Responsum om fysioterapeuters adgang til selvstændigt at udføre manipulationsbehandling

1. Baggrund

Ved mail af 5. maj 2015 har Danske Fysioterapeuter ved Ann Sofie Orth bedt mig besvare følgende spørgsmål:

1. Må fysioterapeuter selvstændigt udføre manipulationsbehandling?
2. Har beretning afgivet af Sundheds- og Forebyggelsesudvalget den 14. april 2015 om ændring af retsstillingen for udvalgte behandlere betydning for fysioterapeuters mulighed for selvstændigt at udføre manipulationsbehandling?

Samtidig har jeg modtaget genpart af Danske Fysioterapeuters skrivelse af 21. april 2014 til Sundhedsstyrelsen om manipulation og fysioterapi, ordførernotat om kiropraktorers forbeholdte virksomhedsområde af 23. januar 2015 (SUU Alm. del, bilag 1337), Danske Fysioterapeuters høringsskrivelse af 13. april 2015 til Sundhedsstyrelsen om vurdering af risici ved manipulationsbehandling samt beretning afgivet af Sundheds- og Forebyggelsesudvalget den 14. april 2015 om ændring af retsstillingen for udvalgte behandlere, svar af 11. maj 2015 fra ministeren for sundhed og forebyggelse til Folketingets Sundheds- og Forebyggelsesudvalg (SUU Alm. del, bilag 1390). Endvidere har jeg modtaget oplysninger om den af fysioterapeuter anvendte definition af udtrykket "manuel terapi" samt oplysninger om praksis på området.

2. Må fysioterapeuter selvstændigt udføre manipulationsbehandling?

§ 59 i autorisationsloven, jf. lovbekendtgørelse nr. 877 af 4. august 2011 med senere ændringer, fastsætter bestemmelser om betingelser for meddelelse af autorisation som fysioterapeut (bestået dansk fysioterapeuteksamen eller en udenlandsk uddannelse, der kan sidestilles hermed), jf. § 59, stk. 1, og om titelbeskyttelse, jf. § 59, stk. 2. Fysioterapeuters virksomhedsområde, der ikke er forbeholdt fysioterapeuter, er ikke beskrevet i loven.

Ved lovens vedtagelse blev det forudsat, at virksomhed som fysioterapeut positivt omfatter undersøgelse, analyse, funktionsdiagnostik, behandling, evaluering samt dokumentation og kvalitetssikring med henblik på at udvikle, styrke, opretholde og genskabe optimal bevægelses- og funktionsevne hos mennesker med henblik på at fremme sundhed og livskvalitet samt forebygge funktionstab og begrænsninger hos det enkelte menneske, jf. FT 2005-06, tillæg A, s. 3226. Efter disse bemærkninger til lovforslaget er manipulationsbehandling ikke udelukket.

På baggrund af autorisationsloven kan fysioterapeuters virksomhedsområde endvidere afgrænses negativt. Fysioterapeuter må ikke selvstændigt udøve virksomhed, herunder udføre behandling, som efter loven er forbeholdt andre grupper af autoriserede sundhedspersoner. Fysioterapeuter må til eksempel ikke selvstændigt udføre tandlægevirksomhed, jf. autorisationslovens § 47, stk. 3, jordemodervirksomhed, jf. autorisationslovens § 55, stk. 3, virksomhed som tandtekniker, jf. autorisationslovens § 64, stk. 3, og virksomhed som tandplejer, jf. autorisationslovens § 65, stk. 3.

Kiropraktorvirksomhed er efter autorisationsloven forbeholdt kiropraktorer. Det fremgår af autorisationslovens § 52, stk. 3, at ret til at udøve kiropraktorvirksomhed har kun den, der har autorisation som kiropraktor. Kiropraktorvirksomhed omfatter efter § 52, stk. 4, diagnostik, forebyggelse og kiropraktisk behandling af biomekaniske funktionsforstyrrelser i rygsøjle, bækken og ekstremiteter. Udtrykket "kiropraktisk behandling" er defineret i § 1, stk. 2, i bekendtgørelse nr. 520 af 30. juni 1993 om kiropraktorvirksomhed. Af § 1, stk. 2, 1. pkt., fremgår det herom:

"Ved kiropraktisk behandling forstås manuel behandling af kroppens led."

Manuel behandling af kroppens led er således efter autorisationslovens § 52, stk. 4, jf. bekendtgørelse nr. 520 af 30. juni 1993, § 1, stk. 2, forbeholdt personer med autorisation som kiropraktor.

Om opgavefordelingen mellem kiropraktorers og fysioterapeuters virksomhedsområder historisk set kan det siges, at indtil autorisationsloven trådte i kraft den 1. januar 2007, måtte en fysioterapeut kun iværksætte behandling efter henvisning fra læge, og såfremt der forelå en lægeordination, skulle denne følges, jf. § 7, stk. 2, i den dagældende lov om terapiassistenter, jf. lovbekendtgørelse nr. 631 af 30. august 1991. Fysioterapeuter kunne efter den dagældende retsstilling ikke selvstændigt iværksætte behandling, og der var for så vidt ikke behov for at fastsætte regler om afgrænsningen af kiropraktorers og fysioterapeuters virksomhedsområder. Den daværende lov om kiropraktorer, jf. lov nr. 415 af 6. juni 1991, indeholdt derimod en bestemmelse om opgavefordelingen mellem læger og kiropraktorer. Det fremgik herom af lovens § 1, stk. 2:

"Lægers virksomhed berøres ikke af denne lov."

Efter forarbejderne til denne bestemmelse var formålet at sikre, at læger fortsat kunne udføre enhver form for patientbehandling, herunder manuel terapi, jf. FT 1990-91, tillæg A, sp. 2191.

Da kravet om lægehenvisning til fysioterapeutisk behandling bortfaldt ved autorisationslovens ikrafttræden, og fysioterapeuter dermed fik adgang til selvstændigt at foretage fysioterapeutisk behandling, blev kiropraktorers virksomhed afgrænset ikke alene i forhold til lægers, men også i forhold til fysioterapeuters virksomhedsområde. Det hedder herom i autorisationslovens § 52, stk. 6:

"Lægers og fysioterapeuters virksomhed berøres ikke af bestemmelserne i stk. 3-5."

Den mest nærliggende forståelse af denne bestemmelse er, at kiropraktorers forbeholdte virksomhedsområde ikke begrænser fysioterapeuters og lægers virksomhed.

I den forbindelse kan der henvises til, at autorisationsloven indeholder lignende bestemmelser om opgavefordelingen mellem andre grupper af autoriserede sundhedsgruppers virksomhedsområder. Til eksempel kan nævnes autorisationslovens § 55, stk. 6, der bestemmer, at lægers virksomhed ikke berøres af jordemødres virksomhedsområde. Denne bestemmelse betyder, at lægers adgang til at yde fødselshjælp m.v. ikke begrænses af jordemødres forbeholdte virksomhed. Endvidere kan nævnes autorisationslovens § 65, stk. 6, der fastsætter, at tandlægers virksomhed ikke berøres af tandplejeres virksomhedsområde, dvs. at tandlæger uanset tandplejeres forbeholdte virksomhed kan foretage tandpleje. Også bestemmelsen i autorisationslovens § 67, stk. 6, kan nævnes i denne forbindelse. Den bestemmer, at lægers virksomhed ikke berøres af optikeres virksomhedsområde. Læger – i praksis speciallæger i øjensygdomme – kan således uanset optikeres forbeholdte virksomhed foretage synsbestemmelse, tilpasning og kontrol. Selvom der i disse eksempler er tale om, at en gruppe af sundhedspersoner med en længerevarende uddannelse, f.eks. tandlæger, ikke begrænses af den forbeholdte virksomhed for en gruppe af sundhedspersoner med en kortere uddannelse, f.eks. tandplejeres, er ordlyden for så vidt angår afgrænsning af virksomhedsområder i disse eksempler i realiteten den samme som i autorisationslovens § 52, stk. 6.

Også motiverne til autorisationslovens § 52, stk. 6, støtter den forståelse, som følger af ordlyden. Det fremgår af bemærkningerne til lovforslaget:

"Den eksisterende opgavefordeling mellem lægers, kiropraktorers og fysioterapeuters virksomhedsområde ændres ikke. Læger må udføre enhver form for behandling, og fysioterapeuter må fortsat udføre manuel terapi i det omfang, det sker som led i fysioterapeutisk behandling."

Det forhold, at "manuel terapi" er særligt fremhævet i bemærkningerne til lovforslaget, taler for, at fysioterapeuter må udføre behandlinger, der går ud over bløddelsbehandling, f.eks. massage. Ifølge Den Danske Ordbog betyder manuel "som udføres eller betjenes med hænderne", og terapi betyder "behandling", jf. http://ordnet.dk. Da manipulationsbehandling er en behandling, som udføres med hænderne, er behandlingen efter en sædvanlig sproglig forståelse omfattet af begrebet "manuel terapi".

Danske Fysioterapeuter har over for mig supplerende oplyst, at fysioterapeuter anvender udtrykket "manuel vævsbehandling" eller "manuel terapi" som en samlet betegnelse for mobilisering, manipulation og bløddelsbehandling samt de dertil relaterede undersøgelsesteknikker. Danske Fysioterapeuter henviser i den forbindelse til følgende referencer: H. Kromann Knudsen, I.B. Bjørnlund og N.E. Sjøberg: Manuel vævsbehandling. I: H. Lund, I.B. Bjørnlund og N.E. Sjøberg: Basisbog i fysioterapi, Munksgaard Danmark, 1. udg., 1. oplag, 2010.

Endvidere er det værd at hæfte sig ved, at der i bemærkningerne til lovforslaget står, at fysioterapeuter "fortsat" må udføre manuel terapi, hvis det sker som led i fysioterapeutisk behandling. Efter de oplysninger jeg har modtaget fra Danske Fysioterapeuter, udførte fysiotera-

peuter i praksis manipulationsbehandling forud for autorisationslovens ikrafttræden. Dette skete efter lægehenvisning, men henvisningskravet bortfaldt som nævnt ved autorisationslovens ikrafttræden. Ledmobilisering og manipulation har efter det for mig oplyste altid været alment anerkendte metoder, som fysioterapeuter benytter til behandling af hypomobilitet og dermed en del af det fysioterapeutiske virksomhedsområde. Jeg har endvidere modtaget oplysninger om, at fysioterapeuters adgang til at foretage manipulation ikke har været særskilt problematiseret i de (få) sager i patientklagesystemet, hvor patienter har klaget over fysioterapeutisk behandling, herunder manipulation. Ledmobilisering og manipulation af columna og led omfattes af overenskomsten, der er indgået mellem Regionernes Lønnings- og Takstnævn (RLTN) og Danske Fysioterapeuter, jf. overenskomst om almindelig fysioterapi af 8. juni 1988 senest ændret ved aftale af 19. juni 2014, bilag 1. Dette betyder, at disse behandlinger er tilskudsberettiget, jf. bekendtgørelse nr. 710 af 27. juni 2008 om tilskud til fysioterapi hos fysioterapeut i praksissektoren, § 7. Tilskud til fysioterapi hos fysioterapeut kræver lægehenvisning, jf. bekendtgørelsens § 6, men der er efter det for mig oplyste ikke praksis for, at lægen skriver specifikt på henvisningen, hvilken behandling der skal udføres. Henvisningen er i øvrigt alene en betingelse for at få tilskud til fysioterapi efter sundhedsloven, mens der efter autorisationsloven ikke er et henvisningskrav. Den hidtidige overenskomstfastsatte bestemmelse om, at lægehenvisningen skulle anvise, hvilken behandling fysioterapeuten skulle udføre, udgik efter det for mig oplyste ved den seneste overenskomst med henblik på at tilpasse overenskomsten til autorisationsloven og dermed understrege, at overenskomsten er en ramme for økonomistyring. Efter overenskomstens § 5, stk. 3, skal henvisningsblanketten fra lægen alene indeholde oplysninger om diagnose. Det er fysioterapeuten, der vurderer, hvilken behandlingsart der skal iværksættes.

Ud fra ordlyden af autorisationslovens § 52, stk. 6, bestemmelsens motiver, hidtidig praksis på området og en sædvanlig sproglig forståelse af udtrykket "manuel terapi" kan fysioterapeuter efter min opfattelse som udgangspunkt selvstændigt foretage manipulationsbehandling af led. Det er dog et almindeligt krav, at behandlingen er fagligt forsvarlig i det enkelte tilfælde, jf. autorisationslovens § 17. Dette betyder bl.a., at en fysioterapeut skal være kvalificeret til at udføre manipulationsbehandling af led. Autorisationslovens § 52, stk. 6, giver ikke en fysioterapeut carte blanche til at udføre behandlinger, som den pågældende ikke selv, men kiropraktorer er kvalificeret til. Med dette forbehold er det min opfattelse, at kiropraktorers virksomhedsområde ikke begrænser fysioterapeuters adgang til at foretage manuel behandling af kroppens led, og at fysioterapeuter selvstændigt kan udføre manipulationsbehandling som led i fysioterapeutisk behandling.

