction (case report from Germany in 2001). Other serious adverse events were loss of consciousness with recovery and hospitalisation for drowsiness and weakness.

Separate to the review of spinal manipulation, we aimed to review studies on the safety and effectiveness of **coccygeal manipulation** in children. Despite a comprehensive search we were unable to identify any relevant studies.

Consistent with the findings of other systematic reviews, due to the paucity of studies and the lack of reported information on the specific treatment techniques employed, it is difficult to draw conclusions about the safety and effectiveness of spinal manipulation in children.

1. Background

1.1 Why we are undertaking this review

Safer Care Victoria (SCV) commissioned this external systematic review in response to concerns raised about the practice of performing spinal manipulation on infants. The findings of this review will inform the deliberations of an expert panel, convened by SCV, ultimately resulting in recommendations from SCV to the Council Of Australian Governments (COAG). The systematic review team was requested to identify, consider and synthesise evidence relating to both the effectiveness and safety of spinal manipulation in children less than 12 years of age. Additional consideration was to be given to the safety and effectiveness of coccygeal manipulation.

1.2 Description of the intervention

Spinal manipulation is a manual therapy technique performed by chiropractors and other manipulative therapists, including osteopaths, physiotherapists and medical practitioners. For the purposes of this review, the expert panel has defined the technique as being characterised by *high velocity, low amplitude (HVLA) thrust, beyond the physiological range of motion, impacting the spine, within the limits of anatomical integrity.*

1.3 Existing systematic review evidence

Existing, high-quality systematic reviews have assessed the evidence for spinal manipulation in children. A comprehensive systematic review published in March 2019 by Parnell Prevost et al. evaluated the use of manual therapy for clinical conditions in the paediatric population delivered by any health profession (1). The review includes an assessment of the methodological quality of the included studies, summarises findings according to health condition, and reports any adverse events within the included studies. The 50 studies included in the review covered several types of manual therapy, including 15 studies of spinal manipulative therapy (SMT) in children, and evaluated spinal manipulation in a wide variety of paediatric conditions (grouped by gastrointestinal, musculoskeletal, respiratory, special needs and structural).

An even more recent systematic review published in June 2019 by Driehuis at al. evaluated SMT in infants, children and adolescents (2). In this review, interventions indicated as SMT were defined as "manual therapeutic interventions in which treatment techniques were primarily performed on the full spine or on specific spinal segments, by any healthcare professional". Distinction was made between two main SMT techniques: manipulation (HVLA or low-velocity thrust) and mobilization (low velocity, low amplitude without thrust).

A systematic review from 2018 by Carnes et al. focused on manual therapy (including spinal manipulation) for unsettled, distressed and excessively crying infants 0-12 months of age (3). Finally, a safety review from 2015 by Todd et al. explored the safety and adverse effects associated with manual therapy in children under 18 years of age (4).

Collectively, these reviews provide a comprehensive evidence base, some extending beyond spinal manipulation to include other manual techniques and other structures. To avoid unnecessary duplication and to complete the commissioned review in a timely manner, we aimed to identify the full subset of evidence on the effectiveness and safety of spinal manipulation in children from these existing reviews, and to include any relevant studies published after their completed search dates.

2. Objectives

To assess the effectiveness and safety of spinal manipulation, defined as *any technique delivered by any health professional that involves a high velocity, low amplitude thrust beyond the physiological range of motion, impacting the spine, within the limits of anatomical integrity,* conducted in children under 12 years for any condition or symptoms.

3. Methods

Our overall approach was to use the reviews by Parnell Prevost 2019, Carnes 2018 and Todd 2015 as the principal source of primary studies for this review and to supplement the evidence included in these reviews by searching for eligible studies published since those reviews were conducted. The most recent review by Driehuis was published in June 2019, after the completion of our searches, but we have been able to include a full assessment of this review and its included studies to ensure there are no additional relevant studies. **Appendix 1** summarises the main characteristics of the most relevant existing systematic reviews on this topic.

3.1 Assessment of the existing systematic reviews

Given the four existing systematic reviews were the main source of primary studies, we assessed the search methods of each review to make sure the searches were comprehensive, both in terms of the range of sources searched and the specific search terms used. In the case of the review by Driehuis, the review that most closely matched our inclusion criteria, we also conducted a risk of bias assessment using the Risk of Bias in Systematic Reviews (ROBIS) tool (5). The ROBIS tool assesses three aspects of systematic reviews: (i) relevance; (ii) how the review was conducted; and (iii) an overall judgement of risk of bias in interpretation of the review's findings.

3.2 Criteria for considering studies for this review

3.2.1 Types of participants

Children under 12 years of age, including babies and infants, treated with spinal manipulation from any healthcare professional for any condition or indication.

If studies included adolescents or adults, in addition to children, and we are unable to extract data separately for children, we included these studies provided the majority of participants were under 12 years or the mean age of participants was less than 12. Where applicable, our interpretation of the findings of these studies takes account of the inclusion of this more indirect evidence.

3.2.2 Types of interventions/exposures

Several therapies include, or may include, manipulation of the spine. For studies in children under 12 years of age that were included in the Parnell Prevost review (and categorised as Spinal Manipulative Therapy (SMT), Chiropractic Manipulative Therapy, Osteopathic Manipulative Therapy and Cranial-Sacral Therapy) we sought confirmation from screening the full-text report of the study whether a form of spinal manipulation meeting our definition was used.

Where relevant we used the explanation of techniques in Figure 1, reproduced from Alcantara 2009, to determine whether the described intervention was consistent with our definition of

spinal manipulative therapy (6). When we were unable to interpret the definition of the intervention, we sought clarification from the panel.

| Technique | Description |
|--------------------------|--|
| Diversified technique | A generic chiropractic technique characterized as HVLA-type thrust that results in cavitation |
| Gonstead techniques | A segment-specific HVLA-type thrust technique that incorporates the use of x-ray analysis (spinography) and temperature gradient instrumentation to assist in the clinical decision making (ie, what spinal segments to perform SMT) |
| Thompson technique | A variation of the diversified technique that utilizes a special table with several "drop-piece" segments; when the thrust is delivered, the table will drop a small distance; the drop pieces assist the thrust while minimizing the force used for the delivery of SMT |
| Activator methods | A hand-held, spring-loaded instrument that delivers a site-specific, low-force type thrust |
| Cranial technique | Not a chiropractic technique per se, but a manual therapy that applies a sustained and prolonged force (non-HVLA) to correct cranial segmental dysfunction |
| Torque release technique | Uses The Integrator,* a torque and recoil release adjusting instrument to deliver the SMT |

HVLA, high velocity, low amplitude; SMT, spinal manipulative therapy.

*The Integrator (Jack M. Holder, Miami Beach, FL).

Figure 1. Description of techniques (reproduced from Alcantara 2009)

Those studies that sought to evaluate spinal manipulation, and for which the majority of participants received SMT, were eligible. We applied these same criteria both for identification of the relevant subset of studies within the existing reviews, and when screening records as part of the search update.

Studies in which SMT is a co-intervention (e.g. with exercise) were to be included provided the comparator group allowed any differences in effect to be attributed to SMT (e.g. SMT + exercise versus exercise alone). In the case of safety studies, we planned to include co-interventions and decide on the likelihood that the adverse event was attributable to SMT, however we did not identify any studies that clearly described SMT and a co-intervention.

3.2.3 Types of outcome measures

For the effectiveness review, any new eligible studies were grouped according to the broad condition categories and associated outcomes used in Parnell Prevost:

- Gastrointestinal (e.g. colic, nocturnal enuresis, breastfeeding)
- Musculoskeletal (e.g. clubfoot, headache, low back pain)
- Respiratory (e.g. asthma, otitis media)
- Special needs (e.g. ADHD, autism, cerebral palsy)
- Structural (e.g. scoliosis, torticollis)

We selected the primary outcome measure(s) or, if these were not specified, the outcomes that most directly addressed the objectives of the study.

For the safety review, we adopted the categories used by Todd to define the seriousness of the adverse event:

- Mild (transient effects lasting less than 24 hours, e.g. crying or discomfort) or Moderate (requiring medical/general practitioner treatment)
- Severe (requiring hospital treatment, including disability or death)

3.2.4 Types of studies

For the effectiveness review, eligible studies included both randomised trials and observational studies, provided the observational studies included a comparator (e.g. non-randomised trial, cohort study, controlled before-and-after study). Exclusions included non-comparative studies (e.g. case reports or case series without pre and post measurements or a control group) and cross-sectional studies.

Other exclusions: studies that were only available as abstracts; feasibility studies without outcome measures; full-text report not available in English.

For the safety review any article reporting adverse events was eligible, irrespective of the study type (i.e. trials, observational studies, case reports, etc.). Articles not reporting case information (e.g. commentaries or editorials) were excluded, as were full-text reports not available in English (unless these had been included and fully described in Todd).

3.3 Search methods for identification of studies

3.3.1 Overall approach

For both the effectiveness and safety reviews, we ran searches covering the period from the last search date in the Parnell Prevost and Todd reviews (searching forward from April 2018 and January 2014, respectively). The decision to rely on these two systematic reviews as the primary source of eligible studies was based on an assessment of their search methods, which in both cases we considered to be extensive. For the effectiveness review, we also searched from 1960 to 1999 since Parnell Prevost only included studies published since 2000.

We revised the search strategies, taking account of differences in scope, and ensured an appropriate range of databases and sources were searched. The shorter time period to search across meant that we could apply broader search criteria for spinal manipulation and adverse events.

The review considered peer reviewed literature, as well as unpublished and grey literature. Only studies reported in English were included (but relevant studies in other languages were noted, and included if they were fully reported in Todd). We also retrieved any additional relevant systematic reviews we came across as a means of identifying any additional eligible primary studies.

The searches across all sources were run on 13 May 2019. We set up a weekly auto alert to capture publications added to PubMed from 13 May to 15 June 2019.

3.3.2 Search terms

The PubMed search strategy combined Medical Subject Headings (MeSH) and equivalent freetext terms and synonyms (see below). The exploded MeSH term Musculoskeletal Manipulations includes Chiropractic, Osteopathic and Orthopedic Manipulations as narrower terms. For the safety review, the MeSH subheadings *adverse effects* and *complications* are included as floating subheadings, such that any record indexed with these subheadings (regardless of the condition or intervention) were retrieved. In developing these search strategies we consulted the Parnell Prevost and Todd reviews, and checked the InterTASC website for search filters for retrieving studies of adverse effects (7).

Effectiveness review

| Intervention terms | Population terms | |
|--|--|--|
| Musculoskeletal Manipulations[Mesh] OR "spinal manipulative therapy" OR "spinal manipulation" OR "spine manipulation" OR HVLA OR ((manipulat*[TIAB] OR adjust*[TIAB] OR manual*[TIAB]) AND (spine[TIAB] OR spinal[TIAB] OR lumbar[TIAB] OR cervical[TIAB])) OR chiropract* OR osteopath* OR cranio-sacral OR craniosacral OR cranial-sacral | Child[Mesh] OR Infant[Mesh] OR Adolescent[Mesh] OR child OR children OR infant OR infants OR newborn* OR neonate* OR baby OR babies OR paediatric OR pediatric OR young[TIAB] OR adolescent* | |
| Limited to records added to PubMed since April 2018 | | |

We evaluated the performance of the search by checking retrieval against the set of 50 studies included in the Parnell Prevost review. Our search retrieved all 46 studies that are included in PubMed. The remaining four studies are included in Index to Chiropractic Literature (ICL), and our ICL search strategy also identified these four studies.

The above PubMed strategy, when applied to the period from 1960 to 1999, retrieved over 3500 records. To make the screening task more manageable, we increased the precision of the search by removing terms that were least relevant (cervical, chiropractic, osteopathic and craniosacral).

| Intervention terms | Population terms | |
|---|---|--|
| Manipulation, Chiropractic[Mesh] OR Manipulation, Spinal[Mesh] OR "spinal manipulative therapy" OR "spinal manipulation" OR "spine manipulation" OR HVLA OR ((manipulat*[TIAB] OR adjust*[TIAB] OR manual*[TIAB]) AND (spine[TIAB] OR spinal[TIAB] OR lumbar[TIAB])) | Child[Mesh] OR Infant[Mesh] OR child[TIAB] OR children[TIAB] OR infant[TIAB] OR infants[TIAB] OR newborn* OR neonate*[TIAB] OR baby[TIAB] OR babies[TIAB] OR paediatric[TIAB] OR pediatric[TIAB] | |
| Limited to records in PubMed with publication year 1960 to 1999 | | |

Safety review

The intervention and population terms were the same as for the effectiveness review search (2018-19). The safety terms were deliberately broad to minimise the chance of missing relevant studies.

| Intervention terms | Population terms | Safety terms |
|---|--|---|
| As for Effectiveness review (2018-19) | As for Effectiveness review (2018-19) | adverse OR unwanted OR "side effect*" OR reaction* OR complication* OR harm* OR injury OR injuries OR risk OR risks OR safe* OR adverse effects[sh] OR complications[sh] |
| Limited to records added to PubMed since January 2014 | | |

3.3.3 Bibliographic databases

In addition to PubMed, we searched the following bibliographic databases: Index to Chiropractic Literature, Embase, Cochrane Central Register of Controlled Trials, CINAHL, Allied and Complementary Medicine (AMED) and Scopus. See **Appendix 2** for the search strategies.

We chose not to search clinical trial registers separately since the Cochrane trials register includes all records of randomised trials from ClinicalTrials.gov and the WHO ICTRP international trials register.

3.3.4 Other sources

The reference lists of eligible studies and relevant systematic reviews were checked for additional studies. We considered using Google Scholar for a general internet search, as indicated in the protocol, but opted against this given the time constraints and the additional safeguards resulting from the ability to cross-check our included studies against very recent published systematic reviews.

3.4 Data collection and analysis

3.4.1 Selection of studies

Records identified from the database searches were imported to EndNote and duplicates removed. Records were then imported to Covidence for screening.

For the effectiveness review, two reviewers (MM and SM) independently screened records (titles and abstracts) to either include (Yes or Maybe) or exclude (No) for full-text review based on the inclusion criteria. Disagreements about eligibility were resolved through referral to a third reviewer (SG). The full-text of all potentially eligible studies were retrieved and independently screened by two reviewers (MM and SM). Studies were excluded based on participant age and intervention, followed by study design. The final decision on the inclusion of studies was agreed among all reviewers.

For the safety review, one reviewer (SG) screened all records (titles and abstracts) and assessed the full-text of potentially eligible studies. The rationale for single screening was the level of content expertise required to efficiently interpret studies (i.e. eligible manipulative techniques) when there are no exclusions around study type.

Systematic reviews

Reviews that overlapped with the scope of this review were identified during the screening phase and the list of included studies (effectiveness and safety) were extracted and cross-checked against Parnell Prevost and Todd. Any primary studies not included in Parnell Prevost or Todd were then retrieved and checked for eligibility for inclusion in this review.

3.4.2 Data extraction and management

For the effectiveness review, for relevant studies included in Parnell Prevost, one reviewer (MM) extracted study characteristics and data as reported in the review (see below) and used the same template for any new included studies. A second reviewer checked data extraction for accuracy and completeness. Disagreements were resolved by discussion within the review team.

The following characteristics were extracted:

- condition category
- author and year published
- setting/country*
- profession of practitioner*
- study objective
- study design
- sample size
- patient description (age) and condition
- description of intervention and comparator*
- outcomes measured*
- results for main outcome
- adverse events
- * information on these characteristics was not included in the tables provided in Parnell Prevost and was therefore extracted from the full-text of all relevant studies.

For the safety review, we adopted the template used in the Todd review for all new studies identified. Within each broad category of adverse event (serious, mild to moderate) the following study characteristics were collected:

- author and year published
- study design/details
- key findings
- number of adverse events
- description of the adverse event
- patient characteristics
- practitioner type
- intervention/technique
- setting/country
- underlying pathology/condition

When given in reports, we extracted information on recovery time and time to onset of adverse event; this information was also used to categorise the severity of the adverse event.

3.4.3 Assessment of risk of bias of included studies

We had intended to use the risk of bias assessments included in Parnell Prevost, since the randomised trials were rated using the Cochrane risk of bias tool (with low, unclear or high risk of bias reported for each risk of bias domain) and observational studies using a modified version of the AHRQ tool (8). Parnell Prevost then gave an overall quality rating of low, moderate or high for each study. When we checked a sample of these risk of bias assessments our rating of bias did not always agree, and we were concerned that study limitations were not appropriately addressed in the overall quality rating for each study. As result, we re-did the bias assessments and applied Cochrane's approach in reaching an overall risk of bias assessment (low, some concerns, high).

For new studies identified, one reviewer (MM or MC) conducted risk of bias assessments using the Cochrane risk of bias tool for randomised trials. A second reviewer (SM or SB) checked the assessment for accuracy and completeness.

For the safety review, the type of study or article reporting the adverse event was noted, but no assessment of study quality was included since the purpose of the review was to collate all reports of adverse events, regardless of source. However, notes regarding the source studies and any methodological considerations in interpreting the reports were included in the data extraction table.

3.4.4 Data synthesis and overall certainty of the evidence

Effectiveness review

For the eligible studies included in the reviews by Parnell Prevost and Carnes, we extracted the results data for the primary outcome from the original report of the study and presented available estimates of effect (95% confidence intervals, p-values) in the characteristics of included studies table, grouped by condition. We conducted meta-analysis where this was feasible and appropriate.

The overall certainty of the evidence was assessed for each condition/outcome using GRADE criteria where feasible (risk of bias, consistency, imprecision, indirectness and publication bias) and the evidence rated as high, moderate, low or very low. Both the Parnell Prevost and Carnes reviews rate the strength of evidence for each outcome using criteria that can be mapped to GRADE.

Summary of findings tables were prepared using the GRADEpro GDT software. For each condition and outcome, the summary of findings table included estimates of treatment effects reported as absolute and relative risks, and the overall GRADE (rating of quality). Additional

information included the study design(s), number of studies and number of participants contributing data (the type and size of the evidence base); and a plain language statement interpreting the evidence (clinical impact) for each comparison and outcome. Footnotes were used to explain judgements.

Safety review

For the eligible studies included in Todd and for new studies identified, we tabulated the findings by study, structured by severity of adverse event. For serious adverse events, we ensured any event listed in multiple studies was included only once, using the primary report as the included study. We did not GRADE results for adverse effects, since GRADE is unlikely to be informative for decisions in this case. In general, findings about adverse effects are likely to come from studies with limitations leading to a GRADE of low or very low certainty evidence.

4. Results

4.1 Effectiveness review

4.1.1 Selection of studies

We included 13 studies in total; six were derived from Parnell Prevost 2019 and seven from new searches (outside the period of the Parnell Prevost search). No additional included studies were derived from Driehuis 2019.

4.1.1.1 Parnell Prevost 2019

The full-text of all 50 studies included in Parnell Prevost were checked for eligibility. Since the inclusion criteria for Parnell Prevost were broader than this review (effectiveness of any manual therapy in children under 18 years of age), we excluded studies initially on the basis of age of participants, followed by an assessment of intervention technique and then study design. Figure 2 shows which studies were excluded at each stage and which studies met the eligibility criteria. A full explanation for excluding the 44 studies from Parnell Prevost is given in **Appendix 3**.

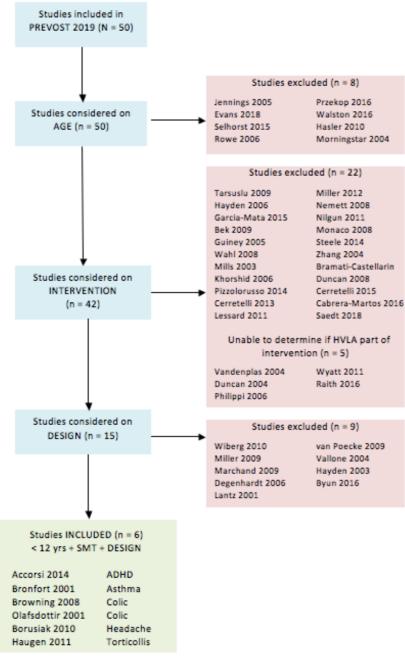


Figure 2. Flow chart of studies in Parnell Prevost 2019

4.1.1.2 Driehuis 2019

This review included 12 studies evaluating the effectiveness of spinal manual therapy, of which nine are included in our review. Two of the studies we excluded were in adolescents and one study we deemed not meet the inclusion criteria for the intervention (Miller 2012; listed in Excluded studies table, **Appendix 3**).

Since the Driehuis review most closely aligns with the question our review addresses, and includes GRADE assessments of the evidence, we conducted a risk of bias assessment using the ROBIS tool. As summarised in Table 1 below, we rated the review to be of sound methodological quality and to have an overall rating of low risk of bias. The full ROBIS assessment is in **Appendix 4**.

