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Author response to Eric Saedt "Spinal mobilization in infants reconsidered"

KEYWORDS Spinal; manipulation; mobilisation; infants; children; adolescents

COMMENT 1. The conclusion to advice against spinal mobilisation in infants is debatable. The symptoms mentioned, such as redness of the face, perspiration, reflux, and temporary apnoea are not life-threatening and can be explained as normal, vegetative responses. Spinal mobilisation in infants is a safe treatment technique.

COMMENT 1 RESPONSE:

We argue that vegetative responses are not 'normal'. Our concern, as mentioned in our report, was that the vegetative responses – apnea, flushing, sweating, opisthotonus muscle contraction, loss of muscle-tension, vomiting – are red flags. They are common with mobilization [1,2]. They parallel those reported in sudden infant death (SID) [3,4]. Are these normal or signs of a near miss, that is, of evoking a SID? Why take the risk (risk rate remains unclear but risk is present nevertheless) when there are alternative treatments? The taskforce strongly recommends that researchers adhere to guidelines for reporting adverse events (PRISMA harms) [5,6]: identifying unintended effects of an intervention, measuring their frequency, and identifying factors associated with the unintended effects (risk factors).

COMMENT 2. The data collection of the Delphi panel is incomplete in several respects. For instance, the clinical data available online which have been gathered by EWMM Netherlands since 2006 have been disregarded[4].

COMMENT 2 RESPONSE:

These data were not available through Google Scholar, PubMed or Web of Science.

COMMENT 3. Extrapolation from specific treatments performed by non-manual therapists with severe consequences to paediatric manual therapists is incorrect and therefore should not result in generalising negative statements regarding the use of manual therapy mobilisation techniques.

COMMENT 3 RESPONSE:

Generalizability of non-manual therapists to pediatric manual therapists is incorrect. We made judgments on available scientific evidence-based information across professions to inform our position statement.

COMMENT 4. There is a publication bias; available articles with positive conclusions are missing and will continue to be missing because the authors do not see the need for any further investigation into mobilisation in infants.

COMMENT 4 RESPONSE:

All research reports from the scoping review [7] that informed the position statements were critically appraised. We followed an evidence-to-decision framework [8] adapted from Alonso-Coello and colleagues making every effort to be transparent and avoid bias.

COMMENT 5. The systematic review of Driehuis et al. from 2019 and the study of Sacher from 2018 are not included in table 2, which is therefore incomplete.

COMMENT 5 RESPONSE:

The systematic review by Driehuis et al. (2019) [9] was in fact included in the scoping review that informed our position statement. It was identified as a National Health and Medical Research Council Level 1b report for our levels of evidence synthesis. The reference by Sacher 2018 [10] that you refer to is not listed in the reference list provided by the authors of the letter to the editor. The paper from Sacher et al. (2022) [11] that is in the authors reference list was published after we had completed our systematic scoping review. At the time of our search, the 'Single Manual Medicine Treatment' was not identified as a synonym for spinal manipulation or mobilization and therefore would not have been identified in our search. We acknowledge that in the reference below, the authors of that paper have provided supplementary files to provide a definition of 'Single Manual Medicine Treatment', however without the words Spinal, Manipulation or Mobilization in the abstract or title, it would not have been captured in our search.

Further, if the authors of this letter are referring to the above-mentioned study by Sacher et al. (2022) [11] the following information would have been extracted:

- Population: ($n = 171$) Kinematic imbalance due to suboccipital strain (KISS)
- Design: Pre-post randomized controlled trial (RCT) using 1-session of mobilization immediate post-treatment data; there was no intermediate or long-term data.
- Outcome: Symmetry score MD −2.00 (95% CI −2.88, −1.12). There was one validation study (Sacher, 2018) [10] for this primary outcome (reliable, some construct validity; with no responsiveness to change data).

The resulting level of evidence statement for our Spinal Mobilisation table would still be 'Insufficient'. Adding these data do not provide any additional clarity to our position statement.

Importantly, the use of outcome measures with good measurement properties was established in the COSMIN checklist (COnsensus-based Standards for the selection of health status Measurement INstruments) and includes:

(1) Reliability: internal consistency, test-retest/intra-rater/inter-rater reliability, measurement error;
(2) Validity: a. content validity including relevance, comprehensiveness, comprehensibility, outcome measurement items assessed and appropriately worded; b. structural validity; c. hypothesis testing for construct validity; d. cross-cultural validity; e. criterion validity; and
(3) Responsiveness for each measurement: when data regarding responsiveness to change is absent, it limits the usefulness of this outcome measure.

COMMENT 6. The psychometric properties of outcome measures mentioned by the Taskforce in the item 'upper cervical dysfunction' are incomplete (table 2), while this evidence is available [10].

COMMENT 6 RESPONSE:

In our scoping review [7], the descriptive synthesis in Supplementary File 5 identified one RCT addressing plagiocephaly in infants, that is, Cabrera-Martos (2016) [12] [Pilot RCT ($n = 46$ I) (Level II) (+)]. Motor development was the outcome of interest.

Aarvivala et al. 2015 [13] was neither identified through review of systematic reviews or our RCT search. The intervention identified was not manipulation or mobilization but rather standard positioning instruction and instructions regarding infant's environment, positioning, and handling, with the goal of creating a nonrestrictive environment that promotes spontaneous physical movement and symmetrical motor development. Their outcome of interest was two- and three-dimensional photogrammetry used to assess cranial shape and goniometry to measure cervical motion. Therefore, this outcome was not addressed in our clinometric reviews that are referenced in our position paper [14].