Det fremgår af ordførernotat af 23. januar 2015 om kiropraktorers forbeholdte virksomhed, at Sundhedsstyrelsen er af den opfattelse, at kiropraktorers virksomhedsområde indebærer en begrænsning i fysioterapeuters adgang til at foretage manuel behandling af kroppens led, således at en fysioterapeut kun må udføre disse behandlinger, hvis den pågældende arbejder som medhjælp for en læge eller en kiropraktor. Sundhedsstyrelsen henviser ikke til en klar hjemmel for denne begrænsning i fysioterapeuters adgang til at foretage manuel terapi som led i fysioterapeutisk behandling. Styrelsen medgiver i ordførernotatet, at manipulationsbehandling er en form for manuel behandling, og at begrebet "manuel behandling" ikke er en

velafgrænset eller veldefineret behandlingsform. Styrelsen anfører endvidere, at begrebet "manuel behandling af kroppens led" ikke er entydigt medicinsk afgrænset, og at der er en gråzone, f.eks. i forhold til ledmobilisering, bløddelsbehandling og anden manuel behandling, der f.eks. også udføres af fysioterapeuter. Ifølge Sundhedsstyrelsen ligger det bærende argument for (fortsat) at reservere manipulationsbehandling af led for læger og kiropraktorer i disse faggruppers uddannelse og autorisation. Sundhedsstyrelsen henviser i denne forbindelse til, at kiropraktorer i kraft af deres uddannelse er autoriseret til at varetage manipulationsbehandling. For at opnå denne autorisation skal der gennemføres en 5-årig universitær uddannelse (bachelor og kandidat) efterfulgt af 1 års turnus. For så vidt angår fysioterapeutuddannelsen anfører styrelsen, at det er en 3 ½ årig professionsbachelor- uddannelse, og at fysioterapeuter ikke vil kunne foretage en medicinsk vurdering af en person og afklare kontraindikationer, ligesom en fysioterapeut ikke kan udføre eller vurdere røntgenoptagelser. Grundlaget for den af Sundhedsstyrelsen antagne begrænsning i fysioterapeuters adgang til at foretage manuel terapi synes således at være hensynet til patientsikkerheden.

Efter autorisationslovens § 1, stk. 1, hvorefter lovens formål er at styrke patientsikkerheden og fremme kvaliteten af sundhedsvæsenets ydelser gennem autorisation af nærmere bestemte grupper af sundhedspersoner, hvor andres virksomhed på det pågældende virksomhedsområde kan være forbundet med fare eller særlig fare for patienter, er det berettiget at inddrage hensynet til patientsikkerheden ved fortolkning af autorisationslovens enkelte bestemmelser. Lovens formål vil dog ikke uden videre slå igennem ved fortolkningen, hvis lovens ordlyd ikke levner tvivl om resultatet, jf. Jens Garde m.fl., Forvaltningsret, Almindelige emner, 5. udgave, s. 165. Som nævnt er det min opfattelse, at autorisationslovens § 52, stk. 6, forholdsvis klart fastsætter, at fysioterapeuters virksomhedsområde ikke begrænses af kiropraktorers forbeholdte virksomhed, og at denne forståelse støttes af motiverne, hvoraf det fremgår, at fortsat fysioterapeuter må udføre manuel terapi i det omfang, det sker som led i fysioterapeutisk behandling. En begrænsning i denne adgang må kræve en klar hjemmel, jf. Jens Garde m.fl., Forvaltningsret, Almindelige emner, 5. udgave, s. 201. En sådan ses ikke at foreligge i dette tilfælde. Sundhedsstyrelsens retsopfattelse, hvorefter kiropraktorers virksomhedsområde begrænser fysioterapeuters mulighed for selvstændigt at foretage manipulationsbehandling, ses således ikke at have fundet det fornødne klare udtryk i loven.

Jeg mangler sagkundskab til at vurdere, om fysioterapeuter fagligt er kvalificeret til at udføre manipulationsbehandling. Med dette forbehold er det min opfattelse, at det følger af autorisationslovens § 52, stk. 6, at fysioterapeuter har adgang til selvstændigt at udføre manipulation som led i fysioterapeutisk behandling.

På baggrund af en traditionel fortolkning må bestemmelsen i autorisationslovens § 52, stk. 6, efter min opfattelse forstås på den måde, at fysioterapeuter selvstændigt kan foretage manipulationsbehandling, hvis det – også med hensyn til fysioterapeutens kvalifikationer – er fagligt forsvarligt i det enkelte tilfælde.

3. Har beretning afgivet af Sundheds- og Forebyggelsesudvalget den 14. april 2015 om ændring af retsstillingen for udvalgte behandlere betydning for fysioterapeuters mulighed for selvstændigt at udføre manipulationsbehandling?

Det fremgår af beretning afgivet af Sundheds- og Forebyggelsesudvalget den 14. april 2015, at et flertal i udvalget har pålagt regeringen inden den 13. maj 2015 at fremsætte et lovforslag, der sikrer, at fysioterapeuter og RAB-godkendte behandlere får ret til at udføre manuel behandling af kroppens led, herunder manipulationsbehandlinger bl.a. omfattende nakke og ryg. Heraf følger indirekte, at flertallet lægger den af Sundhedsstyrelsen (og ministeren for sundhed og forebyggelse) tilkendegivne retsopfattelse til grund, hvorefter fysioterapeuter efter den nugældende retstilstand ikke selvstændigt kan foretage manuel behandling af kroppens led, herunder manipulationsbehandling.

Spørgsmålet er, hvad dette betyder for det under afsnit 2 antagne resultat, hvorefter fysioterapeuter (allerede) efter den nugældende retsstilling kan foretage manuel behandling af kroppens led, herunder manipulationsbehandling, hvis det er fagligt forsvarligt i det enkelte tilfælde.

Dette spørgsmål kan også formuleres på denne måde: Hvilken rolle spiller beretningen for fortolkningen af autorisationslovens § 52, stk. 6?

Indtil en lovændring med det indhold, som ønskes af flertallet i Sundheds- og Forebyggelsesudvalget, måtte blive vedtaget, gælder autorisationslovens § 52, stk. 6, i sin nuværende udformning. Udgangspunktet er, at denne bestemmelse må fortolkes på grundlag af de data, som forelå, da autorisationsloven blev vedtaget, jf. ovenfor afsnit 2. Hensynet til retsbeskyttelsen taler for, at senere tilkomne bidrag (efterarbejder) anvendes med forsigtighed, når det drejer sig om indskrænkning af en foreliggende ret. Det kan dog ikke afvises, at senere tilkomne bidrag efter omstændighederne vil kunne inddrages i friere overvejelser. Dette gælder dog kun, hvis de gængse fortolkningsdata ikke giver noget klart svar, jf. Jens Garde m.fl., Forvaltningsret, Almindelige emner, 5. udgave, s. 155-156, s. 166. Som nævnt er den nugældende § 52, stk. 6, i autorisationsloven, efter min opfattelse forholdsvis klart affattet, og bemærkningerne til lovforslaget understøtter den naturlige sproglige forståelse, hvorefter fysioterapeuters virksomhed ikke begrænses af kiropraktorers forbeholdte virksomhedsområde, og hvorefter fysioterapeuter selvstændigt kan foretage manipulationsbehandlinger som led i fysioterapeutisk behandling, hvis det er fagligt forsvarligt i det enkelte tilfælde. På den baggrund mener jeg ikke, at beretningen fra Sundheds- og Forebyggelsesudvalget har betydning for, dvs. ændrer ved, det ovenfor under afsnit 2 antagne resultat.

4. Sammenfatning

Sammenfattende er det på baggrund af en traditionel fortolkning af autorisationslovens § 52, stk. 6, min opfattelse, at fysioterapeuter selvstændigt må udføre manipulationsbehandling som led i fysioterapeutisk behandling, hvis det er fagligt forsvarligt, herunder med hensyn til fysioterapeutens kvalifikationer, i det enkelte tilfælde.

Det er endvidere min opfattelse, at beretning afgivet af Sundheds- og Forebyggelsesudvalget den 14. april 2015 om ændring af retsstillingen for udvalgte behandlere ikke ændrer ved dette resultat.

Aarhus, den 12. maj 2015

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The risk associated with spinal manipulation: An overview of reviews

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INTRODUCTION

Spinal manipulation therapy (SMT) is a manual treatment where a vertebral joint is passively moved between the normal range of motion and the limits of its normal integrity, though a universally accepted definition does not seem to exist. It often involves a high velocity thrust, a technique in which the joints are moved rapidly by the manipulator, often accompanied by popping sounds, but can also involve joint movements at lower velocities and different amplitudes. Many clinicians and patients see SMT as an effective form of treating a variety of conditions, typically pain. However, the evidence from randomized clinical trials (RCTs) remains contradictory and often unconvincing; particularly for conditions other than "back pain".

As with all interventions, there are risks associated with SMT and many stakeholders have voiced concerns about the safety of SMT. The possible harmful outcomes of SMT includes (but are not limited to) death, stroke, paralysis, fractures, and cauda equine syndromes among the serious events, but also includes less serious and sometimes transient events such as increased pain, soreness, dizziness, and vomiting. Currently the knowledge about the possible harms associated with SMT is insufficient and the uncertain safety profile of SMT is a concern.

Recently the Danish Ministry of Health commissioned the Danish Health Authority and the Patient Safety Authority to make a scientific assessment of the safety profile of manipulation therapy. Subsequently, the Danish Physiotherapists' Association contracted us to perform a systematic review of the scientific literature to assess the risk of adverse events (AEs) associated with manipulations.

Almost all joints and soft tissues can be treated by manual techniques that can be defined as manipulations. However, as the most serious concerns relate to manipulations of the spine, this overview focuses on spinal manipulations, defined SMT. We do not consider any possible benefit of SMT, nor do we contrast harms of SMT delivered by specific professions.

Objectives

The aim of this overview of reviews was to elucidate and quantify the risk of AEs associated with SMT regardless of the indications for the treatment.

METHODS

Protocol and registration

A brief protocol was developed and registered in the International Prospective Register of Systematic Reviews (PROSPERO: CRD42015030068) prior to the initiation of this overview.

Eligibility criteria

We included official health technology assessment reports and peer-reviewed reviews of studies of any type (including cohorts, case reports etc.) that examine individuals receiving at least one spinal manipulation. No restrictions were put on the age, nationality, gender, or health status of the population. The control could be sham, placebo, any, or none. Reporting the outcome(s) of interest was not a criterion for inclusion in the overview, but at least an abstract in English, Danish, Swedish or Norwegian had to be available. For inclusion in the synthesis, data on AEs was required.

In order to ensure that the included reviews were 'systematic', a criterion for inclusion was to include the following two items from the tool Assessment of Multiple Systematic Reviews (AMSTAR); *"Were two or more electronic sources searched?"*, and *"Was the scientific quality of the included studies assessed and documented?"* [1,2]. Other overview authors have used similar approach [3,4]. It was, however, recognized that no commonly accepted quality assessment tool exists for case reports, case series, cross-sectional studies or surveys, so quality assessments of these study types were not required.

Search methods for identification of studies

Five databases were searched; Cochrane Database of Systematic Reviews, Cochrane Database of Abstracts of Reviews of Effects (DARE), Cochrane Health Technology Assessment Database (HTA), MEDLINE via PubMed and EMBASE via Ovid. No language or date restrictions were placed on the search. The initial search strategy was developed for PubMed and adapted to the other databases (**Appendix 1**). It consisted of an intervention filter and review filter. The search was conducted the 8th of December 2015.

In addition, references from relevant reviews, overviews of reviews and relevant national clinical guidelines were checked to identify further potential reviews for inclusion.

Selection of studies

Using Endnote X7.3.1 auto-screening with the default setting for removal of duplicates is inadequate[5]. Therefor duplicates were identified and removed using auto-searching and a subsequent manual search as recommended by Qi et al. (2013)[6]. One reviewer (SMN) screened titles and abstracts, and the same reviewer subsequently screened full texts to identify relevant reviews for the overview. A second reviewer (MH) was consulted when the basis for decision making was not clear. When a full text could not be retrieved, the authors were contacted when possible.

Data extraction and management

One reviewer (SMN) performed the data extraction for each review. When the basis for decision making was not clear, a second reviewer (MH) was consulted. When a review also included trials on interventions, other than SMT, only the data (number of patients receiving intervention, included trials, AEs etc.) for SMT was used. If the data for SMT could not be separated from other interventions (e.g. mobilization) the combined data were used instead.