Table 1. ROBIS assessment for Driehuis 2019

| Did the interpretation of findings address all of the concerns identified in Domains 1 to 4? | The review conclusions are appropriately cautious, and the evidence uncertain. For this reason is it is unlikely that any of the identified concerns are likely to change the conclusions of the review. | Yes |
|--|---|-----|
| Was the relevance of identified studies to the review's research question appropriately considered? | Study characteristics were carefully considered in the review and conclusions (including in GRADEing the evidence). The authors note that there is insufficient description of interventions in primary studies, which poses a challenge for interpretation of findings. | Yes |
| Did the review authors avoid emphasising results on the basis of their statistical significance? | The authors appear to have avoided emphasising results based on statistical significance (i.e. highlighting results that were statistically significant over those that were not). | Yes |
| | Although not a bias, most results are reported as summary statistics for each treatment group. This makes the results more challenging to interpret and GRADE than if effect estimates and the precision of each estimate had been calculated (e.g. the difference in pain scores between the intervention and control groups). | |
| Overall risk of bias | | LOW |

4.1.1.3 Search for additional primary studies

We searched PubMed, Index to Chiropractic Literature, Embase, Cochrane Central Register of Controlled Trials, CINAHL, Allied and Complementary Medicine (AMED) and Scopus on 13 May 2019 (**see Appendix 2**). Further weekly searches of PubMed continued until 15 June 2019. After removing duplicates, 1285 records were screened in Covidence (an online screening tool for systematic reviews). The full-text of 42 potentially eligible studies and relevant reviews were checked. Seven studies met the eligibility criteria and are included in the review; the majority of those excluded were either systematic reviews or deemed not to evaluate spinal manipulation as the intervention (see Figure 3). (The five studies we excluded on the basis of intervention are detailed at the end of **Appendix 3**.)

We identified a protocol for a randomised trial of chiropractic treatment for infantile colic published in 2018 by Holm (9). No results have been reported but it is unlikely the specific treatment would meet our inclusion criteria.

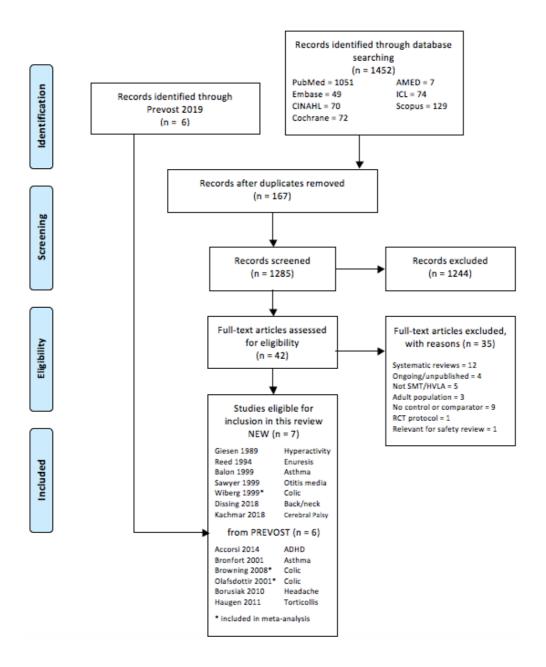


Figure 3. PRISMA flowchart (effectiveness)

4.1.1.4 Other systematic reviews

In addition to Parnell Prevost and Driehuis, we identified 11 potentially relevant reviews published in 2018 or 2019. For each review we cross-checked the included studies against Parnell Prevost and Todd (see Table 2) but identified no additional primary studies meeting our eligibility criteria.

Table 2. Systematic reviews considered during screening

| Review ID | Notes on included studies |
|-------------------------|--|
| Bruberg 2019 (10) | 3 RCTs (in Prevost) and 3 AEs (2 in Todd; 1 published in German, not eligible intervention (11)) |
| Chen 2019 (12) | Not spinal manipulation |
| Gao 2018 (13) | Not spinal manipulation |
| Goncalves 2018 (14) | Adult population |
| Hawk 2018 (15) | 1 RCT (in Prevost) |
| Lai 2018 (16) | Not spinal manipulation |
| Lotan 2019 (17) | 2 RCTs (in Prevost) |
| Öztürk Dönmez 2018 (18) | 1 RCT (in Prevost) |
| Rani 2018 (19) | 1 RCT (in Prevost) |
| Shreeve 2018 (20) | 1 RCT (in Prevost) |
| Will 2018 (21) | Not spinal manipulation |

4.1.1.5 References submitted through public consultation

We considered the following references that were submitted through the public consultation:

Hestbaek 2010 (22) The evidence base for chiropractic treatment of musculoskeletal conditions in children and adolescents: The emperor's new suit. *Chiropractic & Osteopathy*, 18:15.

- This is a review of randomised and non-randomised studies investigating the effect of manual therapy on musculoskeletal disorders in children and/or adolescents (2-18 years of age)
- The four studies included (Lantz 2001, Hayden 2003, Monaco 2008 and Rowe 2006) are included in Prevost and were therefore considered but excluded from this review (see **Appendix 3** for reasons for exclusion).

Beliveau 2017 (23) The chiropractic profession: a scoping review of utilization rations, reasons for seeking care, patient profiles, and care provided. *Chiropractic & Manual Therapies*, 25:35.

• This is an overview of the literature "on the utilization of chiropractic services, reasons for seeking care, patient profiles, and assessment and treatment provided." The review did not consider the effectiveness or safety of chiropractic interventions.

Rome 2019 (24) Medical management of infantile colic with spinal manipulation: a narrative review of the European medical literature. *Journal of Contemporary Chiropractic*, 2(1).

- This is a narrative review that uses the social research method of document analysis to report medical practices regarding "the management of infantile colic by manual means including manipulation." Studies and other information for inclusion were identified from searches of Medline and the Index to Chiropractic Literature, supplemented by hand-searching the private collections of the authors and textbooks by authors known to have also published in the peer-reviewed literature.
- Inclusion criteria were peer-reviewed sources that were categorised as 'manipulation by medical practitioners'. Forty-five papers were analysed for words and phrases reporting the management of infantile colic. The authors used document analysis to extract relevant sentences and paragraphs from the included reports.
- Many reports and documents are included which do not meet the selection criteria for study type in this systematic review. Five of the 45 included reports are identified as randomised trials and one a prospective cohort. The majority of the other includes are from narrative sources, titles and case reports (see Table 3 below).

• The five studies categorised as trials and one cohort study were cross-checked against our existing list of known studies of spinal manipulation in children (see footnotes Table 3 below).

| Table 3 | . Studies | included | in | Rome 2019 |
|---------|-----------|----------|----|-----------|
|---------|-----------|----------|----|-----------|

| Report type (as described in Rome 2019, Table 1) | Number of articles |
|---|-----------------------|
| Review/Narrative/Discussion (textbook) | 2 |
| Concept presentation | 1 |
| Title only | 13 |
| Narrative | 12 |
| Catamnestic (single patient history) | 3 |
| Proposal | 1 |
| Abstract only | 1 |
| Case reports/ case series | 3 |
| Case study | 1 |
| Survey | 1 |
| Statement | 1 |
| Described | 1 |
| RCT | 4 ^{abcd} |
| Prospective observational cohort | 1 ^e |

^a Miller 2012: excluded from this review because intervention not considered to include HVLA.

^b Munck 2988: paper in Danish. No abstract available. From the title it is unlikely to report a randomised trial.

^c Wiberg 2000 (25): not a randomised trial. Reports descriptive variables from an infantile colic behaviour profile administered to the mothers of infants with colic taking part in the randomised trial reported in Wiberg 1999. ^d Wiberg 1999: included in the SCV review.

^d Wiberg 1999: included in the SCV review

^e Saedt 2017: excluded from this review because intervention not considered to include HVLA.

4.1.2 Description of studies included in the effectiveness review

We included 13 studies in the effectiveness review. The conditions covered included colic (three studies), enuresis, back/neck pain, headache, asthma (two studies), otitis media, cerebral palsy, hyperactivity (two studies) and torticollis. Detailed characteristics of each included study are presented in Table 4 below.

Eleven of the 13 studies were individual randomised trials, one was a randomised feasibility study and one a non-randomised pre-post intervention study. The median sample size was 50 (range 7 to 243). The practitioners delivering treatments were mostly chiropractors (nine studies); other practitioners were 'manual therapists', physiotherapists, osteopaths and orthopaedic doctors. Studies were conducted in several countries and settings: USA (four studies), Denmark (2), Norway (2), and one study in each of Germany, UK, Italy, Canada and Ukraine.

Full descriptions of the interventions/techniques used in the included studies are detailed in **Appendix 5.** There was wide variation in the number of visits and the number of manipulations included, often with incomplete reporting, but all intervention descriptions included terms associated with high velocity, low amplitude thrust. One study described SMT to the cervical spine only, two studies to the full spine (lumbar and cervical both mentioned), and in 10 studies the area of SMT was either not described or at the practitioners' discretion.

Table 4. Characteristics of included studies – effectiveness review

| Condition | Study ID / Country Practitioner/ Setting | Study objective | Study design / Sample size | Patient description (age) and condition | Description of intervention and comparator | Outcome(s) measured (main bolded) | Result for main outcome (conclusion if result not reported) | Adverse events |
|-----------|--|--|-------------------------------|--|---|---|---|----------------|
| Colic | Browning 2008 (26) UK Chiropractor Chiropractic clinic | To compare chiropractic manual therapy and occipital-sacral decompression (OSD) in the treatment of infant colic. | RCT n = 43 | Infants < 8 weeks, who cried more than 3 h a day for at least 4 of the previous 7 days | Two weeks of spinal manipulative therapy (SMT) appropriate for neonates vs occipital- sacral decompression (OSD) | Crying time per day (change from baseline, 14 days from start of treatment; crying diary kept by parents). <u>Other:</u> crying episodes per day, sleep hours per day, resolution of symptoms | Mean crying time was reduced by 34 minutes per day with SMT compared to OSD (95% CI 104 minutes less to 37 minutes more; high RoB, see pooled estimate for certainty) | Not mentioned |
| Colic | Olafsdottir 2001 (27) Norway Chiropractor Hospital | To evaluate chiropractic spinal manipulation management on infantile colic. | RCT n = 86 | Infants ages 3–9 weeks, diagnosed with infantile colic | Chiropractic spinal manipulation vs held by nurse | Crying time per day (change from baseline, 8 days from start of treatment; crying diary kept by parents). <u>Other</u> : symptom score | Mean crying time was increased by 18 minutes per day with SMT compared to no SMT (95% CI 56 minutes less to 92 minutes more; high RoB, see pooled estimate for certainty) | Not mentioned |
| Colic | Wiberg 1999 (28) Denmark Chiropractor Private practice | To determine whether there is a short-term effect of spinal manipulation in the treatment of infantile colic. | RCT n = 50 | Infants ages 2-10 weeks, diagnosed with infantile colic | Chiropractic spinal manipulation and health visitor nurse care vs dimethicone and health visitor nurse care | Crying time per day (change from baseline, 8- 11 days from start of treatment; crying diary kept by parents). <u>Other</u> : none reported | Mean crying time was reduced by 102 minutes per day with SMT compared to dimethicone (95% CI 160 minutes to 44 minutes more; high RoB, see pooled estimate for certainty) | Not mentioned |
| Enuresis | Reed 1994 (29) USA Chiropractic students Chiropractic clinic | To evaluate chiropractic management of primary nocturnal enuresis in children. | RCT n = 57 | Children ages 5- 13 with nocturnal enuresis | Chiropractic spinal manipulation (high velocity, short lever thrust) vs sham treatment | Wet nights per fortnight (change from baseline, 12 weeks from start of treatment; dry/wet diary kept by parents). <u>Other</u> : none reported | Mean number of wet nights was 1.6 fewer per fortnight with SMT compared to sham (95% Cl 3.2 fewer to 0 more; low certainty evidence) | Not mentioned |

| Condition | Study ID / Country Practitioner/ Setting | Study objective | Study design / Sample size | Patient description (age) and condition | Description of intervention and comparator | Outcome(s) measured (main bolded) | Result for main outcome (conclusion if result not reported) | Adverse events |
|--------------------|--|---|-------------------------------|---|---|--|---|---|
| Back/ neck pain | Dissing 2018 (30) Denmark Chiropractor Private practices | To investigate the effectiveness of adding manipulative therapy to other conservative care for spinal pain in a school-based cohort of Danish children. | RCT n = 243 | Children ages 9- 15 with spinal pain | HVLA manipulation plus conservative care (advice, exercises, soft- tissue treatment) vs conservative care (advice, exercises, soft- tissue treatment) | Recurrence of spinal pain (new episode of pain > 1 week since end of previous episode). <u>Other</u> : spinal pain duration and intensity, global perceived effect | The rate of recurrence of spinal pain was 26% higher with SMT compared to no SMT (95% CI: from 2% lower to 61% higher, low RoB). In absolute terms, there were 0.4 more recurrences per child per year (95% CI from 0 fewer to 0.7 more, low certainty evidence) | Authors reported there were no adverse events. |
| Headache | Borusiak 2010 (31) Germany Manual therapist Headache outpatient clinic | To investigate the efficacy of spinal manipulative therapy in adolescents with recurrent headache. | RCT n = 52 | Adolescents ages 7–15 with cervicogenic headache | Cervical HVLA lateral directed manipulation without rotation or extension vs sham control | Percentage of days with headache (change from baseline, 2 months from treatment). <u>Other</u> : total duration of headache, days with school absence due to headache, consumption of analgesics, and intensity of headache | Little or no difference in % of days with headache among those who received SMT compared to sham SMT (MD 0.3% fewer days with headache, 95% CI 10.6% fewer to 10.0% more days with headache; very low certainty evidence) | No serious or moderate adverse events were noted. Minor adverse events: hot skin (SMT 6, sham 9), dizziness (SMT 7, sham 4), transitory increase in headache intensity and frequency (SMT 8, sham 6). |
| Asthma | Bronfort 2001 (32) USA Chiropractor Outpatient clinic, paediatric hospital | To determine if chiropractic manipulative therapy in addition to optimal medical management resulted in important changes in asthma- related outcomes. | RCT n = 34 | Children ages 6– 17 with persistent asthma | Chiropractic spinal manipulative therapy carried out with a HVLA thrust vs sham control | Pulmonary function tests, peak expiratory flow (PEF) and inhaler use, questionnaire assessing quality of life, asthma severity and improvement | The effects of SMT compared to sham SMT were not reported (results data are limited to feasibility of conducting an RCT; and PEF in the SMT group before and after treatment) | Not mentioned |

| Condition | Study ID / Country Practitioner/ Setting | Study objective | Study design / Sample size | Patient description (age) and condition | Description of intervention and comparator | Outcome(s) measured (main bolded) | Result for main outcome (conclusion if result not reported) | Adverse events |
|-------------------|--|---|--|---|--|--|--|---|
| Asthma | Balon 1998 (33) Canada Chiropractor Private practices | To determine efficacy of chiropractic manipulation as adjunct treatment for childhood asthma. | RCT n = 91 | Children ages 7- 16 who had continuing symptoms of asthma despite usual medical therapy | Chiropractic spinal manipulative therapy (HVLA directional push) vs sham control | Lung function: morning peak expiratory flow (PEF) before use of bronchodilator (change from baseline 4 months from start of treatment). <u>Other</u> : spirometry, asthma symptoms | Little or no difference in peak expiratory flow with SMT compared to sham (MD 0.7% lower peak flow with SMT; 95% CI 6.6% lower to 5% higher, very low certainty evidence). | Authors reported there were no negative side effects. |
| Otitis media | Sawyer 1999 (34) USA Chiropractor Chiropractic college | To assess the feasibility of conducting a full-scale RCT investigating the efficacy of chiropractic SMT for children with chronic otitis media with effusion. | Randomized feasibility study n = 20 | Infants and children aged 6 months to 6 years with chronic otitis media with effusion | Chiropractic spinal manipulative therapy (HVLA) vs sham control | Days with otitis media symptoms (change from baseline, 8 weeks from start of treatment; daily diary kept by parents). <u>Other</u> : middle ear status profile (otoscopic and tympanometric evaluations), sleep patterns, need for medical care, medications | Mean number of days with otitis media symptoms was 2.1 days more with SMT compared to sham SMT, however the confidence interval includes a reduction and a large increase in symptom days (95% CI 4.3 days fewer to 8.5 days more; low certainty evidence). Results for middle ear status (the primary outcome) are not presented here because the trialists reported problems with data collection such that "data could not be obtained or were unreliable." | No serious side effects were reported. Three children had 'minimal self- limiting side effects' (one reported mid- back soreness that resolved, one irritability, one excessive crying after treatment). |
| Cerebral palsy | Kachmar 2018 (35) Ukraine Orthopaedic doctor Rehabilitation clinic | To investigate short- term effects of spinal manipulation on wrist muscle spasticity and manual dexterity in children with cerebral palsy. | RCT n = 79 | Children ages 8- 18 with spastic forms of cerebral palsy | Spinal manipulation (thoracic, lumbar and cervical HVLA thrust) vs sham treatment | Muscle spasticity in wrist (15 minutes post- treatment; measured with Neuroflexor). <u>Other</u> : manual dexterity | An immediate reduction in muscle spasticity was found with SMT compared to sham manipulation (15 minutes post-treatment); however, the 95% confidence interval includes the possibility of no difference and effects at clinically important time points were not measured (very low certainty evidence). | Not mentioned |

| | Study ID / | | | | | | | |
|--------------------|---|--|---|--|--|---|--|----------------|
| Condition | Country Practitioner/ Setting | Study objective | Study design / Sample size | Patient description (age) and condition | Description of intervention and comparator | Outcome(s) measured (main bolded) | Result for main outcome (conclusion if result not reported) | Adverse events |
| Hyper- activity | Accorsi 2014 (36) Italy Osteopath Neuropsychiatry unit | To evaluate efficacy of osteopathic manipulative treatment of children with ADHD. | RCT n = 28 | Children ages 5– 15 with primary diagnosis of ADHD | Osteopathic manipulation therapy (OMT) plus conventional care vs conventional care | Visual-spatial attention (attention score) as measured by the Biancardi-Stroppa Modified Bell Cancellation Test (baseline, 10 weeks post-intervention). <u>Other</u> : rapidity score on same test | Attention scores increased with OMT plus conventional care compared to conventional care alone, however the confidence interval was very wide, including both a decrease in attention and a potentially important increase (MD 5.9 points higher 95% CI from 8 points lower to 20 points higher; very low certainty evidence). | Not mentioned |
| Hyper- activity | Giesen 1989 (37) USA Chiropractor Private clinic university lab | To determine the effectiveness of chiropractic manipulative therapy in the treatment of hyperactivity. | Pre-post intervention study (non- randomised) n = 7 | Children aged 7- 13 with hyperactivity (with clinical findings of a chiropractic intervertebral subluxation complex) | Chiropractic spinal manipulation (light but specific HVLA thrusts; second period) vs sham treatment (first period) | Motion behavioural scores (change from baseline, using a motion detector during a simulated school task) | This study does not report any usable data for clinically important outcomes. Results reported are of very low certainty due to imprecision (small sample size) and very serious concerns about risk of bias (due to a lack of randomisation). | Not mentioned |
| Torticollis | Haugen 2011 (38) Norway Physiotherapist Primary health care | Evaluate measurement methods and examine short-time effect of manual therapy in addition to physiotherapy in infants with torticollis. | RCT n = 32 | Infants aged 3–6 months, diagnosed with torticollis | Manipulation (moderate force) plus child physiotherapy vs child physiotherapy | Torticollis- improvement of symptoms (8 weeks post treatment, clinical assessment by physiotherapist). <u>Other</u> : body function, activity, participation (12 parameters) | Little or no difference in the proportion of infants whose torticollis symptoms improved with addition of manipulation to physiotherapy compared to physiotherapy alone (RR 2% fewer infants showed improvement in symptoms, 95% CI from 30% fewer to 39% more; very low certainty evidence) | Not mentioned |

Abbreviations: HVLA = high-velocity, low-amplitude. SMT = spinal manipulative therapy. RoB = risk of bias

4.1.3 Risk of bias of studies included in the effectiveness review

Table 5 summarises the risk of bias of the included studies. Six studies were considered to be at high risk of bias overall and five at low risk of bias overall. One study was assessed as having some concerns, and in one, which did not report outcome data, risk of bias was not assessed. There was variation in approach to allocation concealment, but all studies blinded their outcome assessor and reported all outcomes. Where we had concerns about bias, for example in relation to selection bias if randomisation was not adequately described, or performance bias if parents were not blinded, we took these into account when grading the evidence for each result (as presented in the summary of findings table (Table 6)).