COMMENT 7. The composition of the taskforce does not represent the delegation of the Dutch *Association for Manual Therapy (NMVT) and its available clinical and scientific evidence.*

COMMENT 7 RESPONSE:

The IFOMPT Executive Committee put a call out for volunteers for the taskforce on pediatric spinal manipulation to IFOMPT member organizations (MO) and qualified colleagues in March 2020. Based on the response to this call and review of the qualifications of each applicant, a manual therapist/epidemiologist from the Netherlands was included on the taskforce.

COMMENT 8. The more evidence-based interventions/ alternative treatment choices for mobilisation mentioned on page 18 are not substantiated by any explanation or references to literature. I am not aware of any alternative and effective treatments for persistent positional preference in infants with no apparent medical pathology. In the clinic, many colleagues throughout the world see a group of infants with treatment-resistant positional preference which is unbreakable. The evidence on which the pediatric physiotherapy treatment of this target group is based, is limited and primarily focuses on the outcome measure of deformative plagiocephaly and not on the mobility of the cervical spine [12-16]. There is recent external evidence available regarding mobilisation of the cervical spine in infants with a persistent positional preference other than torticollis. The authors received the correct information and articles in digital correspondence with Sacher et al. on 17 and 18 August 2023. Therefore, based on this input, the arguments used by the authors to advice against spinal mobilisation in infants on page 8 must be seriously reconsidered.

COMMENT 8 RESPONSE:

We acknowledge that two articles [11,15] were sent by Sacher on 17 August 2023, to Australian clinicians and researchers on the Gold Coast, Australia (who are not members of the Paediatric Spinal Taskforce). One of these researchers had a distant affiliation with a member of the Paediatric Spinal Taskforce and forwarded on this communication to them. A response as to why Sacher et al.'s papers were not included was sent back to Dr Sacher at the time. This paper [11] was published after our search period (from root up to 18 June 2020 with an updated search up to 4 February 2021).

Sacher 2021 [15] was not retrieved via our search methods. In preparation of our search terms, we identified many different definitions and terminology to describe Spinal Manipulation and Spinal Mobilisation. Unfortunately, the term used in this paper (manual medicine treatment) was not identified by our team as a term representing Spinal Manipulation or Spinal Mobilisation. It was, therefore, not included in our search terms. The study title and abstract do not refer to the Spine, and manual therapy could involve any part of the body, which is why this paper was not identified in our search. The key search terms we used in reference to manual therapy of the spine were:

AND ('spin* manipulation' OR 'Spin* Mobilisation*' OR 'Spin* Mobilization*' OR 'Spin*Adjustment*' OR 'Spin* Manual therapy' OR 'high velocity low amplitude thrust' OR 'HVLA' OR 'Musculoskeletal of the spine' OR 'Spinal musculoskeletal' OR 'manual therapy of the spine' OR 'cervical manual therapy' OR 'thoracic manual therapy' OR 'lumbar manual therapy' OR 'manual therapy of the lumbar spine' OR 'manual therapy of the thoracic spine' OR 'manual therapy of the cervical spine' OR 'spinal osteopath*' OR 'osteopath* of the spine' OR 'osteopath* of the cervical spine' OR 'osteopath* of the thoracic spine' OR 'osteopath* of the

lumbar spine' OR 'Chiro*' OR 'Spinal manipulative therapy')

Whilst Sacher et al. 2021 ($n = 62$ analyzed/72 randomized) describe the techniques used in their Appendix B, we do not know what each infant in the intervention group received and could not therefore attribute results to 'Mobilisation' or 'Manipulation' [15]. Sacher et al. describe: 'All infants exhibited reversible segmental dysfunction in the upper cervical region … all infants in the Intervention Group (IG) received a single manual medicine treatment and children in the control group did not.' We do not know how many infants received a mobilization technique vs a manipulation technique as they state: 'Depending on the individual findings, reversible articular or segmental dysfunctions were treated by several mobilisation or infant-adapted manipulation techniques. The techniques used correspond to the curriculum of the ÄMM. Manual medicine treatments according to Gutmann and Biedermann were only chosen for the treatment of the upper cervical region. A summary of the techniques used can be found in the appendix B.' The intervention of 'Manual medicine treatment' was not clear …. Therefore, this paper would not provide any further clarity for our Position Statements.

COMMENT 9: Finally, I'm pointing out that there was no consensus in the expert panel on cervical spinal mobilisation in infants. However, there was consensus within the panel on manipulation.

COMMENT 9 RESPONSE:

The Delphi study [16] did not achieve consensus on mobilization in infants but did for manipulation. 'Consensus was achieved that spinal mobilisation at all spinal levels is not appropriate, except mobilisation for neurodevelopmental disorders where there was no consensus.' (page 288, Dice et al. 2024)

The Paediatric Spinal Manipulation Taskforce stands by the scientific methods used in our paper to develop the position statements and whilst be acknowledge that papers have been published on related topics following our scoping review period, these publications would not have changed our findings or altered the position statements.

Sincerely,

The Paediatric Spinal Manipulation Taskforce: a joint taskforce of the International Federation of Orthopaedic Manipulative Physical Therapists (IFOMPT) and International Organisation of Physiotherapists in Paediatrics (IOPTP).

Acknowledgements

We thank Mr Saedt for providing meaningful comments to our manuscript entitled "Spinal manipulation and mobilisation in paediatrics – an international evidence-based position statement for physiotherapists". We are very appreciative of these comments and have decided to provide feedback to each comment of Mr Saedt.

Disclosure statement

-No potential conflict of interest was reported by the author(s).

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