The primary outcome was serious adverse events (SAEs) defined as conditions requiring hospital admission (or mortality), and the secondary outcome was any AEs reported. If severity of an AE was not defined in the review, one reviewer (MH) rated the severity of the reported AEs. If the basis for rating AE severity was unclear, another reviewer (HB) was consulted. The data extracted for these outcomes were type of AEs, type of SAEs, conclusion regarding AEs and/or SAEs, and the incidence of SAEs.

Assessment of methodological quality of included reviews

One reviewer (SMN) assessed the quality of each review using the tool AMSTAR [1,2]. This consists of 11 criteria, which were given the rating 'yes' (clearly done), 'can't answer' (unclear if completed), 'no' (clearly not done), or 'not applicable'. A second reviewer (MH) was consulted when the basis for decision making was not clear.

Assessment of the quality of the evidence in reviews

The quality of the evidence in the reviews included was not assessed, but the authors' own ratings (such as GRADE) were extracted, if sufficient information was provided in the publication.

Data synthesis and presentation

As recommended by the Cochrane Collaboration, this overview does as far as possible rely on the analyses reported in the included review and summarize these [7]. It was pre-specified that the AEs and SAEs should be summarized for each review with a subsequent synthesis and meta-analysis. However, the available data on AEs and SAEs were too heterogeneously and insufficiently reported to synthesize, present counts or to calculate proportions (number of patients receiving SMT experiences AEs or SAEs), incidence, risk ratio (RR) and odds ratio (OR).

Instead, we appraised the communicated opinions of each review concerning the safety of SMT based on their conclusions regarding the AEs and SAEs. These conclusions, summarizing the safety of SMT based on the reviewed studies, were assessed by two reviewers independently (SMT, LK). The reviewers rated the communications as either 'safe', 'neutral/unclear', or 'harmful'. As a measure for the agreement, Cohens Weighted Kappa, was calculated for the agreement between the reviewers. A value of 0.40-0.59 is

considered 'fair agreement', 0.60-0.74 is considered 'good agreement', and ≥0.75 is considered 'excellent agreement' [8]. Disagreements were decided by a third reviewer (MH).

To get an "objective" measure of our confidence in the opinions communicated in the conclusion paragraphs, we assessed whether a pattern of conclusions could be identified according to methodological quality of the reviews (AMSTAR). This was done by calculating a RR of a review communicating the opinion 'safe' when meeting the requirements for each AMSTAR item, and a RR of the opinion of a review communicating 'harmful' when meeting the requirements for each AMSTAR item.

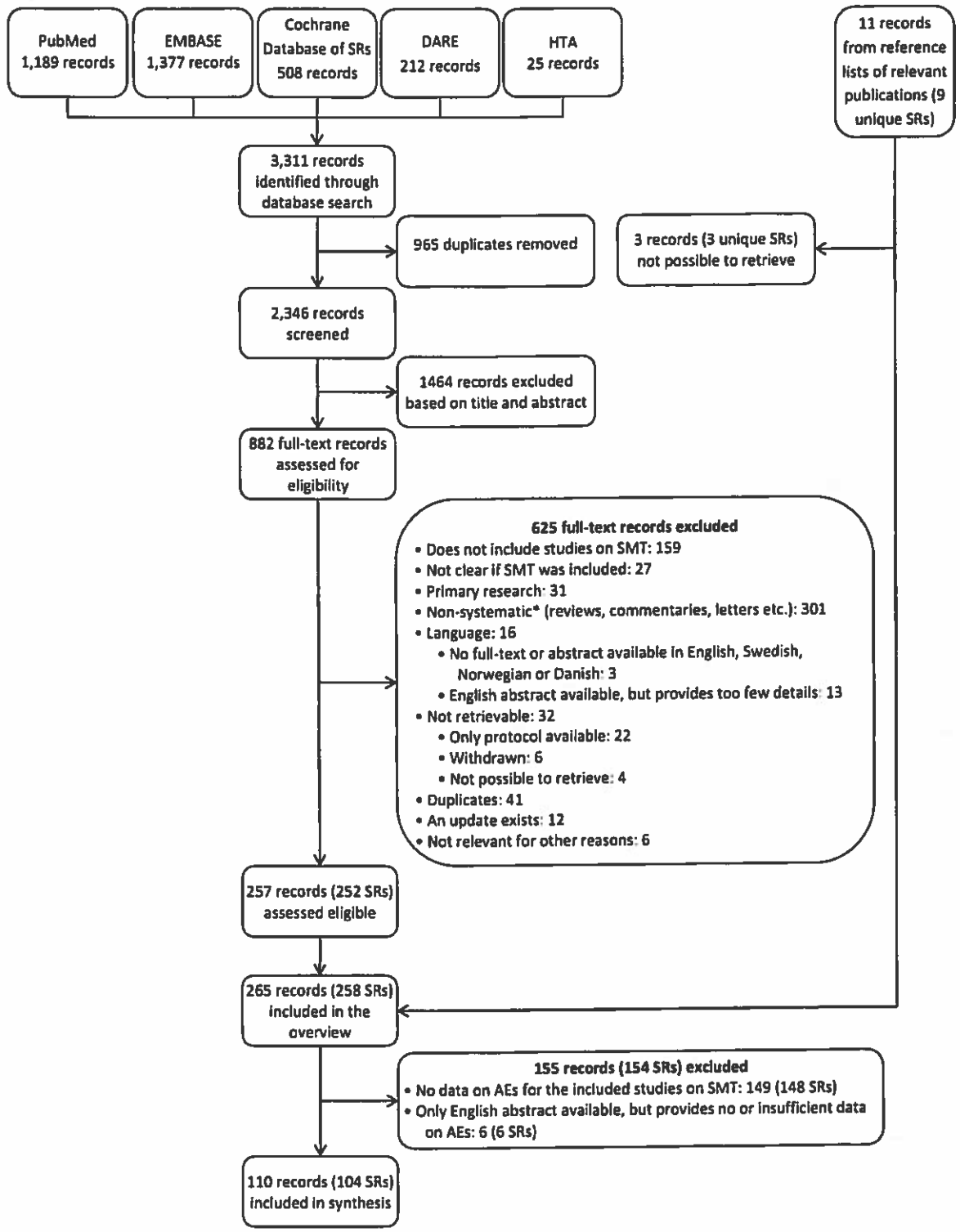
For the reviews that reported risk estimates for SAEs, these are presented in a separate table. A matrix showing which studies the estimates from each review were based on was constructed as well.

RESULTS

Study selection

The outlined search strategy identified 2,346 records after removal of duplicates (**Figure 1**). Of these, 1,464 were excluded because they did not meet the inclusion criteria, and the subsequent full-text assessment resulted in 257 records describing 252 reviews eligible for the qualitative overview. Reviewing reference lists of relevant publications identified 11 potentially relevant records; 8 records on 6 unique SRs were included, and 3 records[9-11] could not be retrieved. In total, 265 records describing 258 reviews met the inclusion criteria for the overview; of these, 110 records describing 104 reviews were eligible for inclusion in the synthesis. Reasons for exclusion are stated in **Figure 1** (reference lists of the excluded studies are available from contact with the corresponding author).

Figure 1: Flow diagram showing the study selection



* Non-systematic: Does not report to have searched at least two electronic databases or does not document an assessment of the quality of the included studies (case reports, case series, cross-sectional studies and surveys were not required to have been quality assessed).
Abbreviations: AEs, adverse events; DARE, Cochrane Database of Abstracts of Reviews of Effects; HTA, Cochrane Health Technology Assessment Database; RCT, randomized controlled trial; SMT, spinal manipulation therapy; SRs, systematic reviews.

Study characteristics

The characteristics of the 104 reviews included are presented in **Table 1** and in **Appendix 2** providing further details (including study types included in the reviews, population, interventions, types of AEs and SAEs, the reviews' own conclusions on AEs, and the reviews' own ratings of the quality of evidence).

The vast majority of the reviews investigated SMT (either as the only intervention or as a separate subgroup). Some of these reviews further specified SMT as cervical, thoracic or lumbar SMT (20 reviews). Other reviews did not further specify than 'manipulation' (10 reviews), 'osteopathic manipulative treatment/therapy' (5 reviews), 'chiropractic care/interventions' (4 reviews).

Box 1: The patient populations most frequently studied in the included reviews (listed after frequency)

1. Cervical pain
2. Low back pain
3. Headache
4. Children/adolescents
5. Asthma
6. Cervical radiculopathy
7. Musculoskeletal (various)
8. Lumbar radiculopathy
9. Carpal tunnel syndrome
10. Dysmenorrhea
11. Pelvic pain
12. Phobia
13. Pregnant
14. Cervical trauma
15. Chronic inflammatory disease
16. Colic
17. Diversity of complaints
18. Dizziness
19. Frozen shoulder
20. Lumbar spinal stenosis

The patients most frequently included in the reviews were patients with cervical pain, low back pain or headache (based on a word count after categorization by the authors; **Box 1**). The number of patients receiving the intervention was often not provided (34 reviews) or was only provided for some of the included studies (20 reviews).

Randomized controlled trial was the study type most frequently included in the reviews, but many other study types were included as well; case report, case series, case-control study, health technology assessment, cohort study, survey, systematic review, narrative review, commentary, pilot study, controlled clinical trials, other types of trials etc.

For 71 of the reviews, their main aim was to investigate efficacy (benefit), for 28 of the reviews, their main aim was to investigate AEs, and for the remaining 5, their aim was to investigate both. Forty-one reviews reported that AEs were observed, and 14 reviews reported that SAEs were observed. Nine reviews did not clearly report if any AEs and/or SAEs were observed (e.g. some stated, that the included studies mentioned AEs, but not if any AEs were observed). A word count of the reported AEs and SAEs, showed, that the most frequently used term describing AEs/SAEs in the reviews, was stroke (counted after categorization by the authors; **Box 2**). However, it should be noted, that a very common subject in the discussion sections, was the poor reporting of AEs in the studies and the possible risk of underreporting. Thirteen of the reviews reported estimates for the incidence of SAEs (**Table 4**), and also here, many of the studies noted that these estimates were rough

Box 2: The terms describing the adverse events and serious adverse events most frequently used in the reviews (listed after frequency)

1. Stroke
2. Headache
3. Vertebral artery dissection
4. Increased pain
5. Radiculopathy
6. Spinal cord injury
7. Death
8. Aggravation of symptoms
9. Fatigue
10. Soreness
11. Cauda equine syndrome
12. Disc herniation
13. Vertebral fracture
14. Discomfort
15. Minor side effects
16. Stiffness
17. Vertebral dislocation
18. Dizziness
19. Nausea
20. Neck-stiffness

estimates (the conclusions of the reviews in Appendix 2).

Only very few studies rated the quality of the evidence for AEs and/or SAEs. GRADE was the most frequently used tool, but other more or less specified tools were used as well.