Table 5. Risk of bias summary

| Author/ year | Condition sample size (n) | Selection bias: sequence generation | Selection bias: allocation concealment | Performance bias: blinding of personnel & participants | Detection bias: blinding of outcome assessment | Attrition bias: incomplete outcome data | Reporting bias: selective reporting | Overall risk of bias |
|------------------|--|--|--|---|---|---|---|---------------------------------|
| Browning 2008 | Colic (<i>n</i> = 43) | L computer generated | U not stated | L blinding of parents and patients | L independent observer blinding to treatment | L minimal missing data with explanation | L all outcomes reported | High |
| Olafsdottir 2001 | Colic (<i>n</i> = 86) | U-PY no details but sealed envelopes suggests adequate method | U-PY sealed, but not opaque, envelopes | L parents and providers blinded | L outcome assessor blinded | H dropouts in control group | L all outcomes reported | High |
| Wiberg 1999 | Colic (<i>n</i> = 50) | L blinded drawing of a ticket | U-PY drawing of a ticket was blinded | H parents not blinded | L blinded observer | H dropouts in control group | U missing data too much after 12 days | High |
| Reed 1994 | Enuresis (<i>n</i> = 57) | U not described | U not described | L personnel not blinded | L unclear if children and parents blinded | L high attrition but not related to intervention | L all outcomes reported | High |
| Dissing 2018 | Spinal pain (<i>n</i> = 243) | L computer generated | L sealed opaque envelopes | L personnel not blinded | L children and parents blinded | L no difference in missing data between groups | L all outcomes reported | Low |
| Borusiak 2010 | Headache (<i>n</i> = 52) | L computer generated | L sequentially numbered identical opaque envelopes | L parents, patients and paediatrician blinded | L parents and patients blinded (parent- reported outcome) | U unexplained loss to follow up in intervention group | L all outcomes reported | Low |
| Bronfort 2001 | Asthma (<i>n</i> = 34) | L computer generated | L sealed in opaque envelopes | L blinding of parents and patients | L outcome assessor blinded | L all patients accounted for | L all outcomes reported | N/A – no results reported |
| Balon 1998 | Asthma (<i>n</i> = 91) | L block randomisation | L sealed numerical randomization code | L children and parents blinded, provider not blinded | L outcome assessor blinded | U 10 drop-outs, 7 for non-compliance | L all outcomes reported | Low |
| Sawyer 1999 | Otitis media (n = 20) | L computer generated | L sealed opaque envelopes | L patients and parents blinded, provider not blinded | L outcome assessors blinded | L for symptom score outcome | L all outcomes reported | Low |
| Accorsi 2014 | Hyper- activity (<i>n</i> = 28) | L computer- generated random sequence | U-PN allocation was concealed but not described | H patients, parents, providers not blinded | L outcome assessors blinded | L all patients accounted for | L except for adverse events (data were collected but not reported) | High |

| Author/ year | Condition sample size (n) | Selection bias: sequence generation | Selection bias: allocation concealment | Performance bias: blinding of personnel & participants | Detection bias: blinding of outcome assessment | Attrition bias: incomplete outcome data | Reporting bias: selective reporting | Overall risk of bias |
|--------------|---------------------------------------|---|--|---|--|---|--|----------------------------|
| Giesen 1989 | Hyper- activity (<i>n</i> = 7) | H authors do not report randomising participants to treatment sequence | H no randomisation (hence no concealment of allocation) | U-PY patients and parents blinded (sham treatment), personnel not blinded | L outcome assessors blinded | L all patients accounted for | L all outcomes reported | High |
| Kachmar 2018 | Cerebral palsy (n = 79) | L block randomization | U-PY | L children blinded, provider not blinded | L outcome assessors blinded | L 1 drop-out | L all pre-specified outcomes reported | Low |
| Haugen 2011 | Torticollis (n = 32) | U-PY no details but use of sealed envelopes suggests adequate method | U-PY sealed, but not opaque, envelope | U-PN patients blinded, manual therapists not blinded and dealt with both groups | L outcome assessor blinded | L minimal missing data | L primary outcome reported in full | Some concerns |

Abbreviations:

H = high risk of bias; L = low risk of bias; U = unclear risk of bias; PY = probably yes; PN = probably no; N/A = not applicable

4.1.3 Summary across studies

A summary of findings for all included studies is presented in Table 6 below.

Infant colic

Based on meta-analysis of three studies (see Figure 4 below), we found low certainty evidence that mean crying time may be reduced among infants who received spinal manipulation compared to a control (sham, no treatment, active comparator) (0.71 hours (43 minutes) per day lower, 95% CI 1.87 hrs (112 mins) lower to 0.46 hrs (28 mins) higher; 3 trials, 156 infants). However, the confidence interval is wide and includes a possible increase in crying time.

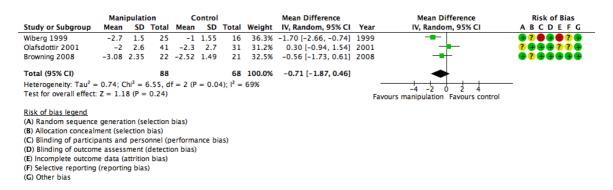


Figure 4: Crying time (hours) (follow up: range 8 to 14 days)

Enuresis

We found low certainty evidence that the mean number of wet nights may be reduced among children with enuresis who received SMT compared to sham SMT (1.6 fewer wet nights per fortnight, 95% CI 3.2 fewer to 0 more; 1 trial, 57 participants). However, the confidence interval is wide and includes the possibility of no effect.

Back and/or neck pain

We found low certainty evidence that the rate of recurrence of spinal pain may be higher among children who receive SMT compared to no SMT (26% higher, 95% CI: from 2% lower to 61% higher, 1 trial, 243 participants). However, the confidence interval is wide and includes a small, probably unimportant reduction in the rate of recurrence.

Other conditions

We found very low certainty evidence about the effect of spinal manipulation on headache (Borusiak 2010), asthma (Balon 1998), cerebral palsy (Kachmar 2018), hyperactivity (Accorsi 2014) and torticollis (Sawyer 1999). The true effect of the spinal manipulation on these conditions is likely to be substantially different from the reported estimates of effect (see Table 3 for results).

The two remaining trials, one on asthma (Bronfort 2001) and one on hyperactivity (Giesen 1989), did not report useable data (see Table 4 for details).

Table 6: Summary of Findings

Spinal manipulation (SMT) compared to sham, no treatment or active comparator for any condition in children under 12 years of age

Patient or population: any condition in children under 12 years of age Setting: healthcare setting (chiropractors in all studies) Intervention: spinal manipulation (SMT) Comparison: sham, no treatment or active comparator

| | Anticipated absolute effects ⁻ (95% CI) | | | | | | |
|--|--|--|--------------------------------------|-----------------------------------|---|--|--|
| Outcomes | Risk with sham, no treatment or active comparator | Risk with spinal manipulation (SMT) | Relative effect (95% CI) | № of participants (studies) | Certainty of the evidence (GRADE) | Comments | |
| Crying time (infant colic) assessed with: crying diary completed by parents follow up: range 8 to 14 days | The mean crying time was 2.7 hours per day ^a | MD 0.71 hours per day lower (1.87 lower to 0.46 higher) | - | 156 (3 RCTs) | ⊕⊕⊝⊝ LOW Þ.c.d | Spinal manipulation may reduce crying time by about 43 minutes per day (95% CI: from a reduction of 1 hour and 50 minutes to an increase of 28 minutes). ^{1,2,3,e} | |
| Wet nights (nocturnal enuresis) assessed with: dry/wet diary completed by parents follow up: mean 12 weeks | The mean wet nights was 11 per fortnight ^f | MD 1.6 per fortnight fewer (3.21 fewer to 0.01 more) | - | 46 (1 RCT) | ⊕⊕⊝⊝ LOW ^{ghi} | Compared to sham SMT, spinal manipulation may reduce bed wetting slightly, by one night per fortnight, (95% CI: from 3 nights fewer to 0 more) among children (5-13 years). ⁴ | |
| Recurrence of spinal pain (back and/or neck pain) follow up: mean 477 days | 5 per 1,000 j | 6 per 1,000 (5 to 7) | Rate ratio 1.26 (0.98 to 1.61) | 56486 (1 RCT) ^k | ⊕⊕⊝⊝ LOW ħi.m | Compared to no SMT, spinal manipulation may increase recurrences of spinal pain (back, neck or both) among children (9- 15 years). If 10 children were followed for one year, 4 more recurrences may occur with spinal manipulation compared to no manipulation (95% CI: from 0 to 7 more recurrences, 238 participants). ^{5,6} | |
| % of days with headache (headache) follow up: mean 60 days | The mean % of days with headache was 32 | MD 0.3 fewer (10.62 fewer to 10.02 more) | - | 52 (1 RCT) | $ \bigoplus_{h,n,o,p} \Theta \Theta \Theta $ | The evidence is very uncertain about the effect of spinal manipulation, compared to sham SMT, on % days of headache among children (7-15 years). ⁷ | |
| Peak expiratory flow (asthma) follow up: mean 4 months | The mean peak expiratory flow was 104 % ^q | MD 0.7 % lower (6.63 lower to 5.23 higher) | - | 80 (1 RCT) | $ \bigoplus \Theta \Theta \Theta \\ VERY LOW \\ h_{r,s} $ | The evidence is very uncertain about the effect of spinal manipulation, compared to sham SMT, on pulmonary function among children (7-16 years). ^{8,9} | |
| Days with otitis media symptoms assessed with: parent report (daily diary) Scale from: 0 to 28 follow up: mean 4 weeks | The mean days with otitis media symptoms was 7 | MD 2.5 more (3.9 fewer to 8.9 more) | - | 19 (1 RCT) | ⊕⊕⊝⊝ LOW' | Compared to sham SMT, spinal manipulation (SMT) may increase days with otitis media symptoms slightly among children (aged 6 months to 6 years): however, the confidence interval is wide and includes a decrease in symptom days and a large increase. ¹⁰ | |

Spinal manipulation (SMT) compared to sham, no treatment or active comparator for any condition in children under 12 years of age

Patient or population: any condition in children under 12 years of age Setting: healthcare setting (chiropractors in all studies) Intervention: spinal manipulation (SMT) Comparison: sham, no treatment or active comparator

| | | bsolute effects [*] % Cl) | | | | |
|--|--|--|----------------------------------|-----------------------------------|--|--|
| Outcomes | Risk with sham, no treatment or active comparator | Risk with spinal manipulation (SMT) | Relative effect (95% CI) | № of participants (studies) | Certainty of the evidence (GRADE) | Comments |
| Muscle spasticity (cerebral palsy) follow up: immediately after treatment | The mean muscle spasticity was 6.54 Newtons | MD 2.76 Newtons lower (6.12 lower to 0.6 higher) | - | 78 (1 RCT) | $ \bigoplus_{\substack{ O \\ h,u,v}} O O O O O O O O O O O O O O O O O O $ | The evidence is very uncertain about the effect of spinal manipulation, compared to sham SMT, on muscle spasticity among children (8-18 years) with cerebral palsy. ¹¹ |
| Attention scores (ADHD) assessed with: Visual- spatial attention test (Biancardi-Stroppa Modified Bell Cancellation Test) follow up: mean 10 weeks | The mean attention scores (ADHD) was 110.5 points | MD 5.9 points higher (7.97 lower to 19.77 higher) | - | 28 (1 RCT) | $\bigoplus \bigcirc \bigcirc \bigcirc \bigcirc$ VERY LOW | The evidence is very uncertain about the effects of spinal manipulation plus conventional care, compared to conventional care alone, on attention scores for children (5-15 years) with a confirmed diagnosis of ADHD. ¹² |
| Improvement of symptoms (torticollis) follow up: mean 8 weeks | 813 per 1,000 | 796 per 1,000 (569 to 1,000) | RR 0.98 (0.70 to 1.39) | 31 (1 RCT) | ⊕⊖⊖⊖ VERY LOW _{h,y,z} | The evidence is very uncertain about the effect of spinal manipulation plus physiotherapy, compared to physiotherapy alone, on torticollis symptoms in infants (3-6 months). ¹³ |
| Adverse events follow up: range immediate to >1 years | Two trials, one on spinal pain and the other on asthma, reported that there were no adverse events. The trial on headache reported minor adverse events: hot skin (SMT 6 children, placebo sham 9), dizziness (SMT 7, placebo sham 4), transitory increase in headache intensity and frequency (SMT 8, placebo sham 4). The trial on otitis media reported 'minimal self- limiting' adverse events: mid- back pain (SMT 1), irritability (SMT 1), excessive crying (placebo 1). The remaining 9 trials did not report on adverse events (including the 3 trials on infant colic). | | | 730 (13 RCTs) | ⊕⊖⊖⊖ VERY LOW ªª | The evidence about adverse events from randomised trials is very uncertain. Nine of 13 trials included for the effectiveness review did not mention (and may not have measured) adverse events. The remaining four trials reported no or minor adverse events. |

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI). CI: Confidence interval; MD: Mean difference; RR: Risk ratio

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. Mean crying time with comparator was calculated from the mean crying time at final follow up in each of the three studies.

b. Serious concerns (-1) about risk of selection bias (unclear randomisation in one study, unclear allocation concealment in two studies), and attrition bias (incomplete data for all studies, with greater attrition from control arms in two studies (31/99; 31%) compared to intervention arms (11/99; 10%)). c. Some inconsistency, but not downgraded because already downgraded for imprecision, which is influenced by inconsistent effects across studies. d. Serious concerns (-1) about imprecision. 95% confidence interval includes reduction in crying time of just under 2 hours per day and an increase

of about half an hour per day. Number of participants is also less than optimal information size of approximately 400. e. Different comparators were used in each study (Browning 2008: occipito-sacral decompression (OSD); Olafsdottir 2001: no manipulation control wherein a nurse brought the baby to the chiropractor, then baby was undressed and held for 10 minutes (comparable to treatment); Wiberg 1999: dimethicone daily for 2 weeks [12-15 days]).

f. Mean nights of bed wetting for comparator at final follow up in the single study.

g. Serious concerns (-1) about risk of selection bias. No information about randomisation method or whether group allocation was concealed. h. Inconsistency could not be assessed (single study, not downgraded but results require replication in other studies).

i. Serious concerns (-1) about imprecision. The 95% confidence interval includes a potentially important reduction in bed wetting (3 nights per

fortnight) and a trivial increase. The number of participants is also less than the optimal information size of approximately 400.

j. Events per 1000 patient days (not per 1000 people) k. Number of patient days (not number of participants)

1. Serious concerns (-1) about indirectness. Participants' mean age was 12.6 years (eligibility 9 to 15 years) and results for children under 12 are not reported separately.

m. Serious concerns (-1) about imprecision. 95% confidence interval includes no difference in recurrence and a small, possibly important increase. Number of participants is also less than optimal information size of approximately 400.

n. Serious concerns (-1) about risk of bias due to unexplained loss to follow in the intervention group (4/28 in the intervention group compared to 0/24 in the control group).

o. Not downgraded for indirectness. Mean age was 11.6 years (SD 2.3).

p. Very serious (-2) concerns about imprecision. The 95% confidence interval includes both a potentially important decrease and a potentially important increase in headache. The number of participants is also less than the optimal information size. The authors re-calculated their sample size after observing greater than expected variation in the frequency of headache, and estimated a sample of 600 would be required to demonstrate difference between groups.

q. Peak expiratory flow (PEF) was measured in the morning prior to bronchodilator use. The mean control group value is the % PEF compared to baseline.

r. Serious concerns (-1) about indirectness. Results are for children 7-16 years of age. Children 12 years and under comprise 66% (25/39) of the intervention group and 52% (22/42) of the comparator group.

s. Very serious concerns (-2) about imprecision. The 95% confidence interval includes an increase in PEF and a decrease in PEF, both of which are small but potentially important. The number of participants is also less than the optimal information size of approximately 400.

t. Very serious concerns (-2) about imprecision. 95% confidence interval includes a reduction in symptom days and a substantial increase. Number of participants is also less than optimal information size of approximately 400.

u. Very serious concerns (-2) about indirectness. Outcomes were measured 15 minutes post-treatment, which is unlikely to be a clinically important time-frame for this population. The outcome measured is muscle tone, which may be less important to patients than functional outcomes.

v. Serious concerns (-1) about imprecision. The 95% confidence interval includes a reduction in muscle spasticity and a trivial increase. The number of participants is also less than the optimal information size of approximately 400.

w. Serious concerns (-1) about risk of selection bias (unclear allocation concealment) and performance bias (patients, parents and providers not blinded).

x. Very serious concerns (-2) about imprecision. 95% confidence interval includes a reduction in attention score and a substantial increase. Number of participants is also less than optimal information size of approximately 400.

y. Serious concerns (-1) about risk of selection bias (unclear randomisation and allocation concealment), and risk of performance bias (manual therapist saw infants in both groups and was unblinded to treatment group).

z. Very serious (-2) concerns about imprecision. The 95% confidence interval includes both a potentially important improvement in torticollis symptoms and worsening of symptoms. The number of events is also much less than the optimal information size (300).

aa. In most studies, the sample size is likely to be too small to detect less common adverse effects. The risk of bias across studies is very serious given that 9 trials did not mention (and potentially did not measure) adverse events.

References

1. Wiberg, J. M., Nordsteen, J., Nilsson, N.. The short-term effect of spinal manipulation in the treatment of infantile colic: a randomized controlled clinical trial with a blinded observer. J Manipulative Physiol Ther; Oct 1999.

2. Olafsdottir, E., Forshei, S., Fluge, G., Markestad, T.. Randomised controlled trial of infantile colic treated with chiropractic spinal manipulation. Arch Dis Child; Feb 2001.

3. Browning, M., Miller, J.. Comparison of the short-term effects of chiropractic spinal manipulation and occipito-sacral decompression in the treatment of infant colic: a single-blinded, randomized, comparison trial. Clin Chiropr; 2008.

4. Reed, W. R., Beavers, S., Reddy, S. K., Kern, G., Chiropractic management of primary nocturnal enuresis. J Manipulative Physiol Ther; Nov-Dec 1994.

5. Dissing, K. B., Hartvigsen, J., Wedderkopp, N., Hestbaek, L.. Conservative care with or without manipulative therapy in the management of back and/or neck pain in Danish children aged 9-15: a randomised controlled trial nested in a school-based cohort. BMJ Open; Sep 10 2018.

6. Dissing, K. B., Hartvigsen, J., Wedderkopp, N., Hestbaek, L.: Conservative care with or without manipulative therapy in the management of back and neck pain in Danish children aged 9-15. Study protocol for a randomized controlled trial. Chiropr Man Therap; 2016.

7. Borusiak, P., Biedermann, H., Bosserhoff, S., Opp, J.. Lack of efficacy of manual therapy in children and adolescents with suspected cervicogenic headache: results of a prospective, randomized, placebo-controlled, and blinded trial. Headache; Feb 2010.

8. Bronfort, G., Evans, R. L., Kubic, P., Filkin, P.. Chronic pediatric asthma and chiropractic spinal manipulation: a prospective clinical series and randomized clinical pilot study. J Manipulative Physiol Ther; Jul-Aug 2001.

9. Balon, J., Aker, P. D., Crowther, E. R., Danielson, C., Cox, P. G., O'Shaughnessy, D., Walker, C., Goldsmith, C. H., Duku, E., Sears, M. R., A comparison of active and simulated chiropractic manipulation as adjunctive treatment for childhood asthma. N Engl J Med; Oct 8 1998.

10. Sawyer, C. E., Evans, R. L., Boline, P. D., Branson, R., Spicer, A.: A feasibility study of chiropractic spinal manipulation versus sham spinal manipulation for chronic otitis media with effusion in children. J Manipulative Physiol Ther; Jun 1999.

Kachmar, O., Kushnir, A., Matiushenko, O., Hasiuk, M.. Influence of Spinal Manipulation on Muscle Spasticity and Manual Dexterity in Participants With Cerebral Palsy: Randomized Controlled Trial. J Chiropr Med; Sep 2018.
 Accorsi, A., Lucci, C., Mattia, L., Granchelli, C., Barlafante, G., Fini, F.. Effect of osteopathic manipulative therapy in the attentive performance of children with attention-deficit/hyperactivity disorder. J Am Osteopath Assoc; 2014.
 Haugen, E., Benth, J., Nakstad, B.. Manual therapy in infantile torticollis: a randomized, controlled pilot study. Acta Paediatr; 2011.

4.2 Safety review

4.2.1 Selection of studies

We included 10 studies in the safety review; nine were derived from Todd 2015 and one additional study was identified from the new searches (outside the period of the Todd search). One study (Sawyer 1999 (34)) was included in both the effectiveness and the safety review.

4.2.1.1 Todd 2015

All studies included in Todd (n = 31) were checked for eligibility. Todd listed as included studies all the systematic and narrative reviews and commentaries they used to source primary studies and reports of adverse events. We first excluded these reviews to ensure adverse events were not included more than once, and focused only on the included primary studies (n = 25). Full-text reports of all primary studies (n = 25) were then screened for eligibility. Since the inclusion criteria for Todd were broader than those of this review ('cases of adverse effects due to chiropractic and other manual therapies for infants and children'), we excluded studies initially on the basis of age of participants (12 to 18 year olds), followed by an assessment of intervention techniques, and finally on whether the study report was available in English or had an English abstract. Figure 5 shows which primary studies were excluded at each stage and which studies met the eligibility criteria.