Table 1: Summary of findings for spinal manipulation therapy

Year	Authors	Main objectives	Number of pts receiving intervention	AEs reported	SAEs reported	Estimate for the incidence of SAEs	Communicated opinion
2015	Cicchintti L. et al.[12]	Effect	NA	yes	no	no	Safe
2015	Gross A. J. et al.[13]	Effect	NA	yes	no	no	Safe
2015	Liddle S. D. & Pennick V.[14]	Effect	289	unclear	no	no	Safe
2015	Puentedura E. J. & O'Grady W. H.[15]	AEs	10	yes	yes	no	Harmful
2015	Southerst D. et al.[16]	Effect	98	yes	no	no	Safe
2015	Yuan Q.-L. et al.[17]	Effect	208	no	no	no	Safe
2015	Zhu L. et al.[18]	Effect	NA	no	no	no	Neutral/unclear
2014	Bryans R. et al.[19]	Both	513	yes	no	no	Safe
2014	Clar C. et al.[20]	Effect	NA	yes	yes	no	Neutral/unclear
2014	Close C. et al.[21]	Effect	NA	yes	no	no	Neutral/unclear
2014	Franke H. et al.[22]	Effect	779	yes	no	no	Safe
2014	Kizhakkeveettil A. et al.[23]	Effect	1799	unclear	unclear	no	Neutral/unclear
2014	Page M. J. et al.[24]	Effect	4	no	no	no	Safe
2014	Sutton D. et al.[25]	Effect	813	yes	no	no	Safe
2014	Todd A. J. et al.[26]	AEs	>34605	yes	yes	yes	Harmful
2014	Tuchin P.[27]	AEs	9	yes	no	no	Neutral/unclear
2014	Yin P. et al.[28]	AEs	94	yes	yes	no	Harmful
2014	Young J. L. et al.[29]	Effect	539	yes	no	no	Safe
2013	Brantingham J. W. et al.[30]	Effect	109	yes	unclear	no	Safe
2013	Hebert J. J. et al.[31]	AEs	77	yes	yes	no	Neutral/unclear
2013	Huisman P. A. et al.[32]	Effect	350	yes	no	no	Neutral/unclear
2013	Parkinson L. et al.[33]	Effect	>520	no	no	no	Safe
2013	Posadzki P. et al.[34]	Effect	>448	yes	no	no	Neutral/unclear
2013	Scholten-Peeters G. G. M. et al.[35]	Effect	626	yes	no	no	Safe
2013	Schroeder J. et al.[36]	Effect	195	yes	unclear	no	Safe
2013	Wynd S. et al.[37]	AEs	901	unclear	yes	no	Neutral/unclear
2013	Yang M. et al.[38]	Effect	39	yes	no	no	Safe
2012	Brantingham J. W. et al.[39]	Effect	>109	yes	no	no	Safe
2012	Dobson D. et al.[40]	Effect	116	no	no	no	Neutral/unclear
2012	Furlan A. D. et al.[41,42]	Both	NA	yes	yes	no	Neutral/unclear
2012	Gleberzon B. J. et al.[43]	Effect	NA	yes	unclear	no	Safe
2012	Haynes M. J. et al.[44]	AEs	NA	unclear	yes	no	Neutral/unclear
2012	Kuczynski J. J. et al.[45]	Effect	268	yes	no	no	Safe
2012	Lin J. H. et al.[46]	Effect	283	no	no	no	Neutral/unclear
2012	Posadzki P. & Ernst E.[47]	Effect	NA	yes	no	no	Neutral/unclear
2012	Puentedura E. J. et al.[48]	AEs	134	yes	yes	no	Harmful
2012	Rubinstein S. M. et al.[49,50]	Effect	1195	yes	no	no	Safe
2012	Stuber K. A. et al.[51]	AEs	NA	yes	yes	no	Neutral/unclear
2011	Brantingham J. et al.[52]	Effect	>266	no	no	no	Neutral/unclear
2011	Cross K. et al.[53]	Effect	187	yes	no	no	Safe
2011	Huang T. et al.[54]	Effect	131	yes	no	no	Safe
2011	Lystad R. P. et al.[55]	Effect	NA	yes	no	no	Safe
2011	Posadzki P. & Ernst E.[56]	Effect	NA	yes	no	no	Harmful
2011	Posadzki P. & Ernst E.[57]	Effect	NA	yes	no	no	Harmful
2011	Posadzki P. & Ernst E.[58]	Effect	NA	unclear	unclear	no	Neutral/unclear
2011	Posadzki P. & Ernst E.[59]	Effect	NA	yes	no	no	Neutral/unclear
2011	Rubinstein S. M. et al.[60,61]	Effect	2435	yes	no	no	Safe
2011	Walker B. F. et al.[62,63]	Effect	NA	yes	no	no	Neutral/unclear
2010	Carlesso L. C. et al.[64]	AEs	NA	yes	no	no	Neutral/unclear
2010	Carnes D. et al.[65]	AEs	25179	yes	yes	yes	Safe
2010	Ernst E.[66]	AEs	26	unclear	yes	no	Harmful
2010	Hahne A. J. et al.[67]	Effect	NA	no	no	no	Safe
2010	Kaminskyj A. et al.[68]	Effect	NA	yes	no	no	Neutral/unclear

Table 1 cont.

Year	Authors	Main objectives	Number of pts receiving intervention	AEs reported	SAEs reported	Estimate for the incidence of SAEs	Communicated opinion
2010	Shin B.-C. et al.[69]	AEs	18	yes	yes	no	Harmful
2009	Boudreau R. et al.[70]	Effect	>52	yes	yes	no	Safe
2009	Boudreau R. & Spry C.[71]	Effect	1	no	no	no	Safe
2009	Brurberg K. G. et al.[72]	Effect	>695	yes	no	no	Safe
2009	Gouveia L. O. et al.[73]	AEs	>2838	yes	yes	yes	Harmful
2009	Hunt K. J. et al.[74]	Effect	NA	yes	no	no	Safe
2009	Khorsan B. et al.[75]	Effect	>297	unclear	yes	no	Neutral/unclear
2009	Reiman M. P. et al.[76]	Effect	>76	yes	unclear	no	Neutral/unclear
2008	Miley M. L. et al.[77]	AEs	NA	unclear	yes	yes	Harmful
2008	Stuber K. J. & Smith D. L.[78]	Effect	285	no	no	no	Neutral/unclear
2008	Vernon H. & Humphreys B. K.[79]	Effect	178	yes	no	no	Safe
2007	Chou R. & Huffman L. H.[80,81]	Effect	NA	yes	yes	yes	Safe
2007	Ernst E.[82]	AEs	>924	yes	yes	no	Harmful
2007	Gross A. R. et al.[83]	Effect	NA	unclear	no	no	Safe
2007	Hawk C. et al.[84]	Effect	NA	yes	no	no	Safe
2007	Luijsterburg P. A. J. et al.[85]	Effect	175	no	no	no	Neutral/unclear
2007	Vernon H. & Humphreys B. K.[86]	Effect	701	yes	no	no	Neutral/unclear
2007	Vernon H. et al.[87]	Effect	593	yes	no	no	Safe
2006	Gemmell H. & Miller P.[88]	Effect	>79	unclear	unclear	no	Safe
2006	Proctor M. et al.[89]	Effect	>162	yes	unclear	no	Safe
2006	Snelling N. J.[90]	Both	>214	yes	yes	yes	Neutral/unclear
2005	Brown A. et al.[91]	Effect	NA	yes	yes	no	Safe
2005	Ernst E.[92]	AEs	14	yes	yes	no	Harmful
2005	Hondras M. A. et al.[93]	Effect	NA	no	no	no	Safe
2005	Lisi A. J. et al.[94]	Effect	183	yes	no	no	Neutral/unclear
2005	Rubinstein S. M. et al.[95]	AEs	7	unclear	yes	no	Neutral/unclear
2004	Brønfort G. et al.[96]	Effect	85	yes	no	no	Safe
2004	Ernst E.[97]	AEs	340	yes	yes	no	Neutral/unclear
2004	Lenssinck M.-L. B. et al.[98]	Effect	NA	yes	no	no	Safe
2004	Oduneye F.[99]	Effect	128	yes	no	no	Neutral/unclear
2004	Oliphant D.[100]	AEs	NA	yes	yes	yes	Safe
2003	Ernst E.[101]	AEs	2	yes	yes	no	Harmful
2002	Ernst E.[102]	AEs	>4	yes	yes	no	Neutral/unclear
2002	Ernst E.[103]	AEs	42	yes	yes	no	Harmful
2002	Gerritsen A. A. M. et al.[104]	Effect	45	yes	no	no	Safe
2002	Gross A. R. et al.[105]	Both	NA	yes	yes	yes	Neutral/unclear
2002	Gross A. R. et al.[106]	Effect	NA	yes	no	no	Neutral/unclear
2002	Stevinson C. & Ernst E.[107]	AEs	>2357	yes	yes	yes	Neutral/unclear
2001	Bronfort G. et al.[108]	Effect	400	yes	no	no	Safe
2001	Ernst E.[109]	AEs	>2016	yes	no	no	Neutral/unclear
2001	Ernst E. & Harkness E.[110]	Effect	NA	yes	no	no	Neutral/unclear
2000	Ernst E.[111]	Effect	NA	yes	no	no	Neutral/unclear
2000	Magee D. J. et al.[112]	Effect	10	no	no	no	Safe
1999	Fabio R. P. D.[113]	Both	177	yes	yes	no	Harmful
1999	Haldeman S. M. et al.[114]	AEs	115	unclear	yes	no	Safe
1999	Vernon H. et al.[115]	Effect	176	yes	no	no	Neutral/unclear
1996	Aker P. D. et al.[116]	Effect	NA	yes	no	no	Neutral/unclear
1996	Assendelft W. J. J. et al.[117]	AEs	>1795	yes	yes	yes	Neutral/unclear
1996	Hurwitz E. L. et al.[118,119]	Effect	>935	yes	yes	yes	Neutral/unclear
1995	Dabbs V. & Lauretti W. J.[120]	AEs	NA	unclear	yes	yes	Safe
1992	Shekelle P. G. et al.[121]	Effect	>1500	unclear	yes	yes	Neutral/unclear

Abbreviations: AEs, adverse events; NA, no data available; pts, patients, SAEs, serious adverse events.

When 'Number of patients in total' has '>' in front, the actual number of patients is higher since incomplete data were provided by the review.

The methodological quality of included reviews

None of the reviews met the requirements for all the 11 AMSTAR items (**Table 2**). The median number of 'yes' was 4 (interquartile range, 2 to 5), with a minimum and maximum of 0 and 9 'yes' respectively. Only very few reviews had combined (e.g. in meta-analysis or other means of synthesis) the findings of AEs and SAEs or done this in an appropriate way, hence item 9 was not applicable in most cases. None of the reviews made any attempt to assess the publication bias specifically for AEs and/or SAEs; hence, none of the reviews met the requirements for item 9.

Table 2: Methodological quality of included systematic reviews assessed with AMSTAR

Year	Authors	1	2	3	4	5	6	7	8	9	10	11	Total score*
2015	Cicchintti L. et al.[12]	no	yes	yes	yes	no	yes	yes	yes	NA	no	yes	7
2015	Gross A. J. et al.[13]	yes	yes	yes	yes	yes	yes	no	no	yes	no	no	7
2015	Liddle S. D. & Pennick V.[14]	no	yes	yes	yes	yes	yes	yes	yes	NA	no	yes	8
2015	Puentedura E. J. & O'Grady W. H.[15]	no	no	yes	no	no	yes	no	no	no	NA	no	2
2015	Southerst D. et al.[16]	yes	yes	yes	yes	no	yes	yes	yes	NA	no	no	7
2015	Yuan Q.-L. et al.[17]	no	unclear	yes	yes	no	yes	yes	yes	NA	no	no	5
2015	Zhu L. et al.[18]	no	yes	yes	yes	no	yes	yes	yes	NA	no	no	6
2014	Bryans R. et al.[19]	no	no	yes	no	no	yes	yes	no	yes	no	no	4
2014	Clar C. et al.[20]	no	yes	yes	no	no	no	yes	yes	NA	no	no	4
2014	Close C. et al.[21]	yes	no	yes	yes	no	yes	yes	yes	NA	no	no	6
2014	Franke H. et al.[22]	no	yes	yes	yes	yes	yes	yes	yes	NA	no	no	7
2014	Kizhakkeveettil A. et al.[23]	no	yes	yes	no	no	yes	yes	no	NA	no	no	4
2014	Page M. J. et al.[24]	yes	yes	yes	yes	yes	yes	yes	yes	NA	no	yes	9
2014	Sutton D. et al.[25]	yes	yes	yes	no	no	yes	yes	yes	NA	no	no	6
2014	Todd A. J. et al.[26]	no	no	yes	yes	no	yes	no	no	NA	no	no	3
2014	Tuchin P.[27]	no	no	yes	no	no	yes	no	no	NA	NA	no	2
2014	Yin P. et al.[28]	no	yes	no	no	no	yes	no	no	NA	NA	no	2
2014	Young J. L. et al.[29]	no	no	no	no	no	yes	yes	yes	NA	no	no	3
2013	Brantingham J. W. et al.[30]	no	no	yes	yes	no	yes	yes	yes	NA	no	no	5
2013	Hebert J. J. et al.[31]	no	no	yes	no	no	yes	no	no	NA	NA	no	2
2013	Huisman P. A. et al.[32]	no	no	yes	no	yes	yes	yes	yes	NA	no	no	5
2013	Parkinson L. et al.[33]	no	yes	no	no	no	yes	yes	yes	NA	no	no	4
2013	Posadzki P. et al.[34]	yes	yes	yes	no	no	yes	yes	yes	NA	no	no	6
2013	Scholten-Peeters G. G. M. et al.[35]	no	yes	yes	no	no	yes	yes	yes	NA	no	no	5
2013	Schroeder J. et al.[36]	no	no	no	no	yes	yes	yes	yes	NA	no	no	4
2013	Wynd S. et al.[37]	no	yes	no	no	yes	no	no	no	no	no	no	2
2013	Yang M. et al.[38]	yes	yes	yes	no	yes	yes	yes	yes	NA	no	yes	8
2012	Brantingham J. W. et al.[39]	no	no	no	no	no	yes	yes	yes	NA	no	no	3
2012	Dobson D. et al.[40]	yes	yes	yes	yes	yes	yes	yes	yes	NA	no	yes	9
2012	Furlan A. D. et al.[41,42]	no	yes	yes	no	no	yes	yes	yes	NA	no	no	5
2012	Gleberzon B. J. et al.[43]	no	no	yes	no	no	yes	yes	yes	NA	no	no	4
2012	Haynes M. J. et al.[44]	yes	no	yes	no	no	no	yes	yes	NA	NA	no	4
2012	Kuczynski J. J. et al.[45]	no	yes	no	no	no	yes	yes	no	NA	no	no	3
2012	Lin J. H. et al.[46]	no	yes	yes	no	no	yes	yes	yes	NA	no	no	5
2012	Posadzki P. & Ernst E.[47]	yes	no	yes	no	no	yes	yes	yes	NA	no	no	5
2012	Puentedura E. J. et al.[48]	no	yes	yes	no	no	yes	no	no	yes	NA	no	4
2012	Rubinstein S. M. et al.[49,50]	yes	no	yes	yes	yes	yes	yes	yes	yes	no	yes	9
2012	Stuber K. A. et al.[51]	no	no	yes	no	yes	no	yes	no	NA	NA	no	3
2011	Brantingham J. et al.[52]	no	no	no	no	no	yes	yes	yes	NA	no	no	3
2011	Cross K. et al.[53]	no	yes	yes	no	yes	yes	yes	yes	NA	no	no	6
2011	Huang T. et al.[54]	yes	yes	yes	no	yes	yes	yes	yes	NA	no	no	7
2011	Lystad R. P. et al.[55]	no	no	yes	no	yes	yes	yes	yes	NA	no	no	5
2011	Posadzki P. & Ernst E.[56]	no	no	yes	no	no	yes	yes	yes	NA	no	no	4
2011	Posadzki P. & Ernst E.[57]	no	no	yes	no	no	yes	yes	yes	NA	no	no	4
2011	Posadzki P. & Ernst E.[58]	no	no	yes	no	no	yes	yes	yes	NA	no	yes	5
2011	Posadzki P. & Ernst E.[59]	no	yes	yes	yes	no	yes	yes	yes	NA	no	no	6
2011	Rubinstein S. M. et al.[60,61]	yes	yes	yes	yes	yes	yes	yes	yes	NA	no	yes	9
2011	Walker B. F. et al.[62,63]	yes	yes	yes	yes	yes	yes	yes	yes	NA	no	no	8
2010	Carlesso L. C. et al.[64]	no	yes	no	yes	no	yes	yes	yes	yes	no	no	6
2010	Carnes D. et al.[65]	no	no	yes	no	no	no	yes	no	no	no	no	2