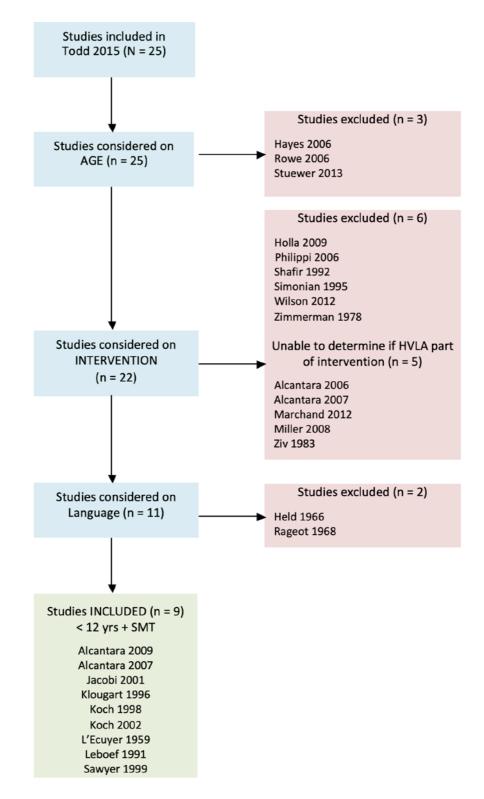


Figure 5. Flow chart of studies in Todd 2015

4.2.1.2 Search for additional primary studies

We searched PubMed, Index to Chiropractic Literature, Embase, Cochrane Central Register of Controlled Trials, CINAHL, Allied and Complementary Medicine (AMED) and Scopus on 13 May 2019 (see Appendix 2). Further weekly searches of PubMed continued until 15 June 2019. After removing duplicates, 1628 records were screened. The full-text of 12 potentially eligible studies were checked. One additional study, not included in the Todd review, met our criteria and is included in this review (Awwad 2018 (39)). The majority of studies excluded after full-text consideration were either editorials and commentaries, or were deemed to not be reporting information about spinal manipulation as we defined the intervention. Figure 6 shows the process of selection of studies for both those sourced from Todd and from the search for additional studies. **Appendix 6** provides further detail of the reasons for exclusion of studies from both the Todd review and from the search for additional primary studies.

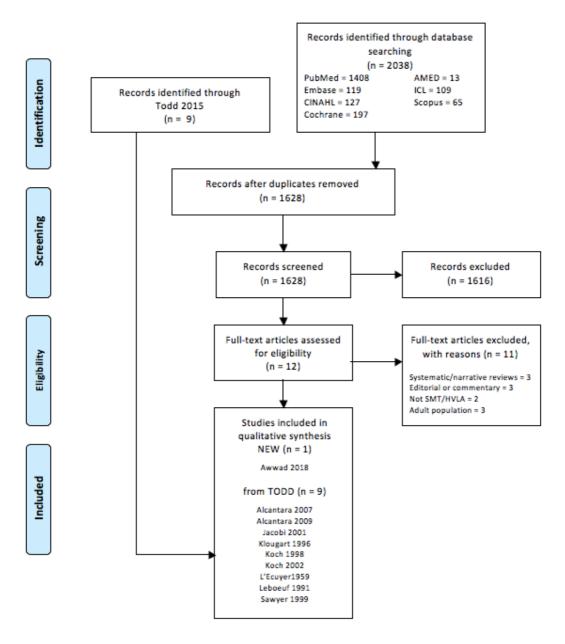


Figure 6. PRISMA flowchart (safety)

4.2.1.3 Driehuis 2019

During the conduct of this review, following completion of the search, another systematic review of the effectiveness and safety of spinal manipulative therapy in infants, children and adolescents was published (Driehuis 2019 (2)). This review is described in section 4.1.1.2 and **Appendix 4** of this report. Driehuis had broader, but overlapping, inclusion criteria compared to our review and included 18 studies describing harms (nine observational studies, five case reports and four controlled studies). We reviewed these included studies to identify any additional studies that met our inclusion criteria for intervention and age, and which added additional reports of adverse effects. No additional studies meeting our inclusion criteria were found.

4.2.1.4 Safety information derived from effectiveness review

Of the 13 trials included in the effectiveness review, only four explicitly mentioned adverse effects (the remaining nine did not mention and may not have measured adverse effects and so do not contribute information to the safety review). Of these four studies, two explicitly reported no adverse effects, and two reported 'minimal self-limiting adverse effects' in infants and children undergoing SMT (Borusiak 2010 and Sawyer 1999), see Table 4. These effects were mid-back pain and irritability. Information about adverse effects derived from the effectiveness review is reported in the Summary of Findings table for the effectiveness review (see Table 6) and reproduced below.

In addition to inclusion in our effectiveness review, Sawyer 1999 is included in Todd, and hence further details of its reported adverse effects are in the results section below.

4.2.2 Description of studies included in safety review

We included 10 studies reporting 159 adverse effects. Full study details are presented in Table 7 below. Presenting conditions included conditions labelled as 'muscle tension, asymmetry and leg length discrepancy' (3 studies), general presentations including wellness check ups (2 studies), torticollis, headache, neck pain, enuresis and otitis media (1 study each).

Study designs were individual case reports presenting details of a single event (2 studies); a retrospective survey to identify incidence of adverse events followed by case reporting of a subset of identified events (1 study); practitioner surveys and audits (2 studies); case series (1 study); prospective cohort studies (3 studies); case series (1 study) and a pilot randomised controlled trial (1 study). Practitioners delivering treatments were predominantly chiropractors (7 studies), with medical manipulators (2 studies) and a physiotherapist (1 study) also included. Five studies were conducted in the USA, three in Germany, and one each in Denmark and Australia.

Table 7. Table of included studies – safety review

| Study ID / Country / Practitioner/ Setting | Study design/ Sample size | Key findings | No. of adverse events | Description of adverse event | Description of patient(s)/ Presenting condition | Description of technique | Underlying pathology | Notes on methods |
|--|---|---|-----------------------------|---|--|---|---------------------------|---|
| Serious Adverse Eve | nt | | | | | | | |
| Jacobi 2001 (40) Germany Physiotherapist Physiotherapy clinic | Case report n = 1 | N/A | 1 | Subarachnoidal haemorrhage and death | 3 month-old female with torticollis | Vojta technique (spinal manipulation and electrical current) | Nil | Reported in German with English abstract and detailed in Todd. Detailed clinical, neuropathological and autopsy report |
| Klougart 1996 (41) Denmark Chiropractor Chiropractic clinics | Retrospective survey with description of identified cases 1981-1988 Survey sample <i>n</i> = 125 chiropractors Case report <i>n</i> = 1 | 1/120,000 CVI incidence during 1981-1988 | 1 | Loss of consciousness in both treatment sessions; quick recovery once treatment stopped | 10 year-old male with headache and nausea | Gonstead technique C7/T1 | Nil | 1 child <12 years of 22 adverse effects across all-ages CVI adverse events retrospectively self-reported by surveyed chiropractors; low response rate to survey |
| L'Ecuyer 1959 (42) USA Chiropractor Chiropractic clinic | Case report n = 1 | N/A | 1 | Neck pain, progression to drowsiness and weakness, hospitalisation | 10 year-old female with neck pain | Chiropractic adjustments, rotating the head and neck in rapid twisting movements and jerks, causing cracking sounds | Congenital torticollis | 60 year-old single case report; intervention description drawn from mother's report |
| Mild to Moderate Ad | verse Event | | | | | | | |
| Alcantara 2009 (43) USA Chiropractor Chiropractic clinics | 2 x cross-sectional surveys – practitioners (Pr) & parents (Pa) n = 577 patients / 5438 consultations (Pr) n = 239 patients / 1735 consultations (Pa) | No treatment-related complications Minor treatment- related aggravations reported in 1/1812 (Pr) and 1/1735 (Pa) SMT consults | 3 (Pr) 1 (Pa) | Muscle stiffness, spine soreness (Pr) Cervical spine stiffness (Pa) | Paediatric patients ≤ 18 years Mean age 7.45 years (Pr) Mean age 6.16 years (Pa) | SMT varied (Pr) SMT (Pa) | NR | Most data collected from practices and parents affiliated with research organization. Selection bias in all data used in review.; study funded by ICPA ¹ |

¹ International Chiropractic Paediatric Association

| Study ID / Country / Practitioner/ Setting | Study design/ Sample size | Key findings | No. of adverse events | Description of adverse event | Description of patient(s)/ Presenting condition | Description of technique | Underlying pathology | Notes on methods |
|---|--|--|-----------------------------|---|--|--|---------------------------------|---|
| Alcantara 2007 (44) USA Chiropractor Chiropractic clinics | Random data collection from chiropractors participating in a review of adverse events after treatment in paediatric population <i>n</i> = 812 patients / 7536 consultations | No treatment-related complications 9 treatment-related aggravations | 9 | Soreness | Paediatric patients ≤ 18 years 80% returning patients Wellness checkups (43%) and diverse presentations | Chiropractic SMT 3 most common techniques: Diversified Technique, Thompson Technique, Cranial Techique | NR | No full-text available Data collected from information in files, no treatment types listed. Selection bias in all data used in review. Study funded by ICPA ¹ |
| Awwad 2018 (39) USA Chiropractor Chiropractic clinic | Case series n = 2 | N/A | 2 | a) missed diagnosis Perthes Disease b) missed diagnosis developmental dislocation of hip (DDH) | a) 4 year-old female with limp b) 2 year-old female with leg length discrepancy | Chiropractic manipulative therapy | a) Perthes Disease b) DDH | Review of case notes of 2 children <12 years of 23- patient case series (<19 years) |
| Koch 1998 (45) Germany Medical manipulator | Prospective cohort study n = 199 | Apnea and flushing of skin observed in 50 infants given the medically induced impulse. | 50 | Apnea of short duration | Infants ≤ 12 months with muscle tension disorders and some form of asymmetry | Suboccipital impulse ("short, gentle thrust administered counter to the direction of the asymmetry") | NR | Changes in observed physiology only and not assessed with breathing monitor or skin sensors. No control group. |
| Koch 2002 (46) Germany Medical manipulator | Prospective cohort study n = 695 | Severe short lasting bradycardia in almost 50% of all infants < 3 months. Bradycardia was mild in children > 4 months. 87 cases of severe, short-lasting bradycardia. | 87 | Moderate to severe brachycardia | Infants diagnosed with orthopedic abnormalities, in particular asymmetries in the horizontal and sagittal plane of body posture and motion | Short, gentle thrust administered onto the suboccipital region with the inner side of the interphalangeal portion of the second digit | Nil | All infants monitored with ECG only. No control group. |

| Study ID / Country / Practitioner/ Setting | Study design/ Sample size | Key findings | No. of adverse events | Description of adverse event | Description of patient(s)/ Presenting condition | Description of technique | Underlying pathology | Notes on methods |
|--|--|---|-----------------------------|--|--|--|-------------------------|--|
| Leboeuf 1991 (47) Australia Chiropractic students Chiropractic clinic | Prospective cohort study n = 171 | 2 events reported across 171 treated | 2 | Severe headache, stiff neck Acute lumbar spine pain | Enuretic children, aged 4 to I5 years | Treatment consisted of specific chiropractic adjustments of the area(s) of aberrant spinal movement as detected at each visit through observation and palpation | NR | Effectiveness study; no control group |
| Sawyer 1999 (48) USA Academic chiropractor Chiropractic college | Pilot RCT n = 22 | Total of 200 chiropractic SMT visits, zero serious adverse events resulted. | 2 | Mid-back soreness and increased irritability | Children 6 months to 6 years with chronic otitis media with effusion | HVLA (motion palpation and light touch of specific spinal segments) | NR | Chiropractic SMT vs sham. Practitioners not qualified or experienced in using measuring devices for effusion associated with chronic otitis media. |

4.2.3 Safety review: summary across studies

Full details of the study characteristics, results and the details of reported adverse effects are presented in Table 7. Overall, we identified few studies (10) and 159 reported adverse effects (including those measured as part of incident surveys but not fully described).

Six of these studies aimed to determine the rates of adverse events occurring across populations of infants and children undergoing SMT. These studies reported rates spanning one minor treatment aggravation (muscle and spine stiffness and soreness) per 1812 consultations (Alcantara 2009) to 1 cerebrovascular incident in 20,000 visits (Klougart 1996). In two individual cohort studies, Koch et al. demonstrated apnoea and skin flushing in 50 of 199 treated infants; and severe but short lasting bradycardia in almost 50% of infants aged less than three months old and in 87 children aged over four months in an overall sample of 695.

The only Australian study (Leboeuf 1991) reported two mild events (severe headache with stiff neck and acute lumbar spine pain) in 171 children undergoing treatment for enuresis.

Four studies described five individual cases of adverse effects from spinal manipulative therapy. Of these, three were classified as severe (Jacobi 2001, Klougart 1996 and L'Ecuyer 1959), and two as moderate (Awwad 2018). The moderate cases involved misdiagnosis and so delayed treatment of underlying conditions (Perthes disease and developmental dislocation of the hip). Of the three reports of a serious adverse event, one resulted in death of a three-month old, attributed to subarachnoid haemorrhage. The technique employed in this case was described as the Vojta technique and involved forced active rotation and head retraction (Jacobi 2001).

Other serious adverse events were loss of consciousness with recovery (Klougart 1996) and hospitalisation for drowsiness and weakness (L'Ecuyer 1959). While other reviews with broader scope in terms of technique have reported more serious adverse effects, and attributed some to the presence of missed or undiagnosed underlying pathology, the three serious adverse events included in this review occurred in children with no reported underlying pathology (two cases) or congenital torticollis (one report).

4.2.3 Safety review: comparison with other systematic reviews

With broader scope and inclusion criteria, Todd described 15 serious adverse events, including three deaths. Two of these deaths were reported in studies excluded from our review on the basis that the description of the technique used was unclear (Rageot 1968 case report published in German) or inconsistent with our definition of spinal manipulation (Holla 2009 'forced, held flexion of the entire vertebral column by a craniosacral therapist not registered with the relevant national body').

Similarly, other studies included in Todd reporting other serious adverse events (e.g. neurological injury, haemothorax) were excluded from our review on the basis that the techniques used were not consistent with our definition of spinal manipulation or were not reported in sufficient detail to be included. Full details of our reasons for excluding studies are given in **Appendix 6**.

We were unable to include six studies in our review due to no details of the treatment used beyond describing it as spinal or chiropractic manipulation. Five of these were included in Todd (Alcantara 2006 and 2007, Marchand 2012, Miller 2008 and Ziv 1983) and one was identified through new searches (Deputy 2014).

Unlike the findings of our review, Todd identified the presence of underlying existing pathologies that may contraindicate spinal manipulation as a key factor in serious adverse

events, and emphasised the importance of excluding anatomical or neurological anomalies prior to performing manual techniques. This difference in results is likely due to Todd's inclusion of additional serious adverse effects on the basis of broader inclusion criteria.

Based on their findings, Todd offers the following recommendations, which may be useful in informing panel deliberations:

- More comprehensive and accessible methods of reporting adverse events, both for practitioners and patients;
- Practitioner education specific to paediatric populations;
- Consideration of the amount of experience and additional training required for treatment of children to ensure appropriate technique selection and application.

Driehuis 2019 undertook a systematic review of both effectiveness and harms of spinal manual therapy, including but not limited to high velocity, low amplitude manipulations. This review details five case reports that described serious injury or death after HVLA manipulations in four infants and one child. All but one of these studies overlap with those of Todd, and includes the cases reported in our review. The additional study (Deputy 2014 (49)) reports arm weakness in a six year-old boy. This study was identified by our search, but was excluded from our review based on insufficient information to determine the nature of the technique used (described as 'some degree of spinal manipulation of the neck').

With respect to potential harms associated with HVLA manipulation in children, consistent with our review, Driehuis concludes that because of the lack of reported information on the specific treatment techniques employed and the specific symptoms and indications for HVLA, conclusions about the risk of harm of spinal manipulation are hard to draw. They call for researchers to include information about harms in their studies and to provide detailed information about the techniques used, including the training and qualifications of treating practitioners. They also highlight the need for continuous review of harms through observational studies, databases and registries.

5. Coccygeal manipulation

Separate to the review of spinal manipulation, we reviewed studies on the safety and effectiveness of coccygeal manipulation in children. Had we identified any relevant studies, we would have applied the same methods as with the spinal manipulation review.

Criteria for including studies

| Intervention | any kind of manipulation or manual therapy of the coccyx delivered by any health |
|--------------|--|
| | professional |
| Population | children under 12 years of age |
| Comparator | any comparator |
| Outcomes | any outcome |
| Study design | Effectiveness: presence of a control or comparator group |
| | Safety: any design |
| Other limits | availability of full-text in English |

Search methods for identification of studies

We searched PubMed, Index to Chiropractic Literature, Embase, Cochrane Central Register of Controlled Trials, CINAHL, Allied and Complementary Medicine (AMED) and Scopus on 28 May 2019 (see **Appendix 7**). No date limits were applied and the same search covered both effectiveness and safety.

Results

The searches retrieved 70 records (see Figure 7). We assessed three studies, none of which was relevant. The table of excluded studies (Table 8) below details the reasons for exclusion.

We therefore are unable to identify any studies reporting information about the effectiveness or safety of coccygeal manipulation in children.

| Study ID | Condition | Reason | Description |
|---------------------------|--------------|--------------------|---|
| Kviberg 1998 (50) | Torticollis | Intervention | Manual pressure over the parasacro-coccygeal structures. |
| Mszwidobadze 1990 (51) | Coccygodynia | Language / Age | Published in Polish with English abstract. Reports case series of 160 cases, 94 of whom underwent surgery. Likely adults. |
| Wray 1991 (52) | Coccydynia | Intervention / Age | Physiotherapy, local injections of corticosteroid and local anaesthesia. Age range 11-76 years (average 38 years women and 48 years men). |

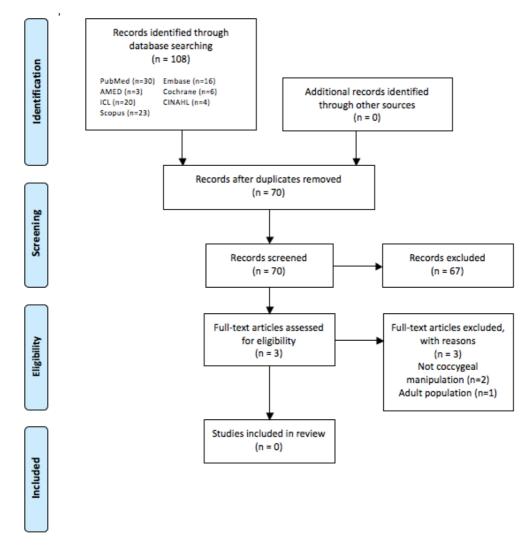


Figure 7. PRISMA flowchart (Coccygeal)

6. References

1. Parnell Prevost C, Gleberzon B, Carleo B, Anderson K, Cark M, Pohlman KA. Manual therapy for the pediatric population: a systematic review. BMC Complement Altern Med. 2019;19(1):60.

2. Driehuis F, Hoogeboom TJ, Nijhuis-van der Sanden MWG, de Bie RA, Staal JB. Spinal manual therapy in infants, children and adolescents: A systematic review and meta-analysis on treatment indication, technique and outcomes. PLoS One. 2019;14(6):e0218940.

3. Carnes D, Plunkett A, Ellwood J, Miles C. Manual therapy for unsettled, distressed and excessively crying infants: a systematic review and meta-analyses. BMJ Open. 2018;8(1):e019040.

4. Todd AJ, Carroll MT, Robinson A, Mitchell EKL. Adverse Events Due to Chiropractic and Other Manual Therapies for Infants and Children: A Review of the Literature. Journal of Manipulative and Physiological Therapeutics. 2015;38(9):699-712.

5. Whiting P, Savovic J, Higgins JP, Caldwell DM, Reeves BC, Shea B, et al. ROBIS: A new tool to assess risk of bias in systematic reviews was developed. J Clin Epidemiol. 2016;69:225-34.

6. Alcantara J, Ohm J, Kunz D. The safety and effectiveness of pediatric chiropractic: a survey of chiropractors and parents in a practice-based research network. Explore (NY). 2009;5(5):290-5.

7. ISSG. The InterTASC Information Specialists' Sub-Group Search Filter Resource [Available from: <u>https://sites.google.com/a/york.ac.uk/issg-search-filters-resource/</u>.

8. Viswanathan M, Berkman ND. Development of the RTI item bank on risk of bias and precision of observational studies. J Clin Epidemiol. 2012;65(2):163-78.

9. Holm LV, Jarbol DE, Christensen HW, Sondergaard J, Hestbaek L. The effect of chiropractic treatment on infantile colic: study protocol for a single-blind randomized controlled trial. Chiropr Man Therap. 2018;26:17.

10. Brurberg KG, Dahm KT, Kirkehei I. Manipulation techniques for infant torticollis. Tidsskr Nor Laegeforen. 2019;138(1).

11. Happle C, Wetzke M, Hermann EJ, Krauss JK, Hartmann H, Lucke T. ['Cases against KiSS': a diagnostic algorithm for children with torticollis]. Klin Padiatr. 2009;221(7):430-5.

12. Chen SC, Yu BY, Suen LK, Yu J, Ho FY, Yang JJ, et al. Massage therapy for the treatment of attention deficit/hyperactivity disorder (ADHD) in children and adolescents: A systematic review and meta-analysis. Complement Ther Med. 2019;42:389-99.

13. Gao L, Jia C, Huang H. Paediatric massage for treatment of acute diarrhoea in children: a meta-analysis. BMC Complement Altern Med. 2018;18(1):257.

14. Goncalves G, Le Scanff C, Leboeuf-Yde C. Effect of chiropractic treatment on primary or early secondary prevention: A systematic review with a pedagogic approach. Chiropractic and Manual Therapies. 2018;26(1).

15. Hawk C, Minkalis A, Webb C, Hogan O, Vallone S. Manual Interventions for Musculoskeletal Factors in Infants With Suboptimal Breastfeeding: A Scoping Review. Journal of Evidence-Based Integrative Medicine. 2018;23.

16. Lai BY, Liang N, Cao HJ, Yang GY, Jia LY, Hu RX, et al. Pediatric Tui Na for acute diarrhea in children under 5 years old: A systematic review and meta-analysis of randomized clinical trials. Complement Ther Med. 2018;41:10-22.

17. Lotan S, Kalichman L. Manual therapy treatment for adolescent idiopathic scoliosis. J Bodyw Mov Ther. 2019;23(1):189-93.

18. Öztürk Dönmez R, Bayık Temel A. Behavioural soothing interventions used for reducing crying in infants: a systematic review. Early Child Development and Care. 2018.

19. Rani M, Kulandaivelan S, Bansal A, Pawalia A. Physical therapy intervention for cervicogenic headache: an overview of systematic reviews. European Journal of Physiotherapy. 2018.

20. Shreeve MW, Troxel AR. Autism and chiropractic: A selective review of literature [review]. J Pediatr Matern & Fam Health - Chiropr. 2018;2018:Online access only p 150-4.

21. Will JS, Bury DC, Miller JA. Mechanical low back pain. Am Fam Physician. 2018;98(7):421-8.

22. Hestbaek L, Stochkendahl MJ. The evidence base for chiropractic treatment of musculoskeletal conditions in children and adolescents: The emperor's new suit? Chiropr Osteopat. 2010;18:15.

23. Beliveau PJH, Wong JJ, Sutton DA, Simon NB, Bussieres AE, Mior SA, et al. The chiropractic profession: a scoping review of utilization rates, reasons for seeking care, patient profiles, and care provided. Chiropr Man Therap. 2017;25:35.

24. Rome P, Waterhouse J, Maginness G, Ebrall P. Medical management of infantile colic with spinal manipulation: a narrative review of the European medical literature. Journal of Contemporary Chiropractic. 2019;2(1):60-75.

25. Wiberg JM, Nilsson N. Infants with colic may have had a faster delivery: a short, preliminary report. J Manipulative Physiol Ther. 2000;23(3):208-10.

26. Browning M, Miller J. Comparison of the short-term effects of chiropractic spinal manipulation and occipito-sacral decompression in the treatment of infant colic: A single-blinded, randomised, comparison trial. Clinical Chiropractic. 2008;11(3):122-9.

27. Olafsdottir E, Forshei S, Fluge G, Markestad T. Randomised controlled trial of infantile colic treated with chiropractic spinal manipulation. Arch Dis Child. 2001;84(2):138-41.

28. Wiberg JM, Nordsteen J, Nilsson N. The short-term effect of spinal manipulation in the treatment of infantile colic: a randomized controlled clinical trial with a blinded observer. J Manipulative Physiol Ther. 1999;22(8):517-22.

29. Reed WR, Beavers S, Reddy SK, Kern G. Chiropractic management of primary nocturnal enuresis. J Manipulative Physiol Ther. 1994;17(9):596-600.

30. Dissing KB, Hartvigsen J, Wedderkopp N, Hestbaek L. Conservative care with or without manipulative therapy in the management of back and/or neck pain in Danish children aged 9-15: a randomised controlled trial nested in a school-based cohort. BMJ Open. 2018;8(9):e021358.

31. Borusiak P, Biedermann H, Bosserhoff S, Opp J. Lack of efficacy of manual therapy in children and adolescents with suspected cervicogenic headache: results of a prospective, randomized, placebo-controlled, and blinded trial. Headache. 2010;50(2):224-30.

32. Bronfort G, Evans RL, Kubic P, Filkin P. Chronic pediatric asthma and chiropractic spinal manipulation: a prospective clinical series and randomized clinical pilot study. J Manipulative Physiol Ther. 2001;24(6):369-77.

33. Balon J, Aker PD, Crowther ER, Danielson C, Cox PG, O'Shaughnessy D, et al. A comparison of active and simulated chiropractic manipulation as adjunctive treatment for childhood asthma. N Engl J Med. 1998;339(15):1013-20.

34. Sawyer CE, Evans RL, Boline PD, Branson R, Spicer A. A feasibility study of chiropractic spinal manipulation versus sham spinal manipulation for chronic otitis media with effusion in children. J Manipulative Physiol Ther. 1999;22(5):292-8.

35. Kachmar O, Kushnir A, Matiushenko O, Hasiuk M. Influence of Spinal Manipulation on Muscle Spasticity and Manual Dexterity in Participants With Cerebral Palsy: Randomized Controlled Trial. J Chiropr Med. 2018;17(3):141-50.

36. Accorsi A, Lucci C, Di Mattia L, Granchelli C, Barlafante G, Fini F, et al. Effect of osteopathic manipulative therapy in the attentive performance of children with attention-deficit/hyperactivity disorder. J Am Osteopath Assoc. 2014;114(5):374-81.

37. Giesen JM, Center DB, Leach RA. An evaluation of chiropractic manipulation as a treatment of hyperactivity in children. J Manipulative Physiol Ther. 1989;12(5):353-63.

38. Haugen EB, Benth J, Nakstad B. Manual therapy in infantile torticollis: a randomized, controlled pilot study. Acta Paediatr. 2011;100(5):687-90.

39. Awwad A, Hennrikus W, Armstrong D. Pediatric Orthopaedic Consults From Chiropractic Care. Journal of surgical orthopaedic advances.27(1):58.

40. Jacobi G. Riepert Do, Kieslich M, Bohl J. Über einen Todesfall während der
Physiotherapie nach Vojta bei einem drei Monate alten Säugling. Klin Pädiatr. 2001;213:76-8.
41. Klausert N. Jakasuf Vda G. Bassurana J.B. Safataia akiasumatia maatia. Bast II.

41. Klougart N, Leboeuf-Yde C, Rasmussen LR. Safety in chiropractic practice. Part II: Treatment to the upper neck and the rate of cerebrovascular incidents. Journal of manipulative and physiological therapeutics. 1996;19(9):563-9.

42. L'Ecuyer J. Congenital occipitalization of the atlas with chiropractic manipulations: a case report. The Nebraska State Medical Journal. 1959;44:546.

43. Alcantara J, Ohm J, Kunz D. The safety and effectiveness of pediatric chiropractic: a survey of chiropractors and parents in a practice-based research network. Explore: The Journal of Science and Healing. 2009;5(5):290-5.

44. Alcantara J, Ohm J, Kunz D. Treatment-related aggravations, complications and improvements attributed to chiropractic spinal manipulative therapy of paediatric patients: a practice-based survey of practitioners. Focus on Alternative and Complementary Therapies. 2007;12(s1):3-.

45. Koch L, Biedermann H, Saternus K-S. High cervical stress and apnoea. Forensic Science International. 1998;97(1):1-9.

46. Koch L, Koch H, Graumann-Brunt S, Stolle D, Ramirez J-M, Saternus K-S. Heart rate changes in response to mild mechanical irritation of the high cervical spinal cord region in infants. Forensic Science International. 2002;128(3):168-76.

47. Leboeuf C, Brown P, Herman A, Leembruggen K, Walton D, Crisp T. Chiropractic care of children with nocturnal enuresis: a prospective outcome study. Journal of Manipulative and Physiological Therapeutics. 1991;14(2):110.

48. Sawyer CE, Evans RL, Boline PD, Branson R, Spicer A. A feasibility study of chiropractic spinal manipulation versus sham spinal manipulation for chronic otitis media with effusion in children. Journal of Manipulative and Physiological Therapeutics. 1999;22(5):292-8.

49. Deputy SR. Arm weakness in a child following chiropractor manipulation of the neck. Seminars in Pediatric Neurology. 2014;21(2):124-6.

50. Kviberg I, Orbe A. Treatment of torticollis in infancy by manual pressure applied over the parasacro-coccygeal structures. Physiother Res Int. 1998;3(3):228-9; discussion 9-30.

51. Mszwidobadze M, Alborow G. [Tactics in management of coccygodynia]. Chir Narzadow Ruchu Ortop Pol. 1990;55(4-6):519-21.

52. Wray CC, Easom S, Hoskinson J. Coccydynia. Aetiology and treatment. J Bone Joint Surg Br. 1991;73(2):335-8.

53. Lanaro D, Ruffini N, Manzotti A, Lista G. Osteopathic manipulative treatment showed reduction of length of stay and costs in preterm infants: A systematic review and metaanalysis. Medicine (Baltimore). 2017;96(12):e6408.

54. Alcantara J, Ohm J, Kunz D. Treatment-Related Aggravations, Complications and Improvements Attributed to Chiropractic Spinal Manipulative Therapy of Pediatric Patients: A Survey of Parents. 14th Annual Symposium on Complementary Health Care; 2007; Exeter, UK. Pathways2007.

55. Hayes NM, Bezilla TA. Incidence of iatrogenesis associated with osteopathic manipulative treatment of pediatric patients. The Journal of the American Osteopathic Association. 2006;106(10):605-8.

56. Held J. Dangers of cervical manipulation in neurology. Ann Med Phys (Lille). 1966:251-9.

57. Holla M, Ijland M, van der Vliet A, Edwards M, Verlaat C. Death of an infant following'craniosacral'manipulation of the neck and spine. Nederlands Tijdschrift voor Geneeskunde. 2009;153(17):828.

58. Marchand AM. Chiropractic care of children from birth to adolescence and classification of reported conditions: an internet cross-sectional survey of 956 European chiropractors. Journal of Manipulative and Physiological Therapeutics. 2012;35(5):372-80.

59. Miller JE, Benfield K. Adverse effects of spinal manipulative therapy in children younger than 3 years: a retrospective study in a chiropractic teaching clinic. Journal of Manipulative and Physiological Therapeutics. 2008;31(6):419-23.

60. Philippi H, Faldum A, Schleupen A, Pabst B, Jung T, Bergmann H, et al. Infantile postural asymmetry and osteopathic treatment: a randomized therapeutic trial. Developmental Medicine and Child Neurology. 2006;48(1):5-9.

61. Rageot E. Complications and accidents in vertebral manipulation. Les Cahiers du College de medecine des hopitaux de Paris. 1968;9(14):1149.

62. Rowe DE, Feise RJ, Crowther ER, Grod JP, Menke JM, Goldsmith CH, et al. Chiropractic manipulation in adolescent idiopathic scoliosis: a pilot study. Chiropractic & Osteopathy. 2006;14(1):15.

63. Shafrir Y, Kaufman BA. Quadriplegia after chiropractic manipulation in an infant with congenital torticollis caused by a spinal cord astrocytoma. The Journal of Pediatrics. 1992;120(2):266-9.

64. Simonian PT, Staheli LT. Periarticular fractures after manipulation for knee contractures in children. Journal of Pediatric Orthopedics. 1995;15(3):288-91.

65. Struewer J, Frangen TM, Ziring E, Hinterseher U, Kiriazidis I. Massive hematothorax after thoracic spinal manipulation for acute thoracolumbar pain. Orthopedic Reviews. 2013;5(3).

66. Wilson PM, Greiner MV, Duma EM. Posterior rib fractures in a young infant who received chiropractic care. Pediatrics. 2012;130(5):e1359-e62.

67. Zimmerman A, Kumar AJ, Gadoth N, Hodges F. Traumatic vertebrobasilar occlusive disease in childhood. Neurology. 1978;28(2):185-.

68. Ziv I, Rang M, Hoffman HJ. Paraplegia in osteogenesis imperfecta. A case report. The Journal of Bone and Joint Surgery British volume. 1983;65(2):184-5.

69. Adams D, Schiffgen M, Kundu A, Dagenais S, Clifford T, Baydala L, et al. Patterns of utilization of complementary and alternative medicine in 2 pediatric gastroenterology clinics. Journal of Pediatric Gastroenterology and Nutrition. 2014;59(3):334-9.

70. Bodensteiner JB. Editorial comment: Stroke following chiropractic manipulation. Seminars in Pediatric Neurology. 2014;21(2):127.

71. Botelho MB, Andrade BB. Effect of cervical spine manipulative therapy on judo athletes' grip strength. Journal of Manipulative and Physiological Therapeutics. 2012;35(1):38-44.

72. Brurberg K, Myrhaug H, Reinar L. Diagnostics and Treatment of Infants Suspected with Kinematic Imbalance Due to Suboccipital Strain (KISS). Oslo: Knowledge Centre for the Health Services; 2009. Report No.: Kunnskapssenteret no. 17-2009.

73. Doyle MF. Chiropractic care for infants and children - there is no evidence for it and it is dangerous? A selective review of the literature and commentary. Chiropractic Journal of Australia. 2016;44(3).

74. Hawk C, Schneider MJ, Vallone S, Hewitt EG. Best practices for chiropractic care of children: a consensus update. Journal of Manipulative and Physiological Therapeutics. 2016;39(3):158-68.

75. Jevne J, Hartvigsen J, Christensen HW. Compensation claims for chiropractic in Denmark and Norway 2004–2012. Chiropractic & Manual Therapies. 2014;22(1):37.

76. Smith MS, Olivas J, Smith K. Manipulative Therapies: What Works. American Family Physician. 2019;99(4).

77. Swait G, Finch R. What are the risks of manual treatment of the spine? A scoping review for clinicians. Chiropractic & Manual Therapies. 2017;25(1):37.

78. Tuchin P. A systematic literature review of intracranial hypotension following chiropractic. International Journal of Clinical Practice. 2014;68(3):396-402.

Appendix 1 – Existing relevant systematic reviews

| Study | Population | Interventions | Conditions / Outcomes | Studies | Included |
|--|--|--|---|---|--|
| Prevost 2019 (1) Manual therapy for the pediatric population: a SR Last search: 31 March 2018 [for studies published 2000 to March 2018] | 0-18 years treated with manual therapy of any type from any healthcare professional for any condition | Spinal manipulative therapy; mobilisation; osteopathic manipulative therapy; cranial-sacral therapy; chiropractic manipulative therapy; visceral osteopathic manipulation; instrument-assisted manipulation; manual therapy | Gastrointestinal (colic; constipation; breast-feeding; enuresis). Musculoskeletal (clubfoot, headache, low back pain, pulled elbow) Respiratory. (asthma, apnoea, otitis media). Special needs (ADHD, autism, cerebral palsy, prematurity). Structural (cranial asymmetry, scoliosis, torticollis) | RCTs and observational studies Exclude: cross-sectional; case report or case series without pre and post measures | 50 studies (32 RCTs; 18 Obs.) |
| Driehuis 2019 (2) Spinal manual therapy in infants, children and adolescents Last search December 2017 | 0-12 months (infants) 1 to 11 years (children) 12 to 18 years (adolescents) | Spinal Manual Therapy "manual therapeutic interventions in which treatment techniques were primarily performed on the full spine or on specific spinal segments, by any healthcare professional" (p3). Eligible techniques: 1. Manipulation: "a HVLA or low- velocity thrust, resulting in a mechanical response of articular surface separation and a cracking sound, which is also defined as cavitation in the affected joint" 2. Mobilization: "low-velocity, low- amplitude oscillating spinal joint play, without a thrust and without cavitation" | Treatment indications: colic, torticollis, autism, asthma, nocturnal enuresis, headache, idiopathic scoliosis <u>Harms:</u> - mild (transient, lasting <24 hrs) - moderate (requiring medical treatment) - severe (requiring hospital treatment; life threatening or death) | Effectiveness: controlled studies <u>Harms</u> : studies using controlled, observational or case report design | 26 studies <u>Effectiveness</u> : 12 RCTs / CCTs <u>Harms</u> : 9 Obs., 5 case reports |
| Carnes 2018 (3) Manual therapy for unsettled, distressed and excessively crying infants: a SR and MA Last search: January 2017 | 0-12 months | Manual therapy delivered in primary care by osteopaths, chiropractors, physiotherapists | Unsettled behaviours (excessive crying, lack of sleep, difficulty feeding) | RCTs, cohorts, observational studies, case-control, case series, surveys and qualitative studies | 19 studies (7 RCTs; 7 case series; 1 service evaluation; 1 qual.) |

| Study | Population | Interventions | Conditions / Outcomes | Studies | Included |
|--|---|--|--|----------------------------------|---|
| Todd 2015 (4) Adverse events due to chiropractic and other manual therapies for infants and children: a review of the | Infants and children (age not defined) | Any kind of manual therapy; any practitioner type | Any adverse events (mild, moderate, or Severe) | All study types | 31 articles (5 systematic reviews; 5 narrative reviews; 4 cross- sectional surveys; 6 RCTs; 4 survey |
| Last search: March 2014 | | | | | studies; 4 case studies; 1 case series) |
| Lanaro 2017 (53) OMT treatment showed reduction in length of stay and costs in preterm infants: a SR and MA | Preterm infants | Osteopathic manipulative treatment performed by osteopaths | Length of hospital stay; costs; weight gain | RCTs and non-RCTs (CBAs; ITS) | 5 studies (4 RCTs; 1 Obs) |
| Last search: 17 May 2015 | | | | | |

Appendix 2 – Search strategies

PubMed

Search run on 13 May 2019, plus weekly auto-alerts (to 15 June 2019)

Effectiveness (March 2018 to June 2019)

(Musculoskeletal Manipulations[Mesh] OR "spinal manipulative therapy" OR "spinal manipulation" OR "spine manipulation" OR HVLA OR ((manipulat*[TIAB] OR adjust*[TIAB] OR manual*[TIAB]) AND (spine[TIAB] or spinal[TIAB] OR lumbar[TIAB] OR cervical[TIAB])) OR chiropract* OR osteopath* OR cranio-sacral OR craniosacral OR cranial-sacral) AND (Child[Mesh] OR Infant[Mesh] OR Adolescent[Mesh] OR child OR children OR infant OR infants OR newborn* OR neonate* OR baby OR babies OR paediatric OR pediatric OR young[TIAB] OR adolescent*) AND 2018/03[EDAT]:2019/06[EDAT]

Effectiveness (1960 to 1999)

(((Manipulation, Chiropractic[Mesh] OR Manipulation, Spinal[Mesh] OR "spinal manipulative therapy" OR "spinal manipulation" OR "spine manipulation" OR HVLA OR ((manipulat*[TIAB] OR adjust*[TIAB] OR manual*[TIAB]) AND (spine[TIAB] OR spinal[TIAB] OR lumbar[TIAB]))) AND (Child[Mesh] OR Infant[Mesh] OR child[TIAB] OR children[TIAB] OR infant[TIAB] OR infants[TIAB] OR newborn* OR neonate*[TIAB] OR baby[TIAB] OR babies[TIAB] OR paediatric[TIAB] OR pediatric[TIAB]))) Filters: Publication date from 1960/01/01 to 1999/12/31

Safety (2014 to June 2019)

(Musculoskeletal Manipulations[Mesh] OR "spinal manipulative therapy" OR "spinal manipulation" OR "spine manipulation" OR HVLA OR ((manipulat*[TIAB] OR adjust*[TIAB] OR manual*[TIAB]) AND (spine[TIAB] or spinal[TIAB] OR lumbar[TIAB] OR cervical[TIAB])) OR chiropract*[TIAB] OR osteopath*[TIAB] OR cranio-sacral[TIAB] OR craniosacral[TIAB] OR cranial-sacral[TIAB]) AND (Child[Mesh] OR Infant[Mesh] OR Adolescent[Mesh] OR child[TIAB] OR children[TIAB] OR infant[TIAB] OR infants[TIAB] OR newborn*[TIAB] OR neonate*[TIAB] OR baby[TIAB] OR babies[TIAB] OR paediatric[TIAB] OR pediatric[TIAB] OR young[TIAB] OR adolescent*[TIAB]) AND (adverse OR unwanted OR "side effect*" OR reaction* OR complication* OR harm* OR injury OR injuries OR risk OR risks OR safe* OR adverse effects[sh] OR complications[sh]) AND 2014/01[EDAT]:2019/06[EDAT]

Index to Chiropractic Literature (ICL)

Search run on 13 May 2019

Effectiveness

(Manipulation, Spinal OR spin* OR lumbar OR cervical OR chiropract* OR osteopath* OR cranio* OR cranial*) AND (Infant OR Child OR Young Adult OR infant* OR child* OR baby OR babies OR newborn* OR neonat* OR paediatric OR pediatric OR adolescent* OR young), Year: from 2018 to 2019, All citations

Safety

(Manipulation, Spinal OR spin* OR chiropract* OR osteopath* OR cranio* OR cranial*) AND (Infant OR Child OR Young Adult OR infant* OR child* OR baby OR babies OR newborn* OR neonat* OR paediatric OR pediatric OR adolescent* OR young) AND (adverse OR unwanted OR "side effect" OR "side effects" OR reaction* OR complication* OR harm* OR injury OR injuries OR risk OR risks OR safe*), Year: from 2014 to 2019, All citations