Table 2 cont.

Year	Authors	1	2	3	4	5	6	7	8	9	10	11	Total score*
2010	Ernst E.[66]	no	no	yes	no	no	yes	no	no	NA	NA	no	2
2010	Hahne A. J. et al.[67]	no	yes	yes	no	no	yes	yes	yes	NA	no	no	5
2010	Kaminskyj A. et al.[68]	no	no	yes	yes	yes	yes	yes	yes	NA	no	no	6
2010	Shin B.-C. et al.[69]	no	unclear	yes	yes	no	yes	no	no	NA	NA	no	3
2009	Boudreau R. et al.[70]	no	no	no	no	no	yes	no	no	NA	no	no	1
2009	Boudreau R. & Spry C.[71]	no	unclear	no	no	yes	yes	no	no	NA	no	no	2
2009	Brurberg K. G. et al.[72]	no	no	yes	no	yes	no	yes	yes	NA	no	no	4
2009	Gouveia L. O. et al.[73]	no	no	yes	no	no	yes	no	no	no	NA	no	2
2009	Hunt K. J. et al.[74]	no	yes	yes	no	no	yes	yes	yes	NA	no	no	5
2009	Khorsan B. et al.[75]	no	no	yes	no	no	yes	yes	yes	NA	no	no	4
2009	Reiman M. P. et al.[76]	no	no	yes	yes	no	yes	yes	yes	NA	no	no	5
2008	Miley M. L. et al.[77]	no	no	no	no	no	no	no	no	no	no	no	0
2008	Stuber K. J. & Smith D. L.[78]	no	no	yes	yes	yes	yes	yes	yes	NA	no	no	6
2008	Vernon H. & Humphreys B. K.[79]	no	no	yes	no	no	yes	yes	yes	NA	no	no	4
2007	Chou R. & Huffman L. H.[80,81]	no	unclear	yes	no	yes	yes	yes	yes	no	no	no	5
2007	Ernst E.[82]	no	no	yes	no	no	yes	no	no	NA	NA	no	2
2007	Gross A. R. et al.[83]	no	no	no	yes	no	no	yes	no	NA	no	no	2
2007	Hawk C. et al.[84]	no	no	yes	no	no	yes	yes	yes	NA	no	no	4
2007	Luijsterburg P. A. J. et al.[85]	no	no	no	no	no	yes	yes	yes	NA	no	no	3
2007	Vernon H. & Humphreys B. K.[86]	no	unclear	no	no	no	yes	yes	yes	NA	no	no	3
2007	Vernon H. et al.[87]	no	no	yes	no	yes	yes	yes	yes	NA	no	no	5
2006	Gemmell H. & Miller P.[88]	no	no	yes	no	no	yes	yes	yes	NA	no	no	4
2006	Proctor M. et al.[89]	yes	yes	yes	yes	yes	yes	yes	yes	NA	no	no	8
2006	Snelling N. J.[90]	no	no	yes	no	no	yes	yes	yes	NA	no	no	4
2005	Brown A. et al.[91]	no	yes	yes	no	yes	yes	yes	yes	NA	no	no	6
2005	Ernst E.[92]	no	no	yes	no	no	yes	no	no	NA	NA	no	2
2005	Hondras M. A. et al.[93]	no	yes	yes	yes	yes	yes	yes	yes	NA	no	no	7
2005	Lisi A. J. et al.[94]	no	no	yes	no	no	yes	yes	yes	NA	no	no	4
2005	Rubinstein S. M. et al.[95]	no	yes	yes	no	no	yes	no	no	NA	no	no	3
2004	Brønfort G. et al.[96]	yes	yes	yes	no	yes	yes	yes	yes	NA	no	no	7
2004	Ernst E.[97]	no	no	yes	no	no	yes	no	no	NA	no	no	2
2004	Lenssinck M.-L. B. et al.[98]	no	yes	yes	no	yes	yes	yes	yes	NA	no	no	6
2004	Oduneye F.[99]	no	no	no	no	no	yes	no	no	NA	no	no	1
2004	Oliphant D.[100]	no	no	yes	no	no	yes	yes	no	no	no	no	3
2003	Ernst E.[101]	no	no	yes	no	no	yes	no	no	NA	no	no	2
2002	Ernst E.[102]	no	no	yes	no	no	no	no	no	NA	no	no	1
2002	Ernst E.[103]	no	no	yes	no	no	yes	no	no	NA	NA	no	2
2002	Gerritsen A. A. M. et al.[104]	no	yes	yes	no	no	yes	yes	yes	NA	no	no	5
2002	Gross A. R. et al.[105]	no	yes	yes	no	no	yes	yes	yes	no	no	no	5
2002	Gross A. R. et al.[106]	no	yes	no	no	no	yes	yes	yes	NA	no	no	4
2002	Stevinson C. & Ernst E.[107]	no	no	yes	no	no	yes	no	no	no	no	no	2
2001	Bronfort G. et al.[108]	no	no	no	no	yes	yes	yes	yes	NA	no	no	4
2001	Ernst E.[109]	no	no	no	no	no	yes	no	no	NA	no	no	1
2001	Ernst E. & Harkness E.[110]	no	no	yes	no	no	yes	yes	yes	NA	no	no	4
2000	Ernst E.[111]	no	no	no	no	no	yes	no	no	NA	no	no	1
2000	Magee D. J. et al.[112]	no	unclear	yes	no	no	yes	yes	yes	NA	no	no	4
1999	Fabio R. P. D.[113]	no	no	yes	no	yes	yes	no	no	no	no	no	3
1999	Haldeman S. M. et al.[114]	no	no	yes	no	no	yes	no	no	NA	no	no	2
1999	Vernon H. et al.[115]	no	no	yes	no	no	yes	yes	yes	NA	no	no	4
1996	Aker P. D. et al.[116]	no	unclear	unclear	yes	no	no	yes	yes	NA	no	no	3
1996	Assendelft W. J. J. et al.[117]	no	no	unclear	unclear	no	no	no	no	no	no	no	0
1996	Hurwitz E. L. et al.[118,119]	no	no	no	no	no	no	yes	yes	no	no	no	2
1995	Dabbs V. & Lauretti W. J.[120]	no	no	no	no	no	yes	no	no	no	no	no	1
1992	Shekelle P. G. et al.[121]	no	no	yes	yes	no	yes	yes	yes	NA	no	no	5
Total number of 'yes' for each item		**16**	**38**	**80**	**26**	**29**	**92**	**75**	**68**	**5**	**0**	**8**	

*The total score is the number of 'yes' for each review. Abbreviations: AMSTAR, A Measurement Tool to Assess Systematic Reviews; NA, not applicable. The total score was calculated giving one point for each 'yes' given for the 11 items.

1. Was an 'a priori' design provided? 2. Was there duplicate study selection and data extraction? 3. Was a comprehensive literature search performed? 4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? 5. Was a list of studies (included and excluded) provided? 6. Were the characteristics of the included studies provided? 7. Was the scientific quality of the included studies assessed and documented? 8. Was the scientific quality of the included studies used appropriately in formulating conclusions? 9. Were the methods used to combine the findings of studies for AEs appropriate? 10. Was the likelihood of publication bias assessed for AEs? 11. Was the conflict of interest included?

Safety of spinal manipulation

The estimates for the incidence of SAEs (**Table 3**) were heterogeneous, as they had different units (e.g. pr. number of manipulations, pr. cervical manipulations, pr. treatments, pr. visits, pr. patients treated, or pr. patients receiving chiropractic treatment) or had no units, were based on different patient types, and were obtained from different types of studies (**Appendix 3**). When not distinguishing between the different types of SMT treatments and assuming that one treatment or visit equals one manipulation, in addition to leaving out the minority of estimates not specifying the units or using pr. patient as the unit, the estimates for the incidence of SAEs ranges from 1 in 20,000 manipulations to 1 in 250,000,000 manipulations (**Box 3**). Even within each of the specific SAEs, the ranges are very wide, e.g. 1 stroke in 20,000 manipulations to 1 stroke in 2,000,000 manipulations.

Box 3: Estimates of the incidences of serious adverse events (some scaled for comparability)

Death
1 in >3,330.000-3,730,000 manipulations

Stroke
1 in 20,000-2,000,000 manipulations

Vertebrobasilar accident (VBA)
1 in 228,050-1,000,000 manipulations

Cerebrovascular accident (CVA)
1 in 228,050- 3,850,000 manipulations

Lumbar disc herniation (LDH)
1 in 8,369,129 manipulations*

Cauda equina syndrome (CES)
1 CES in >1,000,000-128,000,000 manipulations

CES or LDH
1 in >1,000,000-3,720,000 manipulations

'Serious adverse events'
1 in 1,000,000-250,000,000 manipulations

'Serious complication'
1 in 20,000-2,000,000 manipulations

**Only one estimate was available.*

Table 3: Estimates for the incidence of serious adverse events following spinal manipulation therapy

Year	Author	Estimates
2014	Todd A. J. et al.[26]	**From a SR:** 1 SAE in 250 million pediatric visits. **From a discussion paper:** 0 SAEs reported in >30000 treatments by medical manipulators.
2010	Carnes D. et al.[65]	**From a pCohort:** 14 cases of `unbearably severe side effects' in 4712 treatments (0.13%). Upper risk rate for `serious adverse events' of approximately 0.01% (3/28,109 consultations). **Their estimation from all pCohorts:** Upper 95% CI incidence risk rate of major adverse events of 0.007% (0/42,451) after treatment or 0.01% (0/22,833) per patient. **From RCTs:** No 'major adverse events' in the 31 RCTs (which included 2281 participants who received manual therapy and 2779 who received other therapies). Upper incidence rate of major adverse events of ~0.13% (0/2301) after manual therapy treatment.
2009	Gouveia L. O. et al.[73]	**Their own synthesis (*based on surveys*):** Between 5 strokes in 100,000 manipulations to 1.46 SAEs in 10,000,000 manipulations and 2.68 deaths in 10,000,000 manipulations.
2008	Miley M. L. et al.[77]	**From a CC (*which they consider the best available estimate*):** Approximately 1.3 cases of VAD or occlusion attributable to CMT would be observed within one week of manipulative therapy for every 100,000 persons <45 years of age receiving CMT. **From reviews:** Published estimates of the incidence of VAD and stroke after range from 1 in 5.8 million to 1 in 5000.
2007	Chou R. & Huffman L. H.[80,81]	**From SRs:** <1 SAE per 1 million patient visits.
2006	Snelling N. J.[90]	**From a SR:** 1 additional disc herniation or CES in 3.7 million manipulations (in pts, with lumbar disc herniation).
2004	Oliphant D.[100]	**From their own estimation:** <1 worsening LDH or CES in 3,72 million manipulations (in pts. with lumbar disc herniation), 1 worsening lumbar disc herniation or CES in 1,78 million manipulations (including manipulations under anesthesia; in pts. with lumbar disc herniation). **From other reviews:** 1 CES in 128 million manipulations (given the quality score 84%), 1 CES in 100 million manipulations (given the quality score 86%), <1 (CES or herniation) in 1 million manipulations (given the quality score 74%), 1 LDH or CES in 2,789,709 manipulations (1 LDH in 8,369,129 manipulations, and 1 CES in 4,184,564 manipulations) (given the quality score 32%).