Cochrane Central Register of Controlled Trials

| | | - | | 0010 |
|-------|----|----|-----|------|
| Issue | NO | 5, | Мау | 2019 |

| sue no | 5, May 2015 | |
|--------|---|--------|
| #1 | MeSH descriptor: [Musculoskeletal Manipulations] explode all trees | 2612 |
| #2 | ((manipulat* OR adjust* OR manual*) near spine):ti,ab,kw | 451 |
| #3 | ((manipulat* OR adjust* OR manual*) near spinal):ti,ab,kw | 1008 |
| #4 | ((manipulat* OR adjust* OR manual*) near lumbar):ti,ab,kw | 227 |
| #5 | ((manipulat* OR adjust* OR manual*) near cervical):ti,ab,kw | 509 |
| #6 | (chiropract* OR osteopath* OR cranio-sacral OR craniosacral OR cranial- | 1573 |
| | sacral):ti,ab,kw | |
| #7 | #1 OR #2 OR #3 OR #6 | 4703 |
| #8 | MeSH descriptor: [Infant] explode all trees | 15304 |
| #9 | MeSH descriptor: [Child] explode all trees | 1161 |
| #10 | MeSH descriptor: [Adolescent] explode all trees | 99454 |
| #11 | (child OR children OR infant OR infants OR newborn* OR neonate* OR baby | 303920 |
| | OR babies OR paediatric OR pediatric OR young OR adolescent*):ti,ab,kw | |
| #12 | #8 OR #9 OR #10 OR #11 | 303924 |
| #13 | #7 AND #12 with Publication Year from 2018 to 2019, in Trials | 72 |
| | [EFFECTIVENESS] | |
| #14 | MeSH descriptor: [] explode all trees and with qualifier(s): [complications - | 51367 |
| | [CO] | |
| #15 | MeSH descriptor: [] explode all trees and with qualifier(s): [adverse effects - | 123481 |
| | AE] | |
| #16 | (adverse OR unwanted OR "side effect" OR "side effects" OR reaction* OR | 694139 |
| | complication* OR harm* OR injury OR injuries OR risk OR risks OR | |
| | safe*):ti,ab,kw | |
| #17 | #14 OR #15 OR #16 | 694150 |
| #18 | #7 AND #12 | 1217 |
| #19 | #17 AND #18 with Publication Year from 2014 to 2019, in Trials [SAFETY] | 197 |

Embase

EMBASE <1974 to 2019 May 10>

| # | Search Statement | Results |
|----|---|---------|
| 1 | spine manipulation/ | 446 |
| 2 | ((spine or spinal or lumbar or cervical) adj5 (manipulat\$ or adjust\$ or manual\$)).ti,ab. | 5732 |
| 3 | or/1-2 | 5842 |
| 4 | infant/ | 553735 |
| 5 | child/ | 1577966 |
| 6 | (child or children or infant or infants or newborn\$ or neonate\$ or baby or babies or paediatric or pediatric or young or adolescent\$).ti,ab. | 2593207 |
| 7 | or/4-6 | 3224884 |
| 8 | 3 and 7 | 511 |
| 9 | limit 8 to yr="2018 -Current" [EFFECTIVENESS] | 49 |
| 10 | complication.fs. | 1646201 |
| 11 | side effect.fs. | 854688 |
| 12 | (adverse or unwanted or "side effect\$" or reaction\$ or complication\$ or harm\$ or injury or injuries or risk or risks or safe\$).ti,ab. | 6880867 |
| 13 | or/10-12 | 8202076 |
| 14 | 8 and 13 | 265 |
| 15 | limit 14 to yr="2014 -Current" [SAFETY] | 119 |

AMED (Allied and Complementary Medicine)

| AMED | <1985 | t٥ | Mav | 2019> |
|------|-------|----|--------|-------|
| | ~T303 | ιU | IVIA V | 20132 |

| # | Search Statement | Results |
|----|---|---------|
| 1 | exp musculoskeletal manipulations/ | 5733 |
| 2 | ((spine or spinal or lumbar or cervical) adj5 (manipulat\$ or adjust\$ or manual\$)).ti,ab. | 1576 |
| 3 | or/1-2 | 6525 |
| 4 | exp Infant/ | 2058 |
| 5 | Child/ | 16644 |
| 6 | Adolescent/ | 5132 |
| 7 | (child or children or infant or infants or newborn\$ or neonate\$ or baby or babies or paediatric or pediatric or young or adolescent\$).ti,ab. | 25687 |
| 8 | or/4-7 | 31382 |
| 9 | 3 and 8 | 427 |
| 10 | limit 9 to yr="2018 -Current" [EFFECTIVENESS] | 7 |
| 11 | (adverse or unwanted or "side effect\$" or reaction\$ or complication\$ or harm\$ or injury or injuries or risk or risks or safe\$).ti,ab. | 47154 |
| 12 | 9 and 11 | 63 |
| 13 | limit 12 to yr="2014 -Current" [SAFETY] | 13 |

CINAHL

Search run on 13 May 2019

| S15 | S13 AND S14 [SAFETY] | 127 |
|-----|--|-----------|
| S14 | PY 2014 OR PY 2015 OR PY 2016 OR PY 2017 OR PY 2018 OR PY 2019 | 2,254,789 |
| S13 | S7 AND S12 | 310 |
| S12 | S10 OR S11 | 1,133,525 |
| S11 | TI (adverse OR unwanted OR "side effect" OR "side effects" OR reaction* OR | 1,100,355 |
| | complication* OR harm* OR injury OR injuries OR risk OR risks OR safe*) OR | |
| | AB (adverse OR unwanted OR "side effect" OR "side effects" OR reaction* OR | |
| | complication* OR harm* OR injury OR injuries OR risk OR risks OR safe*) | |
| S10 | (MH "Adverse Health Care Event+") | 56,303 |
| S9 | S7 AND S8 [EFFECTIVENESS] | 70 |
| S8 | PY 2018 OR PY 2019 | 554,275 |
| S7 | S5 AND S6 | 1,338 |
| S6 | S3 OR S4 | 856,856 |
| S5 | S1 OR S2 | 21,936 |
| S4 | TI (child OR children OR infant OR infants OR newborn* OR neonate* OR | 635,987 |
| | baby OR babies OR paediatric OR pediatric OR young OR adolescent*) OR AB | |
| | (child OR children OR infant OR infants OR newborn* OR neonate* OR baby | |
| | OR babies OR paediatric OR pediatric OR young OR adolescent*) | |
| S3 | (MH "Child+") | 575,558 |
| S2 | TI ((spine or spinal or lumbar or cervical) N5 (manipulat* or adjust* or | 3,379 |
| | manual*)) OR AB ((spine or spinal or lumbar or cervical) N5 (manipulat* or | |
| | adjust* or manual*)) | |
| S1 | (MH "Chiropractic+") OR (MH "Manipulation, Orthopedic") OR (MH | 20,388 |
| | "Manipulation, Osteopathic") | |

Scopus

Search run on 14 May 2019

Effectiveness

(TITLE-ABS-KEY (((spine OR spinal OR lumbar OR cervical) W/5 (manipulat* OR adjust* OR manual*))) AND ((child OR children OR infant OR infants)) AND (LIMIT-TO (PUBYEAR, 2019) OR LIMIT-TO (PUBYEAR, 2018))

Safety

(TITLE-ABS (((spine OR spinal OR lumbar OR cervical) W/5 (manipulat* OR adust* OR manual*)) OR chiropract*)) AND (TITLE-ABS ((child OR children OR infant OR infants OR baby OR babies OR newborn* OR neonate* OR young OR paediatric OR pediatric))) AND (TITLE-ABS (adverse OR unwanted OR "side effect" OR "side effects" OR reaction* OR complication* OR harm* OR injury OR injuries OR safe*)) AND (LIMIT-TO (PUBYEAR , 2019) OR LIMIT-TO (PUBYEAR , 2018) OR LIMIT-TO (PUBYEAR , 2017) OR LIMIT-TO (PUBYEAR , 2016) OR LIMIT-TO (PUBYEAR , 2015) OR LIMIT-TO (PUBYEAR , 2014))

Appendix 3 – Table of excluded studies – effectiveness

| Study ID | Condition | Reason for exclusion | Description |
|---------------------|--------------------------------|----------------------|---|
| Studies sourced f | rom Parnell Prevost 2 | 019 | |
| Jennings 2005 | Cuboid syndrome | Age | Mean age 21.1 years |
| Przekop 2016 | Headache | Age | Adolescents, > 12 years |
| Evans 2018 | Low back pain | Age | Adolescents, 12-18 years |
| Walston 2016 | Low back pain | Age | Adolescents, 13-17 years |
| Selhorst 2015 | Low back pain | Age | Adolescents, 13-17 years |
| Hasler 2010 | Scoliosis | Age | Adolescents, > 12 years |
| Rowe 2006 | Scoliosis | Age | 10-16 years (only 1 out of 6 participants <12 years) |
| Morningstar 2005 | Scoliosis | Age | Adolescents, > 12 years |
| Tarsuslu 2009 | Constipation | Intervention | 'Treatments included fascial release , iliopsoas muscle release , sphincter release , and bowel mobilizations iliopsoas muscle release was performed by increasing the flexion angle of the other hip and applying mild pressure on the target iliopsoas' |
| Miller 2012 | Colic | Intervention | 'Treatments were pragmatic, individualized to examination findings, and consisted of chiropractic manual therapy of the spine. Specifically, this involved low force tactile pressure to spinal joints and paraspinal muscles where dysfunction was noted on palpation. The manual therapy, estimated at 2 N of force, was given at the area of involvement without rotation of the spine .' |
| Hayden 2006 | Colic | Intervention | 'those in the treated group received cranial osteopathic manipulative therapy as required (week 0). Treatment was individualized, according to clinical findings, and involved standard cranial osteopathic techniques until a palpable release of tensions and dysfunction was achieved.' |
| Nemett 2008 | Dysfunctional voiding | Intervention | 'MPT-OA (manual physical therapy based on an osteopathic approach) treatments were customized for each child based on results from the initial MPT-OA evaluation, and included gentle mobilization of body tissues to relieve movement restrictions, and thereby achieve balanced alignment and mobility and postural symmetry, with particular attention to the thoracolumbar spine, thoracic and pelvic diaphragms, pelvis, pelvic organs, and lower extremities.' |
| Garcia-Mata 2014 | Pulled elbow | Intervention | Two reduction techniques for pulled elbow - hyperpronation or supination-flexion; no spinal manipulation |
| Nilgun 2011 | Clubfoot | Intervention | 'The physical therapy program of the study group involved moist heat application to increase tissue flexibility prior to stretching, light stretching exercises performed at the posterior and medial parts of the foot, mobilization techniques applied to tibiotalar, subtalar and midtarsal joints and application of high voltage pulsed galvanic stimulation to the peroneal muscle group for stimulation of eversion movement and re-education of the elongated peroneal muscles.' |
| Bek 2009 | Pulled elbow | Intervention | Two reduction techniques for pulled elbow - hyperpronation or supination-flexion; no spinal manipulation |
| Monaco 2008 | Temporomandi bular disorder | Intervention | No description of OMT intervention, apart from 'manipulative treatment of non stomathognatic areas'. |

Please note: the references for these studies follow below the table.

| Study ID | Condition | Reason for exclusion | Description |
|---------------------------------|-----------------------|----------------------|--|
| Studies sourced fr | rom Parnell Prevost 2 | 019 | |
| Guiney 2005 | Asthma | Intervention | 'OMT on pediatric patients using any of the following osteopathic manipulative (OM) techniques, as appropriate: rib raising, muscle energy for ribs , and myofascial release . These techniques are described in the benchmark osteopathic textbook Foundations for Osteopathic Medicine.' |
| Steele 2014 | Otitis media | Intervention | 'The protocol used myofascial release and balanced ligamentous tension techniques to the pelvis, abdominal diaphragm, torso, and cervical area as well as osteopathy in the cranial field.' |
| Wahl 2008 | Otitis media | Intervention | 'Treatment modalities were limited to cranial osteopathy , balanced membranous/ligamentous tension , and/or myofascial release (applied directly or indirectly). These treatments consist of gentle manipulations of the cranium, pelvis, diaphragm, and other structures. No high velocity or thrusting maneuvers were performed. At the discretion of the osteopathic physician, an osteopathic percussion hammer could also be used for treatment, which allowed gentle vibration in tissues at variable frequencies.' |
| Zhang 2004 | Otitis media | Intervention | 'The Toftness System of Chiropractic Adjusting is a low force techniqueThe practitioner delivered a low force (2-32 oz.) Toftness chiropractic adjustment by a metered hand-held pressure applicator at the cervical, thoracic, lumbar and sacral contact site. This applicator is a rubber-tipped, spring-loaded device that indicates the amount of force that is being applied at the contact site. The adjustment contact line of drive, amount of force applied and duration of the contact are determined by constant monitoring of the adjustment site with the TCL.' |
| Mills 2003 | Otitis media | Intervention | 'OMT as indicated by examination results and child's cooperation. Gentle techniques ; articulation, myofascial release, balanced membranous tension, balanced ligamentous tension, facilitated postural release and/or counterstrain treatment no high-velocity popping techniques entire body, including head/neck' |
| Bramati- Castellarin 2016 | Autism | Intervention | 'VOT is an osteopathic treatment approach commonly used by osteopaths in which mobilisation (similar to massage but more specifically applied) of the abdominal viscera is the main aim. All subjects were treated using standardized VOT techniques (Barral and Mercier, 2005; 2007; Stone, 1999) which were applied to the general abdominal area including the specific anatomical regions as listed.' |
| Khorshid 2006 | Cerebral palsy | Intervention | 'The percussion adjustment instrument is used in Atlas Orthogonal technique. The patient is placed on his [<i>sic</i>] side with head support at four inches below the mastoid. A metal stylus is placed between the mastoid and the ramus of the mandible. An adjustment, an impulse imparted to the stylus by a plunger that excites a compressional wave in the stylus, is then delivered to the patient. At the patient-stylus interface, a portion of the wave energ y is transmitted to the patient and a portion is reflected back to the plunger. The former portion of energy is enough to direct the atlas vertebra to move to its normal orthogonal position.' |
| Duncan 2008 | Cerebral palsy | Intervention | 'Osteopathic manipulative treatment was limited to the use of direct or indirect techniques of osteopathy in the cranial field , myofascial release , or both.' |
| Pizzolorusso 2014 | Preterm | Intervention | OMT techniques used: indirect myofascial release, balanced ligamentous tension, balanced membranous tension.' |

| Study ID | Condition | Reason for exclusion | Description | | |
|---|-------------------------------|-------------------------|--|--|--|
| Studies sourced from Parnell Prevost 2019 | | | | | |
| Cerretelli 2015 | Preterm | Intervention | 'The treatment included the application of a selected range of manipulative techniques aimed at relieving the somatic dysfunctions. Techniques used were in line with the benchmarks on osteopathic treatment available in the medical literature and were limited to indirect techniques such as: myofascial release and balanced ligamentous/membranous tension .' | | |
| Cerretelli 2013 | Preterm | Intervention | 'The OMT techniques of choice in treating preterm infants are myofascial release, balanced ligamentous/ membranous tension, indirect fluidic and v-spreadtreatment was based on the application of indirect techniques as described above.' | | |
| Cabrera- Martos 2016 | Cranial asymmetry | Intervention | Moulding and decompression techniques were used adapted to the previous assessment. The moulding techniques require a slow, gradual restoration of normal shape and function using the physiologic mechanisms to facilitate the body's response toward homeostasis. It was used to normalise the position and motion of the sacrum. Decompression techniques were used to normalise tissue around cranial sutures. The physical therapist guides the segments away from one another in a gentle distraction force maintaining this position until the tension released.' | | |
| Lessard 2011 | Cranial asymmetry | Intervention | Most frequently used techniques were interosseous de- compression techniques and suture releases, intraosseous moulding work, correction of sphenobasilar symphysis strains (mostly lateral), vault normalization, basilar expansion, membranous reciprocal tension techniques, occipital condyles and falx cerebri normalization, myofascial release techniques, treatment of the pelvic and shoulder girdles. | | |
| Saedt 2018 | Upper cervical dysfunction | Intervention | 'only mild mobilization techniques are recommended, which focus primarily on dysfunction of the atlas (C1) in relation to C0-C2, whereas high-velocity thrust manipulation is avoided In line with recent recommendations to use techniques with a maximum of 20 N in infants, 29 Dutch MTs are trained to apply manual pressure of about 11 N instead.' | | |
| Vandenplas 2004 | Apnoea | Intervention (HLVA?) | 'the infants in the osteopathic treatment group were mainly treated with functional techniques for the specific dysfunctions found at that visit. In this group a " black box " design was chosen to meet the individuality of the child and the treatment principles of osteopathy.' | | |
| Wyatt 2011 | Cerebral palsy | Intervention (HLVA?) | 'No attempt was made to constrain the form of cranial osteopathic therapy givencranial osteopathic techniques are said to enable osteopaths to palpate and treat using very small movements and the application of small amounts of force.' | | |
| Duncan 2004 | Cerebral palsy | Intervention (HLVA?) | OMT craniosacral and myofascial release techniques. | | |
| Raith 2016 | Preterm | Intervention (HLVA?) | 'exploration of the cranial system (step 1), treatment of asymmetry (step 2), evaluation of the overlapping of the cranial bones (step 4), exploration of the balance of the membranes of the cranial and spinal dura mater (step 7), exploration and treatment of the sacrum (step 8), and exploration and treatment of the chest (step 9). After the evaluation craniosacral therapy was initiated to achieve the greatest relaxation. [Two physiotherapists involved in the study were trained to use only indirect and fluidic techniques .]' | | |

| Study ID | Condition | Reason for exclusion | Description | | | |
|--------------------|---|-------------------------|--|--|--|--|
| Studies sourced f | Studies sourced from Parnell Prevost 2019 | | | | | |
| Philippi 2006 | Postural asymmetry | Intervention (HLVA?) | 'Fine manipulative palpation techniques, which are individually adapted to tissue quality, are the hallmark of this alternative form of therapy. For the parents the difference between sham therapy and osteopathic treatment was unrecognizableFor instance, so-called primary respiration and the cranial rhythmic impulse, thought to be very fine autonomous rhythmic changes of tissue quality, were used to disengage fixations of adjoining structures.' | | | |
| Wiberg 2010 | Colic | Study design | <u>Study design</u> : 'The study was designed as a retrospective inspection of standardized infant examination records from the past 11 years (1997-2007)' <u>Intervention</u> : 'Chiropractic management, as decided by the treating doctor of chiropractic, had already been performed.' | | | |
| van Poecke 2009 | Nocturnal enuresis | Study design | Study design: 'Thirty-three consecutive records of children 3 to 18 years of age who presented with nocturnal enuresisThis study is a description of a number of consecutive clinical observations . Therefore, no control group was included.' <u>Intervention</u> : 'The chiropractic manipulation methods are based on the generation of impulse using a combination of sustained light force and high-acceleration, low-amplitude thrusts, procedures which draw their underlying principles from toggle recoil and Logan Basic techniques.' | | | |
| Miller 2009 | Difficulty breastfeeding | Study design | <u>Study design</u> : 'a series of clinical cases of sub-optimal infant breastfeeding (SIB) collected consecutively when referred to a chiropractic teaching clinic data were collected from parents, patient files, and discharge surveys. <u>Intervention</u> : 'Treatment for the biomechanical problem was aimed at releasing the area of tension, imbalance or pain producing tissue through routine low force chiropractic manual therapy .' | | | |
| Vallone 2004 | Difficulty breastfeeding | Study design | Study design: self-referral of 25 neonates to chiropractic practice when other intervention measures failed to resolve breastfeeding difficulties. All 25 received assessment + chiropractic treatment. Additional assessment of 10 successfully BF neonates without complaint. Focus was on comparing descriptive assessments of non-BF (25) vs BF infants (10). [No comparator for effectiveness of chiropractic intervention for BF] Intervention: 'Treatment consisted of manual therapies including craniosacral therapy, Logan Basic to reduce dural torque, myofascial release and massage to reduce hypertonic muscle activity and gentle manual diversified chiropractic adjustments of associated subluxated cranial bones and vertebral segments. | | | |
| Marchand 2009 | Headache | Study design | Study design: retrospective case series of 13 infants with suspected headachesThe cases were selected during a file audit of cases of infants who presented to the clinic over the last year. Outcomes were reported by the parents and were recorded verbatim. Intervention: In the cases where a biomechanical diagnosis was made (in conjunction with headache), specialized low-force chiropractic manipulation was applied to the spinal areas where tension was found. The cervical spine was implicated in all cases. | | | |

| Study ID | Condition | Reason for exclusion | Description |
|--------------------|-----------------------|----------------------|--|
| Studies sourced f | rom Parnell Prevost 2 | .019 | |
| Hayden 2003 | Low back pain | Study design | Study design: 'Prospective cohort study of consecutive pediatric patients with LBP seeing randomly selected chiropractorsmaximum of 5 consecutive cases presenting to each [no comparator].' Intervention: 'Patient management, including treatment techniques and strategies, was left to the discretion of the chiropractors.' |
| Degenhardt 2006 | Otitis media | Study design | <u>Study design</u> : 'Pilot cohort studyall subjects received weekly osteopathic structural examinations and osteopathic manipulative treatment [no comparator]'. <u>Intervention</u> : The OMT provided by the primary investigatorwas pragmatic, based on the findings of the physical examinations.' |
| Byun 2016 | Scoliosis | Study design | <u>Study design</u> : 'Five students with a Cobb angle above 10° were selected as final study participants [no comparator].' <u>Intervention</u> : 'the part of the spine that does not maintain correct alignment is identified, and the spine is adjusted with force to achieve proper alignmentpelvic and lumbar correction methods, thoracic vertebral correction techniques, cervical vertebra correction methods' |
| Lantz 2001 | Scoliosis | Study design | <u>Study design</u> : 'Cohort time-series trial with all subjects electing chiropractic care [no control].' <u>Intervention</u> : ' osseous adjustive proceduresusing the Diversified or Gonstead procedures, which included high- velocity, low-amplitude thrusts, generally employing a short lever.' |

| Study ID | Condition | Reason for exclusion | Description |
|-------------------------------------|-------------------------------|-------------------------|---|
| Studies sourced from other searches | | | |
| Holm 2018 | Colic | Intervention | 'The study is pragmatic and assesses the effect of the treatment the clinician finds indicated, rather than a standard treatment. Therefore the study does not investigate a specific manual treatment , but investigates the whole chiropractic intervention with individual attention to the children's potential biomechanical dysfunctions, as described below.' |
| Vismara 2019 | Oral feeding / prematurity | Intervention | 'osteopathic procedures were focused on the myo-fascial and connective tissues , prevalently in the following areas: cranial (cranial techniques) and occipital,10 the C1-C2-C3 areas, hyoid, sacrum, diaphragm, upper chest, scapulae, left iliac fossa and the structures connected in anatomical and physiological ways to these structures. |
| Pothmann 2018 | Headache | Intervention (HVLA?) | 'a special, one- off manual intervention .' Unable to determine if HVLA thrust applied. Only abstract in English; full-text in German. |
| Keklicek 2018 | Torticollis | Intervention | 'The study group (SG) also received STM (soft tissue mobilization techniques) three times a week. |
| Zmyslna 2019 | Postural defects | Intervention | 'The therapy employed techniques associated with the proprioceptive neuromuscular facilitation (PNF) and Vojta's approaches combination of global patterns based on Vojta's method (reflex creeping and the first phase of reflex rolling), a combination of patterns for the limbs and the shoulder and pelvic girdles according to the PNF concept' |