		From a retrospective study: "They stated they were 95% confident that the risk of complication of manipulation for patients with back pain and sciatica was between 0% and 5%.". **From a prospective study:** "A prospective evaluation of 2000 patients attending a chiropractic college clinic failed to reveal even one major complication", "1000 new patients and 4700 treatments and found no permanent complications". **From surveys:** 1 minor or transient complication but no serious or permanent complications in 38,137 lumbar spinal manipulations. **From pooling the prospective and retrospective studies together:** 0 major, serious, or permanent complications in >2100 patients (>13,100 treatments). 0 complications in 117 patients diagnosed as having LDH (>2000 spinal manipulation of probable disk herniations).
2002	Gross A. R. et al.[105]	**From SRs:** 1 serious complication in 20,000 to 5 serious complications in 10,000,000 cervical spine manipulations (rated as low accuracy and level V evidence), 1 stroke from cervical manipulation in 100,000 (0.001%). **From a survey:** 1 CVA in 228,050 manipulations, 1 CVA in 1.3 million, 5 CVA in one million.
2002	Stevinson C. & Ernst E.[107]	**Their own summarization:** "Estimates of the incidence of serious complications range from 1 per 2 million manipulations to 1 per 400,000". **From reviews and a letter:** 1 SAE per 1-2 million treatments. **From surveys:** 1 sleight neurologic complication pr. 40,000 manipulations, 1 severe complication per 400,000 manipulations, 1 stroke pr. 1,300,000 treatments of cervical SMT. **From insurance claim data referred to in a SR:** 1 stroke pr. 2 million manipulations. **From a CC:** 1.3 VBA within 1 week of treatment in 100,000 pts <45 years receiving chiropractic treatment.
1996	Assendelft W. J. J. et al.[117]	**Their own conclusion (*partly based on the articles not appearing in their result section*):** From 1 VBA in 20,000 patients to 1 VBA in 1 million cervical manipulations. <1 CES in 1 million treatments. **From a SR:** No complications in 1500 patients treated with manipulation in clinical trials. **From surveys:** 1 slight neurological complication in 40,000 cases, 1 important complication in 400,000 manipulative procedures, 1 VBA in 228,050 manipulations, <5 strokes in 100.000 patients receiving neck manipulations.
1996	Hurwitz E. L. et al.[118]	**From their own estimation:** 5-10 VBA or other complications (spinal cord compression, vertebral fracture, trachael rupture, diaphragm paralysis, internal carotid hematoma, cardiac arrest) in 10,000,000 manipulations, 3-6 major impairment (paralysis, neurologic deficit, other permanent functional impairment) in 10,000,000 manipulations, <3 deaths in 10,000,000 manipulations. **From surveys:** 1 serious complication in 400,000 to >1 million manipulations, 1 CVA accident in 3.85 million cervical spine manipulations. *They compare the incidence rates with NSAID consumption (0.39-3.2 serious gastrointestinal event in 1000 subjects) and cervical spine surgery (15.6 neurologic complications (spinal cord or nerve root injury, recurrent laryngeal nerve palsy, dural leak, and injury to cervical sympathetic nerve trunk (Horner's syndrome)) in 1000 surgeries and 6.9 deaths in 1000 surgeries.*
1995	Dabbs V. & Lauretti W. J.[120]	**Their own summarization:** 0.5-2 strokes in one million cervical manipulations performed, 1 serious vascular complication in 100.000 patients who undergo a course of treatment (10-15 sessions of cervical manipulation over the course of a year) with cervical manipulation, or 0.001%, 1 death in 400.000 pts. treated, or an "overall death rate of 0.0025% per course of treatment for patients with neck pain who are treated with cervical manipulation." *They compare this with a risk of 0.4% for getting serious gastrointestinal ulcers requiring hospitalization because of NSAID use, and a risk of 0.04% for death from gastrointestinal bleeding caused by NSAID use.* **Their own calculation based on insurance company data:** <1 stroke in 2 million cervical manipulations. **From surveys:** 1 serious complication in 400.000 cervical manipulations (no reported deaths), 1 complication in 518.000 manipulations, 1 stroke in 500.000 cervical manipulations, no serious incidence in >500.000 manipulations, 2-3 "more-or-less serious incidents" in one million treatments. **From reports:** no vertebral artery injury or stroke in 5 million cervical manipulations, no significant complications in 168.000 cervical manipulations. **From a review:** 1-2 strokes in one million manipulations.
1992	Shekelle P. G. et al.[121]	**Their own estimation:** <1 case of CES in 100 million lumbar spinal manipulations.

Abbreviations: CC, case-control study; CES, cauda equina syndrome; CMT, cervical manipulative therapy; CVA, cerebrovascular accident; LDH, lumbar disc herniation; NSAID, non-steroidal anti-inflammatory drug; pCohort, prospective cohort study; RCT, randomized controlled trial; SAE, serious adverse event; SMT, spinal manipulation therapy; SR, systematic review; VAD, vertebral artery dissection; VBA, vertebrobasilar accident.

Based on the conclusions of the reviews regarding AEs and SAEs, 46 reviews (44.2%) expressed that SMT is safe, 15 (14.4%) expressed that SMT is harmful, and 43 reviews (41.3%) were neutral or unclear regarding the safety of SMT, with a fair agreement between the two reviewers (Cohens Weighted Kappa, 0.52).

The calculations of RRs shows, that there is a higher chance of a review communicating that SMT is safe, when having a higher methodological quality, compared to reviews of lower methodological quality (statistically significant for the AMSTAR items 2, 5, 7 or 8; Table 4). And *vice versa*, there is a lower chance of a review communicating that SMT is harmful, when it has a lower methodological quality.

Table 4: The risk ratio of having the opinion that spinal manipulation therapy is safe or harmful, respectively, if a 'yes' was obtained in the individual AMSTAR items (104 reviews)

	Risk ratio (RR)			
	RR (95% CI) for communicating that SMT is safe	P values	RR (95% CI) for communicating that SMT is harmful	P values
AMSTAR #1	1.5 (1.0 to 2.4)	0.111	Not estimable**	-
AMSTAR #2	1.6 (1.0 to 2.4)	0.034	0.3 (0.1 to 1.1)	0.045
AMSTAR #3	1.1 (0.6 to 1.8)	0.774	2.0 (0.5 to 8.0)	0.336
AMSTAR #4	1.2 (0.7 to 1.9)	0.496	0.5 (0.1 to 1.9)	0.262
AMSTAR #5	2.2 (1.5 to 3.2)	<0.001	0.2 (0.0 to 1.3)	0.049
AMSTAR #6	1.9 (0.7 to 5.1)	0.156	1.8 (0.3 to 12.7)	0.525
AMSTAR #7	3.2 (1.4 to 7.2)	<0.001	0.1 (0.0 to 0.2)	<0.001
AMSTAR #8	1.9 (1.1 to 3.4)	0.014	0.1 (0.0 to 0.3)	<0.001
AMSTAR #9	1.4 (0.7 to 2.9)	0.469	1.4 (0.2 to 8.7)	0.717
AMSTAR #10	Not estimable*	-	Not estimable*	-
AMSTAR #11	1.8 (1.1 to 2.9)	0.070	Not estimable**	-

Abbreviations: AMSTAR, A Measurement Tool to Assess Systematic Reviews; CI, confidence interval; RR, risk ratio; SMT, spinal manipulation therapy.

*No SRs had a "yes" for this item.

** No SRs had a "yes" for this item and communicated "safe".

(For descriptions of each AMSTAR item, see foot note for Table 2)

When only considering the subset of reviews, whose objective was to investigate AEs (33 reviews), then 5 reviews (15.2%) expressed that SMT is safe, 13 SRs (39.4%) expressed that SMT is harmful, and 15 reviews (45.5%) was neutral or unclear regarding the safety of SMT. The calculations of RRs did not obtain enough power to show any statistically significant RRs (Table 5).

Table 5: The risk ratio of having the opinion that spinal manipulation therapy is safe or harmful, respectively, if a 'yes' was obtained in the individual AMSTAR items (33 reviews, whose objective was to investigate adverse events)

	Risk ratio (RR)			
	RR (95% CI) for communicating that SMT is safe	P values	RR (95% CI) for communicating that SMT is harmful	P values
AMSTAR #1	Not estimable**	-	Not estimable**	-
AMSTAR #2	Not estimable**	-	0.7 (0.2 to 2.4)	0.516
AMSTAR #3	1.1 (0.1 to 8.2)	0.943	1.5 (0.4 to 5.2)	0.516
AMSTAR #4	Not estimable**	-	1.8 (0.7 to 4.6)	0.318
AMSTAR #5	Not estimable**	-	0.8 (0.2 to 4.4)	0.824
AMSTAR #6	1.1 (0.1 to 8.2)	0.943	3.2 (0.5 to 20.8)	0.131
AMSTAR #7	4.0 (0.8 to 20.1)	0.079	Not estimable**	-
AMSTAR #8	Not estimable**	-	Not estimable**	-
AMSTAR #9	2.5 (0.4 to 15.8)	0.364	0.8 (0.2 to 4.4)	0.824
AMSTAR #10	Not estimable*	-	Not estimable*	-
AMSTAR #11	Not estimable*	-	Not estimable*	-

Abbreviations: AMSTAR, A Measurement Tool to Assess Systematic Reviews; CI, confidence interval; RR, risk ratio; SMT, spinal manipulation therapy.

*No SRs had a "yes" for this item.

** No SRs had a "yes" for this item and communicated "safe".

(For descriptions of each AMSTAR item, see foot note for Table 2)

DISCUSSION

Our aim was to elucidate and quantify the risk of AEs associated with SMT. However, the included reviews did not provide sufficient data for synthesis, thus it is currently not possible to provide an overall estimate for the risk of AEs associated with SMT. Across the individual reviews, no reliable single estimate for the incidence of SAEs were provided and it was not possible to identify any agreement regarding the safety of SMT across the included reviews.

Our extensive search strategy resulted in a large amount of relevant systematic reviews (more than 100 reviews). Consequently, this overview is to our knowledge, the most comprehensive overview conducted on SMT, and the only one with a sole focus on the safety aspects of SMT. Such extensive amount of data usually provides a solid basis for quite precise estimates of the outcome(s) of interest. However, despite our best intentions and efforts we must accept that it is not possible to provide any reliable estimates of the risk associated with SMT.

While it was not possible to calculate incidences, the most frequently mentioned AEs/SAE across the 104 reviews range from minor events, such as soreness, to significant events, such as spinal cord injury and death. While some of these events have major impact on not only the individual, but also the SMT provider and society, it is not possible to assess the benefit-harm balance based on the current evidence. We strongly encourage efforts to illuminate the risk/benefit ratio reliably. This would be of value when comparing SMT with other treatment options; some of our included reviews suggest that NSAID involves a substantially higher risk of SAEs (including death) than SMT [118,120], but did not take into account the possible benefits.

To provide reliable estimates for the incidence of SAEs and AEs, reliable numbers of patients experiencing SAEs/AEs following SMT and the total number of patients receiving SMT or the total number SMT treatments performed, is necessary. These data were either not available from the included reviews or not reported in a way that allowed for adequate methods of data synthesis (e.g. meta-analysis). While this may be due to poor methodological quality or lack of attention to safety in the included reviews, it can also be caused by limitations in the underlying primary studies reviewed in the reviews.