References

1. From Parnell Prevost 2019 (ordered A to Z)

Bek D, Yildiz C, Kose O, et al. Pronation versus supination maneuvers for the reduction of 'pulled elbow': a randomized clinical trial. Eur J Emerg Med 2009;16(3):135-8. doi: 10.1097/MEJ.0b013e32831d796a

Bramati-Castellarin I, Patel VB, Drysdale IP. Repeat-measures longitudinal study evaluating behavioural and gastrointestinal symptoms in children with autism before, during and after visceral osteopathic technique (VOT). J Bodyw Mov Ther 2016;20(3):461-70. doi: 10.1016/j.jbmt.2016.01.001

Byun S, Han D. The effect of chiropractic techniques on the Cobb angle in idiopathic scoliosis arising in adolescence. J Phys Ther Sci 2016;28(4):1106-10. doi: 10.1589/jpts.28.1106

Cabrera-Martos I, Valenza MC, Valenza-Demet G, et al. Effects of manual therapy on treatment duration and motor development in infants with severe nonsynostotic plagiocephaly: a randomised controlled pilot study. Childs Nerv Syst 2016;32(11):2211-17. doi: 10.1007/s00381-016-3200-5

Cerritelli F, Pizzolorusso G, Ciardelli F, et al. Effect of osteopathic manipulative treatment on length of stay in a population of preterm infants: a randomized controlled trial. BMC Pediatr 2013;13:65. doi: 10.1186/1471-2431-13-65

Cerritelli F, Pizzolorusso G, Renzetti C, et al. A multicenter, randomized, controlled trial of osteopathic manipulative treatment on preterms. PLoS One 2015;10(5):e0127370. doi: 10.1371/journal.pone.0127370

Degenhardt BF, Kuchera ML. Osteopathic evaluation and manipulative treatment in reducing the morbidity of otitis media: a pilot study. J Am Osteopath Assoc 2006;106(6):327-34.

Duncan B, Barton L, Edmonds D, et al. Parental perceptions of the therapeutic effect from osteopathic manipulation or acupuncture in children with spastic cerebral palsy. Clin Pediatr (Phila) 2004;43(4):349-53. doi: 10.1177/000992280404300406

Duncan B, McDonough-Means S, Worden K, et al. Effectiveness of osteopathy in the cranial field and myofascial release versus acupuncture as complementary treatment for children with spastic cerebral palsy: a pilot study. J Am Osteopath Assoc 2008;108(10):559-70.

Evans R, Haas M, Schulz C, et al. Spinal manipulation and exercise for low back pain in adolescents: a randomized trial. Pain 2018;159(7):1297-307. doi: 10.1097/j.pain.00000000001211

Garcia-Mata S, Hidalgo-Ovejero A. Efficacy of reduction maneuvers for "pulled elbow" in children: a prospective study of 115 cases. J Pediatr Orthop 2014;34(4):432-6. doi: 10.1097/BPO.00000000000130

Guiney PA, Chou R, Vianna A, et al. Effects of osteopathic manipulative treatment on pediatric patients with asthma: a randomized controlled trial. J Am Osteopath Assoc 2005;105(1):7-12.

Hasler C, Schmid C, Enggist A, et al. No effect of osteopathic treatment on trunk morphology and spine flexibility in young women with adolescent idiopathic scoliosis. J Child Orthop 2010;4(3):219-26. doi: 10.1007/s11832-010-0258-6

Hayden C, Mullinger B. A preliminary assessment of the impact of cranial osteopathy for the relief of infantile colic. Complement Ther Clin Pract 2006;12(2):83-90. doi: 10.1016/j.ctcp.2005.12.005

Hayden JA, Mior SA, Verhoef MJ. Evaluation of chiropractic management of pediatric patients with low back pain: a prospective cohort study. J Manipulative Physiol Ther 2003;26(1):1-8. doi: 10.1067/mmt.2003.11

Jennings J, Davies GJ. Treatment of cuboid syndrome secondary to lateral ankle sprains: a case series. J Orthop Sports Phys Ther 2005;35(7):409-15. doi: 10.2519/jospt.2005.35.7.409

Khorshid K, Sweat R, Zemba D, et al. Clinical efficacy of upper cervical versus full spine chiropractic care on children with autism: a randomized clinical trial. J Vertebral Subluxation Res 2006:1-7.

Lantz CA, Chen J. Effect of chiropractic intervention on small scoliotic curves in younger subjects: a time-series cohort design. J Manipulative Physiol Ther 2001;24(6):385-93. doi: 10.1067/mmt.2001.116419

Lessard S, Gagnon I, Trottier N. Exploring the impact of osteopathic treatment on cranial asymmetries associated with nonsynostotic plagiocephaly in infants. Complement Ther Clin Pract 2011;17(4):193-8. doi: 10.1016/j.ctcp.2011.02.001

Marchand AM, Miller JE, Mitchell C. Diagnosis and chiropractic treatment of infant headache based on behavioral presentation and physical findings: a retrospective series of 13 cases. J Manipulative Physiol Ther 2009;32(8):682-6. doi: 10.1016/j.jmpt.2009.08.026

Miller JE, Miller L, Sulesund AK, et al. Contribution of chiropractic therapy to resolving suboptimal breastfeeding: a case series of 114 infants. J Manipulative Physiol Ther 2009;32(8):670-4. doi: 10.1016/j.jmpt.2009.08.023

Miller JE, Newell D, Bolton JE. Efficacy of chiropractic manual therapy on infant colic: a pragmatic single-blind, randomized controlled trial. J Manipulative Physiol Ther 2012;35(8):600-7. doi: 10.1016/j.jmpt.2012.09.010

Mills MV, Henley CE, Barnes LL, et al. The use of osteopathic manipulative treatment as adjuvant therapy in children with recurrent acute otitis media. Arch Pediatr Adolesc Med 2003;157(9):861-6. doi: 10.1001/archpedi.157.9.861

Monaco A, Cozzolino V, Cattaneo R, et al. Osteopathic manipulative treatment (OMT) effects on mandibular kinetics: kinesiographic study. Eur J Paediatr Dent 2008;9(1):37-42.

Morningstar MW, Woggon D, Lawrence G. Scoliosis treatment using a combination of manipulative and rehabilitative therapy: a retrospective case series. BMC Musculoskelet Disord 2004;5:32. doi: 10.1186/1471-2474-5-32

Nemett DR, Fivush BA, Mathews R, et al. A randomized controlled trial of the effectiveness of osteopathy-based manual physical therapy in treating pediatric dysfunctional voiding. J Pediatr Urol 2008;4(2):100-6. doi: 10.1016/j.jpurol.2007.11.006

Nilgun B, Suat E, Engin SI, et al. Short-term results of intensive physiotherapy in clubfoot deformity treated with the Ponseti method. Pediatr Int 2011;53(3):381-5. doi: 10.1111/j.1442-200X.2010.03243.x

Philippi H, Faldum A, Schleupen A, et al. Infantile postural asymmetry and osteopathic treatment: a randomized therapeutic trial. Dev Med Child Neurol 2006;48(1):5-9; discussion 4. doi: 10.1017/S001216220600003X

Pizzolorusso G, Cerritelli F, Accorsi A, et al. The Effect of Optimally Timed Osteopathic Manipulative Treatment on Length of Hospital Stay in Moderate and Late Preterm Infants: Results from a RCT. Evid Based Complement Alternat Med 2014;2014:243539. doi: 10.1155/2014/243539

Przekop P, Przekop A, Haviland MG. Multimodal compared to pharmacologic treatments for chronic tension-type headache in adolescents. J Bodyw Mov Ther 2016;20(4):715-21. doi: 10.1016/j.jbmt.2015.02.003

Raith W, Marschik PB, Sommer C, et al. General Movements in preterm infants undergoing craniosacral therapy: a randomised controlled pilot-trial. BMC Complement Altern Med 2016;16:12. doi: 10.1186/s12906-016-0984-5

Rowe DE, Feise RJ, Crowther ER, et al. Chiropractic manipulation in adolescent idiopathic scoliosis: a pilot study. Chiropr Osteopat 2006;14:15. doi: 10.1186/1746-1340-14-15

Saedt E, Driehuis F, Hoogeboom TJ, et al. Common Manual Therapy Practices in the Netherlands for Infants With Upper Cervical Dysfunction: A Prospective Cohort Study. J Manipulative Physiol Ther 2018;41(1):52-61. doi: 10.1016/j.jmpt.2017.08.003

Selhorst M, Selhorst B. Lumbar manipulation and exercise for the treatment of acute low back pain in adolescents: a randomized controlled trial. J Man Manip Ther 2015;23(4):226-33. doi: 10.1179/2042618614Y.000000099

Steele KM, Carreiro JE, Viola JH, et al. Effect of osteopathic manipulative treatment on middle ear effusion following acute otitis media in young children: a pilot study. J Am Osteopath Assoc 2014;114(6):436-47. doi: 10.7556/jaoa.2014.094

Tarsuslu T, Bol H, Simsek IE, et al. The effects of osteopathic treatment on constipation in children with cerebral palsy: a pilot study. J Manipulative Physiol Ther 2009;32(8):648-53. doi: 10.1016/j.jmpt.2009.08.016

Vallone S. Chiropractic evaluation and treatment of musculoskeletal dysfunction in infants demonstrating difficulty breastfeeding. J Clin Chiropr Ped 2004;6(1):349–68.

van Poecke AJ, Cunliffe C. Chiropractic treatment for primary nocturnal enuresis: a case series of 33 consecutive patients. J Manipulative Physiol Ther 2009;32(8):675-81. doi: 10.1016/j.jmpt.2009.08.019

Vandenplas Y, Denayer E, Vandenbossche T, et al. Osteopathy may decrease obstructive apnea in infants: a pilot study. Osteopath Med Prim Care 2008;2:8. doi: 10.1186/1750-4732-2-8

Wahl RA, Aldous MB, Worden KA, et al. Echinacea purpurea and osteopathic manipulative treatment in children with recurrent otitis media: a randomized controlled trial. BMC Complement Altern Med 2008;8:56. doi: 10.1186/1472-6882-8-56

Walston Z, Yake D. Lumbar Thrust Manipulation and Exercise for the Treatment of Mechanical Low Back Pain in Adolescents: A Case Series. J Orthop Sports Phys Ther 2016;46(5):391-8. doi: 10.2519/jospt.2016.6366

Wiberg KR, Wiberg JM. A retrospective study of chiropractic treatment of 276 danish infants with infantile colic. J Manipulative Physiol Ther 2010;33(7):536-41. doi: 10.1016/j.jmpt.2010.08.004

Wyatt K, Edwards V, Franck L, et al. Cranial osteopathy for children with cerebral palsy: a randomised controlled trial. Arch Dis Child 2011;96(6):505-12. doi: 10.1136/adc.2010.199877

Zhang J, Snyder B. Effect of the Toftness chiropractic adjustments for children with acute otitis media. J Vertebral Sublux Res 2004:1-4.

2. From other searches (ordered A to Z)

Holm LV, Jarbol DE, Christensen HW, et al. The effect of chiropractic treatment on infantile colic: study protocol for a single-blind randomized controlled trial. Chiropr Man Therap 2018;26:17. doi: 10.1186/s12998-018-0188-9

Keklicek H, Uygur F. A randomized controlled study on the efficiency of soft tissue mobilization in babies with congenital muscular torticollis. J Back Musculoskelet Rehabil 2018;31(2):315-21. doi: 10.3233/BMR-169746

Pothmann R, Koch LE, Wiegand G, et al. Headache in children with cervical components: Comparative study of oneoff manual intervention and a self-help home program. Manuelle Medizin 2018;56(2):162-69. doi: 10.1007/s00337-017-0365-2

Vismara L, Manzotti A, Tarantino AG, et al. Timing of oral feeding changes in premature infants who underwent osteopathic manipulative treatment. Complement Ther Med 2019;43:49-52. doi: 10.1016/j.ctim.2019.01.003

Zmyslna A, Kiebzak W, Zurawski A, et al. Effect of physiotherapy on spinal alignment in children with postural defects. Int J Occup Med Environ Health 2019;32(1):25-32. doi: 10.13075/ijomeh.1896.01314

Appendix 4 – ROBIS assessment of Driehuis 2019

Summary of assessment for each domain

| Concerns regarding specification of study eligibility criteria | LOW | The review was pre-registered. Eligibility criteria are comprehensive, unambiguous and there are no important restrictions likely to bias the findings of the review. |
|--|-----|--|
| Concerns regarding methods used to identify and/or select studies | LOW | The search appears sufficiently comprehensive that it is unlikely that important studies will have been missed. Searching a trials register may have ensured no incompletely reported or ongoing trials were missed. |
| Concerns regarding methods used to collect data and appraise studies | LOW | The data in many of the included studies is challenging to extract, with multiple outcomes, measures and time points, and hence there is potential for error because a single author extracted data. Although this is the case, the review authors' interpretation is cautious, and the certainty of evidence is low, hence concerns on this domain were rated as low since they were unlikely to alter the conclusions of the review. As noted by the review authors, the limited description of interventions in primary studies hampers interpretation of findings. |
| Concerns regarding synthesis and findings | LOW | Studies are grouped for synthesis according to the pre- specified plan for the review and all relevant studies are included in the synthesis. Analysis methods are appropriate, and biases are addressed in the synthesis. The only concern is that the authors have downgraded findings from single studies for inconsistency, which is contrary to GRADE guidance. In most instances, other concerns would lead to an equivalent or similar downgrading, however there is a possibility that the reported GRADE may be lower than necessary for some conditions. |

Describe whether conclusions were supported by the evidence:

| Overall, the review is judged to | o be of sound methodological quality. | |
|--|---|-----|
| Did the interpretation of findings address all of the concerns identified in Domains 1 to 4? | The review conclusions are appropriately cautious, and the evidence uncertain. For this reason is it is unlikely that any of the identified concerns are likely to change the conclusions of the review. | Yes |
| Was the relevance of identified studies to the review's research question appropriately considered? | Study characteristics were carefully considered in the review and conclusions (including in GRADEing the evidence). The authors note that there is insufficient description of interventions in primary studies, which poses a challenge for interpretation of findings. | Yes |
| Did the review authors avoid emphasising results on the basis of their statistical significance? | The authors appear to have avoided emphasising results based on statistical significance (i.e. highlighting results that were statistically significant over those that were not). | Yes |
| | Although not a bias, most results are reported as summary statistics for each treatment group. This makes the results more challenging to interpret and GRADE than if effect estimates and the precision of each estimate had been calculated (e.g. the difference in pain scores between the intervention and control groups). | |
| Overall risk of bias | | LOW |

Detailed assessment for each domain

Y=yes; PY=probably yes; N=no; PN=probably no; NI=no information

DOMAIN 1: STUDY ELIGIBILITY CRITERIA

| 1.1 Did the review adhere to pre-defined objectives and eligibility criteria? | Y/ <mark>PY</mark> /PN/N/NI |
|---|-----------------------------|
| The protocol was registered on PROSPERO; however, there is very little description of the planned methods. In contrast, the PICO criteria are comprehensively specified in the review which means that changes were made at some stage after registration of the review. It is likely that the PICO elements were specified in more detail during the review process, rather than changed in a way that might alter inclusion or synthesis decisions. For a review of this breadth, it is unlikely that the authors narrowed or broadened their criteria in a way that would alter the findings of the review. | , <u> </u> |
| 1.2 Were the eligibility criteria appropriate for the review question? The criteria seem appropriate and a clear rationale is provided for the way in which intervention techniques, population age groups, outcomes (effectiveness, harms), and study designs would be handled. <u>Excluded population</u>: studies that included both adults and children without stratification by age group (add file 1) <u>Exclude intervention</u>: Manual therapies with the primary focus on manipulating fractures (orthopedics), multiple body parts, extremities, fasciae, soft tissue, nervous system. (add file 1) Broader study design criteria were applied to the review of harms (including observational descriptive and case report studies), compared to effectiveness (controlled studies only) which is appropriate. | <mark>Y</mark> /PY/PN/N/NI |
| 1.3 Were eligibility criteria unambiguous? The eligibility criteria are clearly specified in the review for the purpose of determining study eligibility, but also for deciding how different intervention techniques, population groups (age), and outcomes would be handled in the synthesis. | <mark>Y</mark> /PY/PN/N/NI |
| 1.4 Were all restrictions in eligibility criteria based on study characteristics appropriate (e.g. date, sample size, study quality, outcomes measured)? There were no restrictions based on sample size or study quality. Note, only outcome data on harms were extracted from studies using an observational descriptive and case report design (which is appropriate, as indicated above). | <mark>y</mark> /py/pn/n/ni |
| 1.5 Were any restrictions in eligibility criteria based on sources of information appropriate (e.g. publication status or format, language, availability of data)? The review authors did not report any restrictions based on publications status (but only published studies, so this is likely) or availability of data. Excluded languages. Studies not published in English, Dutch or German (add file 1) | Y/ <mark>PY</mark> /PN/N/NI |
| Concerns regarding specification of study eligibility criteria | LOW/HIGH/ UNCLEAR |
| Rationale for concern: | |

DOMAIN 2: IDENTIFICATION AND SELECTION OF STUDIES

| Describe methods of study identification and selection (e.g. number of reviewers involved): | |
|--|------------------------------------|
| 2.1 Did the search include an appropriate range of databases/electronic sources for published and unpublished reports? | Y/ <mark>PY</mark> /PN/N/N |
| • PubMed, Index to Chiropractic Literature, Embase, CINAHL and Cochrane Library. | |
| • No indication that the authors searched a trials register for unpublished or ongoing trials | |
| (which would be helpful for assessing reporting bias). | |
| 2.2 Were methods additional to database searching used to identify relevant reports? | <mark>y</mark> /py/pn/n/n |
| • Reference lists of included articles (p3) and identified systematic reviews ("systematic reviews | |
| were not included, but studies embedded in these reviews were" add file 1). | |
| 2.3 Were the terms and structure of the search strategy likely to retrieve as many eligible studies as possible? | Y/ <mark>PY</mark> /PN/N/N |
| Terms seem complete. There is one study in the SCV review which is not mentioned in either the list of included or excluded studies (Sawyer 1998). | |
| 2.4 Were restrictions based on date, publication format, or language appropriate? | Y/ <mark>PY</mark> /PN/N/N |
| • Language. There were some language restrictions, but this is common practice, and studies in | |
| some languages other than English were eligible. | |
| • <u>Date</u> . It appears that there were no restrictions by date, but this is not completely clear since | |
| the start date for searches/inclusion appears not to be reported. | |
| • <u>Publication format</u> . It is unclear whether grey literature was eligible; however, the authors | |
| contacted study authors for further information (e.g. authors of the Bronfort et al study were | |
| contacted to request data for the comparator group). | |
| 2.5 Were efforts made to minimise error in selection of studies? | Y/ <mark>PY</mark> /PN/N/N |
| One author screened abstracts. Two independently screened full text. There is always a risk that studies may be missed when one author screens (depending on experience). However, for the effectiveness question, the authors appear to have identified a similar set of studies to that identified for the SCV review, so it is unlikely that important studies were missed. | |
| Concerns regarding specification of study eligibility criteria | <mark>LOW/</mark> HIGH, UNCLEAF |
| Rationale for concern: | |
| The search appears sufficiently comprehensive that it is unlikely that important studies will have | |
| been missed. Searching a trials register may have ensured no incompletely reported or ongoing trials | |
| were missed. | |