Underreporting of AEs and/or SAEs in the primary studies of the reviews may be a huge issue, as highlighted in several of the included reviews. In retrospective studies, recall bias may be present, and in the poorly controlled prospective studies, reporting may be poor. However, if only considering reviews on controlled prospective studies, such as RCTs, then the population size may have been insufficient to detect SAEs reliably. Ernst and Posadzki (2012)[122] showed that even in RCTs, the reporting of AEs is poor, since only half of their 60 included RCTs on manipulation mentioned AEs, with 16 reporting that no AEs had occurred. Only one RCT provided complete information on AEs (i.e. incidence, severity, duration, frequency and method of reporting). Carlesso et al (2010)[64] used, in addition to the a general risk of bias tool, the McHarm quality assessment tool for assessing the reporting of harms, and found a high risk of bias in the vast majority of the included studies. Tang et al. (2015)[123] assessed the consistency between the SAEs posted at www.ClinicalTrials.gov and the SAEs published in the corresponding journal articles, in 300 trials that all had posted SAEs at www.ClinicalTrials.gov. They found that 202 trials had a corresponding publication, of which 26 did not mention SAEs, 4 reported no SAEs, and 44 trials reported numbers of SAEs for the treatment groups that did not match those at www.ClinicalTrials.gov, with 31 reporting a smaller number of SAEs than posted at www.ClinicalTrials.gov. Hence, even high quality reviews may fail to provide reliable estimates due to poor reporting in the primary journal reports. Poor reporting of AEs is however also present on the level of the reviews[124], which may have been the case for many of the reviews we excluded due to missing data on AEs.

The primary studies included in the reviews encompassed multiple study types (ranging from case reports to RCTs), which provides various levels of evidence, and therefore obstructing the possibility to assess a causal association between SMT and AE/SAEs reliably. Coincidental occurrence of SAEs cannot be ruled out as possible explaining factors for some of the observed SAEs. The causal relationship between SMT and SAEs was systematically investigated in 6 of the included reviews[77,82,92,97,101,107]. Five of these had for each case report or case series assessed the likelihood of causality using the ratings 'certain', 'likely', 'possible', or 'not assessable'/'???' [82,92,97,101,107]. In all cases, 'certain' was not the single most used rating (see **Table 6**). Miley et al. (2008)[77] used another approach by aiming to answer the question "*Does cervical manipulative therapy cause vertebral artery dissection and subsequent ischemic stroke?*" by using the Bradford Hill's criteria for causation and the strength of the research designs. Based on their selected

studies, they found that 5 of the 7 criteria were met, providing weak to moderate strength of evidence for a causal relationship between cervical SMT and vertebral artery dissection. However, they also express that comprehensive prospective studies are needed to confirm this relationship. The reporting of AE/SAEs needs improvement as well, since Wynd et al. (2013)[37] found that data on the factors included in the Bradford Hill's criteria were infrequently reported in studies on cervical arterial dissection following cervical SMT (including case reports, case series, surveys, cohort studies and a commentary).

Table 6: Ratings of the causal relationship between SMT and SAEs in reviews [82,92,97,101,107]

Rating of causal relationship	Ernst 2007[82]	Ernst 2005[92]	Ernst 2004[97]	Ernst 2003[101]	Stevinson 2002[107]
"Certain", n(%)	8 (21.6%)	6 (42.9%)	12 (30%)	0 (0%)	5(22.7%)
"Likely" , n(%)	18 (48.6%)	6 (42.9%)	16 (40%)	0 (0%)	14 (63.6%)
"Possible" , n(%)	8 (21.6%)	2 (14.3%)	9 (22.5%)	2 (100%)	0 (0%)
"Not assessable" or "???", n(%)	3 (8.2%)	0 (0%)	3 (7.5%)	0 (0%)	3 (13.6%)
Total, n(%)	37 (100%)	14 (100%)	40 (100%)	2 (100%)	22 (100%)

This overview has several limitations. Firstly, as reviews include published reports there is a high risk of missing the most recently published primary studies or other published studies not yet been included in reviews. This limitation is shared in an overview of reviews (and possible enhanced). Further, the included studies in the reviews may overlap, i.e. the same primary studies may be included in several reviews. Indeed this was the case among the included reviews that provided safety estimates. Further, this overview of reviews relies on both the methodological quality of the reviews, and the methodological quality of the primary studies.

The methodological quality of the included reviews was low. 75% of the included reviews had an overall AMSTAR score of 5, which highlights the general poor methodological quality of the available reviews of SMT. Only a minority of the reviews reported that an 'A priori' design or protocol dictated the review (AMSTAR item 1) and even fewer of the reviews used appropriate methods to combine findings across studies (AMSTAR item 9). Also, none assessed the risk of publication bias related to AEs (AMSTAR item 10), and few reviews mentioned potential conflicting interests among the authors (AMSTAR item 11).

In acceptance of the limited data we took an alternative approach in the pursuit of underlying messages regard safety of SMT embedded in the included reviews. Interestingly, we found indications of towards reviews with higher methodological quality generally used language that suggests SMT to be safer (or less harmful). This was particularly evident for the reviews that assessed the scientific quality of the primary studies (AMSTAR item 7) and if this quality assessment was used appropriately in the formulation of the conclusions of the review (AMSTAR item 8). However, when analyzing this across the reviews whose objective was to investigate safety, this could not be replicated. Overall; our confidence in the evidence

regarding safety of SMT is very low, but reviews with less methodological limitations tend to communicate that SMT may be safe.

Another possible limitation is that we set no limitations on patient populations (e.g. low back pain, cervical pain, etc.). Neither did we classify the reviews according to populations as the included reviews often were multi-indication reviews. The included reviews were very heterogeneous with respect to their aim, included study types, and their methodological quality. Including different study types may be less of a problem, since meta-analyses of AEs from RCTs and meta-analyses of AEs from observational studies have been shown to give similar results[125]. Heterogeneity was present in communicated opinions regarding the safety of SMT as well, which further diminishes our confidence in the overall impression about safety of SMT. Altogether; this precludes any conclusions about the safety SMT in different populations, which further reduces the capability to comment on the safety profile of SMT.

Our methodological approach has limitations too. These include the absence of a double data selection and data extraction, and a very brief protocol. These methodological compromises were taken due to limited time resources. However, our search strategy was broad and we are quite confident that we have identified the vast majority of the relevant scientific literature on SMT. Given the available data and its quality we find it unlikely that more thorough data selection and extraction procedures would result in different conclusions.

While, it is not possible to provide reliable estimates on the risk associated with SMT, Denmark seems like the ideal place to gather such important information. The Danish health care system is characterized by a detailed level of registration on a national level. The registers include diagnoses, treatments, professions, reimbursements, medication, AEs etc. Thus, the data necessary for a reliable nationwide estimation of AE/SAE incidence is readily available, and we encourage such effort to be instigated.

CONCLUSION

This overview has indeed demonstrated how extensive the literature on SMT is. Unfortunately the majority of studies are non-systematic and of poor quality. The available evidence showed a broad range of communicated opinions and very variable estimates of SAE incidence, making it evident that reliable estimates are absent and it is not currently possible to provide an overall conclusion about the safety of SMT.

However, the types of SAEs reported can indeed be significant, sustaining that there is some risk present; sometimes SMT may even lead to death or permanent disability. Whether SMT can be considered safe or harmful cannot be clearly agreed upon, but this overview suggests that studies on SMT with less methodological flaws typically communicate that SMT may be safe. However, the methodological quality

was in general quite low and the included reviews very heterogeneous, which all in all eliminate our confidence in any conclusions regarding the safety of SMT. Research of high quality is needed if reliable risk estimates are to be obtained.

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Competing interests

MH is a member of the Association of Danish Physiotherapists that could benefit from this publication.

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Appendix 1

Search strategy

The initial search strategy was developed for PubMed and adapted to the other databases. It consists of an intervention filter and review filter:

PubMed:

(((manipulat*[Title/Abstract] AND spine[Title/Abstract]) OR (manipulat*[Title/Abstract] AND spinal[Title/Abstract]) OR (manipulat*[Title/Abstract] AND lumbar[Title/Abstract]) OR (manipulat*[Title/Abstract] AND back[Title/Abstract]) OR (manipulat*[Title/Abstract] AND neck [Title/Abstract]) OR (manipulat*[Title/Abstract] AND cervical[Title/Abstract]) OR (manipulat*[Title/Abstract] AND thrust[Title/Abstract]) OR (manipulat*[Title/Abstract] AND osteopath*[Title/Abstract])) OR "Manipulation, Chiropractic"[Mesh] OR "spinal adjustment*" OR chiropractic*)

NOT (animals NOT humans)

AND

(Cochrane[Title/Abstract] OR CENTRAL[Title/Abstract] OR MEDLINE[Title/Abstract] OR EMBASE[Title/Abstract] OR pubmed[Title/Abstract] OR search*[Title/Abstract] OR "systematic review"[Title/Abstract] OR meta-analysis[Title/Abstract] OR metaanalysis[Title/Abstract] OR "network meta-analysis"[Title/Abstract] OR "Comparative effectiveness"[Title/Abstract] OR "Indirect comparison"[Title/Abstract] OR "mixed treatment comparison"[Title/Abstract]

OR "Systematic Literature"[Title/Abstract])

Cochrane Database of Systematic Reviews, DARE and HTA:

#1 MeSH descriptor: [Manipulation, Chiropractic] explode all trees

#2 "spinal adjustment" and "spinal adjustments" or chiropracti*

#3 (manipulat* and spine) or (manipulat* and spinal) or (manipulat* and lumbar) or (manipulat* and back) or (manipulat* and neck) or (manipulat* and cervical) or (manipulat* and thrust) or (manipulat* and osteopath*)

#4 #1 or #2 or #3

EMBASE:

1. (animals not humans).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

2. ((manipulat* and spine) or (manipulat* and spinal) or (manipulat* and lumbar) or (manipulat* and back) or (manipulat* and neck) or (manipulat* and cervical) or (manipulat* and thrust) or (manipulat* and osteopath*)).ti,ab.

3. ("spinal adjustment" or "spinal adjustments" or chiropracti*).ti,ab.

4. (Cochrane or CENTRAL or MEDLINE or EMBASE or pubmed or search* or "systematic review" or meta-analysis or metaanalysis or "network meta-analysis" or "Comparative effectiveness" or "Indirect comparison" or "mixed treatment comparison" or "Systematic Literature").ti,ab.

5. ((2 or 3) and 4) not 1

6. (conference).pt.

7. 5 not 6

Appendix 2

Table: Summary of findings for spinal manipulation therapy

Author (year) [ref]	Included studies on SMT (pts. In total)	Population receiving SMT	Interventions including SMT	AEs reported* associated with SMT)	Conclusion on AEs from SMT (quote)	Quality of the evidence for AEs (tool)
Cicchintti L. et. al (2015)	1 CC, 6 RCTs, 1 observational study, 1 laboratory study, 1 cross-over pilot study (NA)	Pts 'with medical conditions classified also as CID' (CID: chronic inflammatory disease)	OMT (may include SMT)	Musculoskeletal soreness or pain, elevated blood pressure in the morning, mild heart palpitations, sore back, feeling mildly light headed No SAEs	"No major side effects were reported by those receiving OMT. (...) the OMT appears to be a safe approach (...) Only seven studies reported data on side effects. In five studies none of the participants showed side effects after osteopathic treatments. In the study conducted by Noll et al., 14 subjects over 25 reported mild side effects characterized by musculoskeletal soreness or pain. Post-hoc calculation of RR showed a reduction of side effects in the minimal touch control group compared to all other groups (data not showed). A further study conducted by Noll et al reported two patients with symptoms of muscle soreness after the OMT session, while in the sham group the side effects were recorded in four subjects who reported "elevated blood pressure in the morning", "mild heart palpitations", "a little muscle soreness" and "back was a little sore". Again, post-hoc RR computations demonstrated no significant reduction of side effects in the study group compared to controls (data not showed)."	Not reported
Gross A. J. et. al (2015)	39 RCTs (NA)	Pts with cervical pain, cervicogenic headache or cervical disorders with radicular findings	Manipulation (may be entirely SMT)	Increased neck pain, soreness, headache, stiffness, dizziness, nausea, paraesthesia, upper limb pain, fatigue, mid-lower back pain and "unpleasant change in spinal posture" No SAEs	"Among participants receiving manipulation, 22% (105/469 participants) experienced adverse events. All adverse events reported for manipulation or mobilisation were benign and transient side effects (...)"	Not reported
Liddle S. D. & Pennick V. (2015)	5 RCTs (289 pts in total)	Pregnant women with risk for or suffering from low-back pain, pelvic pain or both	SMT, manual therapy provided by a chiropractic specialist, osteopathic treatments, OMT (all treatments include or may include SMT)	NA No SAEs	"When reported, adverse effects were minor and transient." *(Of the five trials on SMT, two did not report on AEs, two trials reported no AEs, and for one trial it was unclear if AEs was reported or not)*	Not reported
Puentedura E. J. & O'Grady W. H. (2015)	7 CRs (10 pts in total)	Pts in studies reporting AEs following thoracic SMT	Thoracic SMT	Progressive weakness/paraesthesia in the lower extremities, thoracic pain, nausea, shortness of breath/dyspnoea at rest, neck stiffness, photophobia, severe headache (*most common*) **SAEs**: Injury (mechanical or vascular) to the spinal cord, pneumothorax,	"This review showed that serious AEs do occur in the thoracic spine. The most commonly reported AE involved trauma to the spinal cord, followed by pneumothorax. This suggests that excessive peak forces may have been applied to thoracic spine, and it should serve as a cautionary note for clinicians to work on their TJM skills to decrease these peak forces."	Not reported