DOMAIN 3: DATA COLLECTION AND STUDY APPRAISAL

| Describe methods of data collection, what data were extracted from studies or collected through | |
|---|-----------------------------|
| other means, how risk of bias was assessed (e.g. number of reviewers involved) and the tool used to assess risk of bias: | |
| 3.1 Were efforts made to minimise error in data collection? | Y/PY/ <mark>PN</mark> /N/NI |
| • A single author extracted data, with checks of a random sample of eight studies by a second author. There is some risk of error without a second author checking all data, although less so if the author is experienced. | |
| <i>3.2 Were sufficient study characteristics available for both review authors and readers to be able to interpret the results?</i> | Y/PY/ <mark>PN</mark> /N/NI |
| The review authors have reported adequately (i.e. study PICO, risk of bias etc reported in tables and text). However, the review authors identify important gaps in the description of the interventions in the included studies (extract below). While not a limitation of the review methods (and not something that can be overcome by the review authors), item 3.2 requires judgement of whether the characteristics reported in primary studies were adequate for interpretation of findings. Given the review authors' description below, this appear not to be the case. | |
| "We would like to highlight that for adequate interpretation it is of great importance that studies provide a detailed description of the SMT technique performed. <i>Important information regarding</i> <i>the specific treatment technique was often omitted from publications. As a consequence, it is</i> <i>challenging (or even impossible) for researchers and, maybe more importantly, healthcare</i> <i>professionals to interpret study findings and draw scientifically substantiated conclusions about</i> <i>effective treatment techniques.</i> As such, this will hamper translation of study findings to clinical practice." (p16) | |
| 3.3 Were all relevant study results collected for use in the synthesis? | Y/ <mark>PY</mark> /PN/N/NI |
| In at least some circumstances, the authors appear to have requested data from primary study authors where the data were not available in the included paper. | |
| 3.4 Was risk of bias (or methodological quality) formally assessed using appropriate criteria? | <mark>Y</mark> /PY/PN/N/NI |
| Appropriate risk of bias tools were used for all study designs, and the assessments are completely reported (additional file 3). | |
| 3.5 Were efforts made to minimise error in risk of bias assessment? | <mark>Y/</mark> PY/PN/N/NI |
| Two authors independently assessed risk of bias. | |
| | |
| Concerns regarding methods used to collect data and appraise studies | LOW/HIGH/ UNCLEAR |
| Rationale for concern: | |
| The data in many of the included studies is challenging to extract, with multiple outcomes, measures and time points, and hence there is potential for error because a single author extracted data. Although this is the case, the review authors' interpretation is cautious, and the certainty of evidence is low, hence concerns on this domain were rated as low since they were unlikely to alter the | |
| conclusions of the review. As noted by the review authors, the limited description of interventions in primary studies hampers interpretation of findings. | |

DOMAIN 4: SYNTHESIS AND FINDINGS

| 4.1 Did the synthesis include all studies that it should? | Y/ <mark>PY</mark> /PN/N/N |
|---|---------------------------------|
| (see note re. item 4.3) | 1/ <mark>1 1</mark> /1 10/10/10 |
| 4.2 Were all pre-defined analyses reported or departures explained? | Y/ <mark>PY</mark> /PN/N/N |
| The analyses appear consistent with the protocol, which describes how studies will be grouped for analysis. The planned statistical methods are not described in the protocol; however, the methods used reflect standard practice and the analyses are limited to one condition, which is consistent with available data and hence does not raise concern. | |
| 4.3 Was the synthesis appropriate given the nature and similarity in the research questions, study designs and outcomes across included studies? | Y/ <mark>PY</mark> /PN/N/N |
| • With the exception of one condition (colic, 4 studies), all conclusions are based on single studies (i.e. not meta-analysis), so this item is only relevant for findings for colic. The authors judged that the comparators used were too different to pool all four studies, so decided to pool only the two studies with a sham or no intervention comparator. This is acceptable. | |
| 4.4 Was between-study variation (heterogeneity) minimal or addressed in the synthesis? | Y/PY/PN/ <mark>N</mark> /N |
| With the exception of one condition (colic), all conclusions are based on results from single studies, so this item is only relevant for findings for colic. The authors report heterogeneity statistics and considered inconsistency when drawing conclusions, which is appropriate. For results for conditions other than colic, the authors downgraded the certainty of evidence from single studies for 'very serious inconsistency'. This is contrary to GRADE guidance which advises not to downgrade single studies for inconsistency. | |
| 4.5 Were the findings robust, e.g. as demonstrated through funnel plot or sensitivity analyses? | Y/PY/PN/N/ <mark>N</mark> |
| Insufficient data to do these analyses. Reporting bias may be a concern in these studies, but cannot be assessed from the data available to the review authors. | |
| 4.6 Were biases in primary studies minimal or addressed in the synthesis? | <mark>Y</mark> /PY/PN/N/N |
| The risk of bias was assessed for each study, reported in tables, and considered in the GRADE assessment of the certainty of the evidence. The certainty of evidence was reported in all relevant places in the review, including the abstract. | |
| Concerns regarding the synthesis and findings | LOW/HIGH UNCLEA |
| Rationale for concern: | |
| Studies are grouped for synthesis according to the pre-specified plan for the review and all relevant studies are included in the synthesis. Analysis methods are appropriate, and biases are addressed in the synthesis. The only concern is that the authors have downgraded findings from single studies for inconsistency, which his contrary to GRADE guidance. In most instances, other concerns would lead to an equivalent or similar downgrading, however there is a possibility that the reported GRADE may be lower than necessary for some conditions. | |

Appendix 5 – Intervention description table for effectiveness studies

| Author/ year | Description of intervention/ technique | Description of comparator | |
|--|--|---|--|
| 2008 neonates and appropriate to the age of the patient as indicated chirc Colic on examination the in are c district cranit cranit | | Two weeks of occipital-sacral decompression is a chiropractic paediatric technique for infants. With the infant supine the occiput and the sacral base are contacted simultaneously and gentle distraction is applied for up to 30 s. It is not a cranial technique but rather a technique that affords gentle spinal distraction. | |
| Olafsdottir 2001 Colic | Palpation of the infant's spinal articulations with respect to areas of dysfunction. Dysfunctional articulations were manipulated and mobilised using light fingertip pressure. The treatment was given three times, at intervals of two to five days, for a period of eight days. | Infants were held by the nurse for 10 minutes (the approximate time of treatment) after being partially undressed in a similar way as treated infants. | |
| Wiberg 1999 Colic | Physical examination performed, including motion palpation of the articulations of vertebral column and pelvis. Those articulations found to be restricted in movement were manipulated /mobilized with specific light pressure with the fingertips for a period of up to 2 weeks (3 to 5 treatment sessions) until normal mobility was found in the involved segments. | Dimethicone daily for 2 weeks as prescribed in the Danish PDR. | |
| Reed 1994 Enuresis | Patients with spinal subluxation were adjusted utilizing a high velocity, short lever thrust. Two 5th year chiropractic students performed the adjustments consistent with Palmer Package Adjusting Technique under the direct supervision and assistance of two clinical faculty. | The sham adjustment consisted of using an Activator at nontension setting administered to the examiner's own underlying contact point (i.e., thumb/finger) over the thoracic area. | |
| Dissing 2018 Back/neck pain | High-velocity, low -amplitude manipulation and/or mobilisation of the joints to restore segmental spinal motion, delivered at the discretion of the chiropractor. | Pragmatic advice (activity level, ergonomics, cold packs, etc); Exercises (stretching and/or strengthening exercises); Soft-tissue treatment (manual trigger point therapy or massage) | |
| Borusiak 2010 Headache | Patients were lying on the side and a cervical high-velocity , low-amplitude lateral directed manipulation without rotation or extension was performed. Forces of this intervention are known and vary from 50 Nm in newborns and infants to 350 Nm in adults. | Light touch of specific spinal segments so that the placebo treatment was identical to the active treatment except for the low-amplitude, high- velocity thrust, given the impression of a cervica manipulation that however was not directed to correct the assumed cervical blockage. | |
| 2001carried out with the patient placed on a chiropractic treatment table with separate cushion sections for the cervical, thoracic, and lumbar spine. Drop mechanisms are built into these sections, enabling them to be quickly released and lowered 2 to 3 cm when the force from the manual treatment exceeds a certain preset level according to the weight of the patient. This technique is used to facilitate and accentuate the specific manual treatment. The manual spinal thrusting technique received light manual contact to th no manipulative thrust. The sham t consisted of gentle manual pressur contact point with one hand, while hand pushed on the drop section w purpose of releasing it. As a result of procedure, the patient experienced momentary change in position of the | | Patients in the sham manipulation group received light manual contact to the spine with no manipulative thrust. The sham treatment consisted of gentle manual pressure over a spinal contact point with one hand, while the other hand pushed on the drop section with the purpose of releasing it. As a result of this procedure, the patient experienced a rapid, momentary change in position of the spinal section under influence, similar to an active treatment. | |
| Balon 1999 Asthma | The specifics of treatment for each subject (vertebral segments treated, direction and type of manipulation, and use of soft-tissue therapy) were determined by the treating chiropractor. All the chiropractors used the diversified technique in common use in Canada and the United States, which involves manual contact with spinal or pelvic joints followed by a low-amplitude, high-velocity directional push often associated with joint opening, creating a cavitation, or "pop". | A distraction maneuver was performed by turning the subject's head from one side to the other while alternately palpating the ankles and feet. The subject was positioned on one side, a nondirectional push, or impulse, was applied to the gluteal region, and the procedure was repeated with the subject positioned on the other side; then the subject was placed in the prone position, and a similar impulse was applied | |

| Author/ year | Description of intervention/ technique | Description of comparator | |
|---------------------------------------|---|---|--|
| | The subjects visited the selected chiropractor three times weekly for four weeks, twice weekly for four weeks, then weekly for eight weeks, with each subject required to receive between 20 and 36 treatments during the four-month study. | bilaterally to the scapulae. The subject was then placed supine, with the head rotated slightly to each side, and an impulse applied to the external occipital protuberance. Low-amplitude, low- velocity impulses were applied in all these nontherapeutic contacts, with adequate joint slack so that no joint opening or cavitation occurred. | |
| Sawyer 1999 Otitis media | SMT was applied to the full spine, with emphasis on the upper cervical area. The areas treated were determined by the clinician using manual static and motion palpation. Treatment consisted of low-amplitude, high-velocity manual spinal manipulation applied to specific spinal segments. | Manual static and motion palpation and light touch of specific spinal segments so that the placebo treatment was identical to the active treatment except for the low-amplitude, high- velocity thrust. | |
| Kachmar 2018 Cerebral palsy | Average duration of SM was ~ 5 minutes. Thoracic manipulation was performed in prone position by applying postero-anterior pressure to take up the slack along with a counterclockwise rotation force driving the right hand away from the left. High-velocity, low-amplitude thrust was then applied in the vertical direction while the participant exhaled. Lumbar spine manipulation was performed in lateral recumbent position with the upper leg flexed at the hip and knee, the lower leg straight, and lumbar spine placed in slight extension. Joint pretension produced by the rotational force was applied to the shoulder and thigh. High-velocity, low-amplitude thrust was delivered, targeting the facet joints in a posterior to anterior direction. Cervical spine manipulation was conducted in a seated position with the head flexed sideways and slightly rotated and the weight of the head supported by the practitioner's hand. Traction and side-bending force were employed, and when the slack was taken out and this premanipulation position was determined to be comfortable, a high-velocity, low-amplitude thrust was applied. Lumbar and cervical manipulations were performed symmetrically on both right and left side. | Participants were placed in the same positions and performing movements identical to those performed during SM, but without applying substantial force. | |
| Accorsi 2014 Hyper- activity | OMT techniques were chosen according to each participant's needs, as well as the physical condition and age of the participant. Manipulative techniques used included myofascial release, craniosacral, balanced ligamentous tension, and balanced membranous tension. The sequence and dose of OMT techniques were left to the discretion of the osteopaths and not based on a predetermined protocol. Participants allocated to the intervention group received six 40-minute OMTh sessions. Conventional care, including drug therapy and psychosocial interventions. | Conventional care, including drug therapy and psychosocial interventions. | |
| Giesen 1989 Hyper- activity | Light but specific high-velocity, low-amplitude thrusts for the correction of chiropractic intervertebral subluxation complexes. All were treated by standard diversified and Gonstead techniques, with the intervention selective for the specific spinal dysarthrias detected by examination. | Placebo treatment at baseline using nonspecific contact points and avoidance of specific spinal dysarthrias. Use of mechanical device to make 'popping' sound. Same "gentle touch" before and after treatment as received during actual intervention. | |
| Haugen 2011 Torticollis | Manipulation is conducted with the child supine and the head in neutral position, without extension of any structures. Only very moderate force is used. Child physiotherapy (see comparator description). | Child physiotherapy. The primary health care physiotherapists who followed up the children at home were instructed not to stretch the neck against resistance from the child. The main focus was encouragement of symmetrical motor performance through a variety of methods. | |

Appendix 6 – Excluded studies – Safety review

| Study ID | Condition | Reason | Description |
|-----------------------------|------------------|--------------------|--|
| Studies sourced from Tode | d 2015 | | |
| Alcantara 2006 | All | Intervention | Unable to track down publication despite extensive search. Abstract of conference presentation, likely a duplicate of Alcantara 2007 (below) |
| Alcantara 2007 (54) | All | Intervention | SMT undefined |
| Hayes 2006 (55) | All | Age | HVLA only used in adolescents |
| Held 1966 (56) | | Language | Published in French |
| Holla 2009 (57) | Unclear | Intervention | Forced, held, flexion of entire vertebral column |
| Marchand 2012 (58) | All | Intervention | Does not describe technique but does describe practitioner survey results re type of treatment appropriate for age |
| Miller 2008 (59) | All | Intervention | Paediatric SMT undefined |
| Philippi 2006 (60) | Posture | Intervention | Tissue and fascial release to cranial and dural connections |
| Rageot 1968 (61) | | Language | Published in German |
| Rowe 2006 (62) | Scoliosis | Age | 6 cases, only 1 under 12 years old, not individually reported |
| Shafrir 1992 (63) | Torticollis | Intervention | Manipulation that included flexion, extension, axial loading and unloading |
| Simonian 1995 (64) | Unclear | Intervention | High velocity long lever thrusts of legs for leg contractures |
| Struewer 2013 (65) | | Age | 17 years |
| Wilson 2012 (66) | | Intervention | Infant held upside down grasping firmly around rib cage in assessment. Activator instrument applied to thoracic spine. |
| Zimmerman 1978 (67) | Headache | Intervention | Rapid manual rotations of the head from side to side with flexion and hyperextension |
| Ziv 1983 (68) | Headache | Intervention | Chiropractic treatment not defined |
| Full-text studies sourced f | rom database sea | arches (2014-2019) | |
| Adams 2014 (69) | All | Intervention | Survey to explore CAM use, not limited to manual therapy but 27% had used chiropractic. No information re technique. |
| Bodensteiner 2014 (70) | All | Commentary | Editorial comment on Deputy 2014 |
| Botelho 2012 (71) | All | Age | 18 years |
| Brurberg 2009 (72) | All | Review | Review |
| Deputy 2014 (49) | Sinusitis | Intervention | 'Some degree of spinal manipulation of the neck' reported by caregiver 6 months post-treatment without referral to chiropractor records |
| Doyle 2016 (73) | All | Commentary | Commentary |
| Hawk 2016 (74) | All | Review | Consensus guideline/review |
| Jevne 2014 (75) | All | Age | Age range 11 to 80 years |
| Smith 2019 (76) | All | Commentary | Editorial on adults, with small section on children |
| Swait 2017 (77) | All | Review | Scoping review |
| Tuchin 2014 (78) | All | Age | Adults (range 34 to 54 years) |

Appendix 7 – Search strategies for coccygeal manipulation

PubMed

((((coccyx[Mesh] OR coccyx OR coccygeal OR coccydynia OR coccygodynia) AND (Musculoskeletal Manipulations[Mesh] OR chiropract* OR manipulat* OR manual OR conservative OR adjust*) AND (Child[Mesh] OR Infant[Mesh] OR child OR children OR infant OR infants OR newborn* OR neonates OR baby OR babies OR paediatric OR pediatric OR adolescent*))))

Index to Chiropractic Literature (ICL)

coccyx OR coccygeal OR coccydynia OR coccygodynia

Cochrane Central Register of Controlled Trials

Issue No 6, Jun 2019

| # | Search Statement | Results |
|---|--|---------|
| 1 | MeSH descriptor: [Coccyx] explode all trees | 5 |
| 2 | (coccyx OR coccygeal OR coccydynia OR coccygodynia):ti,ab,kw | 73 |
| 3 | #1 OR #2 | 73 |
| 4 | MeSH descriptor: [Infant] explode all trees | 15368 |
| 5 | MeSH descriptor: [Child] explode all trees | 1170 |
| 6 | MeSH descriptor: [Adolescent] explode all trees | 99786 |
| 7 | (child OR children OR infant OR infants OR newborn* OR neonate* OR baby OR babies OR paediatric OR pediatric OR young OR adolescent*):ti,ab,kw | 303908 |
| 8 | #4 OR #5 OR #6 OR #7 | 303908 |
| 9 | #3 AND #8 | 6 |

Embase

Embase <1974 to 2019 May 24>

| # | Search Statement | Results |
|----|---|---------|
| 1 | coccyx/ | 262 |
| 2 | coccygeal vertebra/ | 138 |
| 3 | (coccyx or coccygeal or coccydynia or coccygodynia).ti,ab. | 2405 |
| 4 | or/1-3 | 2595 |
| 5 | exp musculoskeletal manipulation/ | 2963 |
| 6 | (chiropract\$ or manipulate\$ or manual or conservative or adjust\$).ti,ab. | 1212287 |
| 7 | or/5-6 | 1213371 |
| 8 | 4 and 7 | 224 |
| 9 | Infant/ | 555065 |
| 10 | Child/ | 1582464 |
| 11 | (child or children or infant or infants or newborn\$ or neonate\$ or baby or babies | 2600300 |
| | or paediatric or pediatric or young or adolescent\$).ti,ab. | |
| 12 | or/9-11 | 3233365 |
| 13 | 8 and 12 | 16 |

AMED (Allied and Complementary Medicine)

| AMED | <1985 to | May | ,2019> |
|------|----------|-----|--------|
| AMED | ~1303 [0 | May | 2013- |

| # | Search Statement | Results |
|----|--|---------|
| 1 | (coccyx or coccygeal or coccydynia or coccygodynia).ti,ab. | 31 |
| 2 | exp musculoskeletal manipulations/ | 5733 |
| 3 | (chiropract\$ or manipulate\$ or manual or conservative or adjust\$).ti,ab. | 16933 |
| 4 | or/2-3 | 20868 |
| 5 | 1 and 4 | 13 |
| 6 | exp Infant/ | 2058 |
| 7 | Child/ | 16644 |
| 8 | Adolescent/ | 5132 |
| 9 | (child or children or infant or infants or newborn\$ or neonate\$ or baby or babies or paediatric or pediatric or young or adolescent\$).ti,ab. | 25687 |
| 10 | or/6-9 | 31382 |
| 11 | 5 and 10 | 3 |

CINAHL

Search run on 28 May 2019

| S11 | S7 AND S10 | 4 |
|-----|---|---------|
| S10 | S8 OR S9 | 859,873 |
| S9 | TI (child OR children OR infant OR infants OR newborn* OR neonate* OR | 638,776 |
| | baby OR babies OR paediatric OR pediatric OR young OR adolescent*) OR | |
| | AB (child OR children OR infant OR infants OR newborn* OR neonate* OR | |
| | baby OR babies OR paediatric OR pediatric OR young OR adolescent*) | |
| S8 | (MH "Child+") | 577,135 |
| S7 | S3 AND S6 | 46 |
| S6 | S4 OR S5 | 385 |
| S5 | TI (coccyx OR coccygeal OR coccydynia OR coccygodynia) OR AB (| 302 |
| | coccyx OR coccygeal OR coccydynia OR coccygodynia) | |
| S4 | (MH "Coccyx") | 203 |
| S3 | S1 OR S2 | 233,510 |
| S2 | TI (manipulat* or adjust* or manual* or chiropract*) OR AB (manipulat* | 223,515 |
| | or adjust* or manual* or chiropract*) | |
| S1 | (MH "Chiropractic+") OR (MH "Manipulation, Orthopedic") OR (MH | 20,397 |
| | "Manipulation, Osteopathic") | |
| | | |

Scopus

(TITLE-ABS KEY (chiropract* OR manipulat* OR manual OR conservative OR adjust*)) AND ((TITLE-ABS-KEY (coccyx OR coccygeal OR coccydynia OR coccygodynia)) AND (TITLE-ABS-KEY (child OR children OR infant OR infants))