				hematothorax, cerebrospinal fluid leak secondary to dural sleeve injury (*most common*)		
Southerst D. et. al (2015)	2 RCTs (98 pts in total)	Pts with thoracic spine pain or acute chest pain	Cervical or thoracic SMT	Local tenderness, headache, fatigue No SAEs	"One study reported on adverse events. Stochkendahl et al reported no serious adverse events in the multimodal care group (including SMT). However, 75% of participants in this group reported transient and benign adverse events such as local tenderness, headache, and fatigue."	Not reported
Yuan Q.-L. et. al (2015)	3 RCTs (208 pts in total)	Pts with cervical pain	Chinese manipulation	None	"Two studies mentioned adverse events, none were observed in either study."	Not reported
Zhu L. et. al (2015)	3 RCTs (NA)	Pts with degenerative cervical radiculopathy	Cervical SMT	None	"The safety of cervical manipulation cannot be taken as an exact conclusion so far. (...) Only one trial reported the adverse events and none were observed in the trial with a small sample size. The other two trials did not mention whether adverse events have occurred in the intervention or control group."	Not reported
Bryans R. et. al (2014)	12 RCTs (513 pts in total)	Pts with cervical pain	Manipulation or thoracic manipulation	"Minor events" No SAEs	"There were no serious adverse events reported in any of the citations used in developing these treatment recommendations. A summary of the adverse event reporting from the literature summary is shown in Table 7. Of the 43 studies included in this summary, 14 made no mention of adverse events. Of the remaining 33, all studies reported either none or only minor adverse events from a total of 1682 study participants and several treatment sessions (on average) per participant." *(The tables shows, that 8 trials reported no AEs, 3 trials did not record AEs, and 1 trial reported minor events)*	Not reported
Clar C. et. al (2014)	96 RCTs, 72 SRs, 10 non-randomized primary studies (NA)	Pts 'with musculoskeletal and non-musculoskeletal conditions'	Interventions including 'an element of manipulation or mobilisation'	Worsening symptoms, increased pain, soreness, headache, dizziness, tiredness, nausea, vomiting (*very sparse information with respect to AEs*) **SAEs**: Cerebrovascular events, disc herniation, vertebral artery dissection, cauda equine syndrome, stroke, dislocation, fracture, transient ischemic attack	"Poorly and scarcely reported harms data limited our ability to make meaningful comparisons of rates of adverse events between the treatments (...) Seven systematic reviews and seven primary studies were identified specifically concerning adverse events of manual therapy. Mild-to-moderate adverse events of transient nature (...) were relatively frequent. For example, evidence from high, medium, and low quality systematic reviews specifically focusing on adverse events suggested that approximately half of the individuals receiving manual therapy experienced mild-to-moderate adverse event which had resolved within 24–74 hours. In agreement with the UK evidence report, evidence indicated that serious (or major) adverse events after manual therapy were very rare (...). Evidence on safety of manual therapies in children or pediatric populations was scarce; the findings from two low quality cohort studies and one survey were consistent with those for adults that transient mild to moderate intensity adverse events in manual treatment were common compared to more serious or major adverse events which were very rare."	Not reported
Close C. et. al (2014)	1 RCT, 1 feasibility RCT (NA)	Pregnant women with low-back pain or pelvic pain	SMT or OMT	Soreness *(very sparse information with respect to AEs)*	"In this review, adverse effects reported were minor, which would imply that participants that dropped out were unhappy with the treatment they were receiving.	Not reported

				No SAEs	or they may have perceived no improvements. However, possible under-reporting of adverse effects cannot be ruled out, considering the few studies that reported adverse effects and the limited detail provided. (...) There was also limited information on adverse effects. This is a cause for concern as the under-reporting of adverse effects could make treatments appear safer than they actually are, as well as possibly breaching publication ethics."	
Franke H. et. al (2014)	15 RCTs (779 pts in total)	Pts with non-specific low-back pain	OMT (may include SMT)	Stiffness and tiredness *(very sparse information with respect to AEs)* No SAEs	"Of the 15 included studies, only 4 studies reported on adverse events. Two studies reported minor adverse events such as stiffness and tiredness. In the 2013 study, Licciardone et al. reported that 6% of patients had adverse events, but none of the serious events appeared to be related to the treatment intervention, and there were no significant differences between the treatment groups in the frequency of adverse events or serious adverse events. In a personal communication, the authors of another study reported that no adverse events occurred."	Not reported
Kizhakkeveet til A. et. al (2014)	12 RCTs (1799 pts in total)	Pts with low-back pain	SMT	Not specified/may be none SAEs: Not specified/may be none	None *(Unclear descriptions. No AEs were reported in 2 RCTs, AEs may have been reported in 4 RCTs and AEs were not reported in 6 RCTs)*	Not reported
Page M. J. et. al (2014)	1 RCT *(9 other trials included manual therapy, but were not further specified and were not included)* (4 pts in total)	Pts with adhesive capsulitis (frozen shoulder)	SMT	None	"Only seven trials measured adverse events, with three reporting marginal differences between groups, and four reporting no adverse events in any group [including one trial on SMT]."	Not reported *(The SMT study was not included in the quality of evidence assessment of AEs (GRADE))*
Sutton D. et. al (2014)	8 RCTs (813 pts in total)	Pts diagnosed with whiplash-associated disorders or cervical pain and associated disorders	Multimodal care (SMT mixed with other interventions)	Headache, increased neck pain, tingling in upper extremities, dizziness, odd arm sensation but had normal neurologic examination, muscle soreness, tiredness, increased pain after first and second appointments *(the interventions were very mixed, and all of these AEs may not be related to SMT)* No SAEs	"Nine admissible RCTs reported adverse events [7 of these included SMT]. No RCT reported serious adverse events. Most adverse events were minor (e.g., headache, increased neck pain, tingling in upper extremities, dizziness). The proportion of adverse events in participants enrolled in a multimodal program of care ranged from 3% after one multimodal osteopathic treatment [in a study including SMT] to 63% after a multimodal program of care [in a study not including SMT]."	Not reported
Todd A. J. et. al (2014)	4 CRs, 1 CS, 8 surveys, 6 RCTs, 5 SRs, 5 narrative reviews, 2 discussion papers (>34605 pts in total)	Infants or children in studies reporting AEs following chiropractic or other manual treatments	Chiropractic and other manual treatments (including SMT in the majority of the studies)	Soreness, stiffness, headache, severe headache, crying, sleeplessness, mid-back soreness and increased irritability, stiff neck, moderate to severe bradycardia, apnea of short duration, worsening symptoms, behavior problems/irritability, pain/soreness, headache,	"High-velocity, low-amplitude thrust (HVLA) spinal manipulative therapy (SMT) was applied in 10 of the 15 cases of serious adverse events. In addition, in 8 of the 15 cases of a serious adverse event, it was revealed that before the application of chiropractic or manual therapy, there was present a preexisting but undetected underlying pathology or existing neurologic symptoms. Three deaths were recorded, and 2 of these were in infants under 3 months of age who had previously been healthy."	Not reported

				dizziness/flu-like symptoms/treatment, reaction/tiredness, vomiting, left facial weakness, diplopia, ataxia, leg fractures, hematothorax **SAEs**: Loss of consciousness, anterior dislocation of atlas and fracture of odontoid axis at C2, dislocation of atlas, death, subarachnoidal hemorrhage and death		
Tuchin P. (2014)	9 CRs (9 pts in total)	Pts experiencing intracranial hypotension following SMT	SMT	Intracranial hypotension No SAEs	"To date, the evidence that CSMT [chiropractic SMT] is a cause of IH [intracranial hypotension] is inconclusive."	Not reported
Yin P. et. al (2014)	34 CRs, 4 CSs (94 pts in total)	Pts experiencing AEs following pain-related massage (including SMT)	Different types of manipulations (SMT or not further specified)	Disc herniation, soft tissue trauma, neurologic compromise, bone fracture, hematoma or hemorrhagic cyst, syncope, pain, dislocation (*most common*) **SAEs**: Spinal cord injury, dissection of the vertebral arteries, cauda equina syndrome (*most common*)	"The symptoms are frequently life-threatening, though in most cases the patient made a full recovery. In the majority of cases, the problems were related to spinal manipulations, including rotational movements, which seem to be the probable cause of the AEs. (...) Spinal manipulation in massage has repeatedly been associated with serious AEs especially. But the incidence of such events is probably low."	Not reported
Young J. L. et. al (2014)	1 CS, 1 pCohort, 10 RCTs, 1 'quasi-experimental study lacking randomization', 1 'secondary analysis of a RCT' (539 pts in total)	Pts with mechanical neck pain	Thoracic SMT	Aggravation of symptoms, muscle spasm, neck stiffness, headache, and radiating symptoms No SAEs	"In addition, no significant differences were observed in the number of side effects experienced by the manipulation or mobilization groups." *(No descriptions linking the AEs to the individual trials)*	Not reported
Brantingham J. W. et. al (2013)	5 CRs, 2 CSs, 1 RCT (109 pts in total)	Pts with upper extremity problems (including carpal tunnel syndrome, shoulder impingement syndrome, soft tissue disorder or associated myofascial pain and dysfunction syndrome, frozen shoulder adhesive capsulitis, Parsonage-Turner syndrome, temporomandibular joint dysfunction and	SMT	Not specified **SAEs**: Not specified/may be none	"Yet with local MMT [Manual or Manipulative Therapy] management of CTS [carpal tunnel syndrome] there are no reported serious adverse reactions beyond occasional minimal and temporary soreness, stiffness and/or temporary aggravation; bruising and/or soreness from soft tissue MMT [not SMT]. Such bruising and soreness caused only one subject to leave treatment in the Burke et al study and none in the vigorous ST MMT (trigger point therapy) CTS study of Hains and Hains [not SMT]. There are then almost no reports of serious adverse reactions (permanent disability or death) and minimal to nearly no side-effects reported for ultrasound, splinting, mobilization of the carpal bones, and/or upper extremity FKC MMT [Full Kinetic Chain Treatment Manual or Manipulative Therapy] in treatment of CTS [including 2 studies on SMT]."	Not reported

		disorder, lateral epicondylitis, epicondylosis, epicondylalgia, tennis elbow, etc.)				
Hebert J. J. et. al (2013)	41 CRs (77 pts in total)	Pts experiencing SAEs following SMT of the lumbar spine or pelvis	SMT of the lumbar spine or pelvis (including a few studies on spinal mobilization)	Lumbar disk herniation, fracture, hematoma or hemorrhagic cyst, soft tissue trauma, muscle abscess formation, disrupted fracture healing SAEs: Signs and symptoms consistent with cauda equina syndrome, neurologic or vascular compromise, esophageal rupture	"Additional high-quality research is needed to better estimate the incidence of adverse events associated with lumbopelvic SMT and to elucidate the relationship between this therapy and the types of adverse events reported in this systematic review. (...) The most commonly reported adverse events were signs and symptoms consistent with cauda equina syndrome (29 cases, 38% of total) and lumbar disk herniation (23 cases, 30% of total)."	Not reported
Hulsman P. A. et. al (2013)	10 RCTs (350 pts in total)	Pts with non-specific cervical pain	Thoracic SMT	"Benign transient side effects" No SAEs	"Five studies provided information regarding adverse events, which if occurred, were benign transient side effects. In future studies, better reporting of adverse events is needed."	Not reported
Parkinson L. et. al (2013)	1 pCohort, 4 RCTs, 1 observational study (>520 pts in total)	Pts with lower back pain	SMT	None	"(...) and two considered adverse events. (...) Giles et al. found that patients were highly satisfied with chiropractic treatment, and that no adverse events related to chiropractic occurred in a hospital setting. (...) Both studies which considered this reported no adverse events associated with chiropractic, but this was not significantly different from other treatments in the UCLA low back pain study." *(AEs reported by two studies, both reported no AEs)*	Not reported
Posadzki P. et. al (2013)	17 RCTs (>448 pts in total)	Children and adolescents with 'pediatric conditions'	OMT (may include SMT)	"Aggravation of vegetative symptoms" No SAEs	"Eleven (64%) of the included RCTs failed to report the incidence rates of AEs. This may amount to a serious breach of publication ethics. (...) Four RCTs mentioned that no AEs had occurred. Philippi et al reported that 4 patients had had aggravation of vegetative symptoms after OMT. Two AEs reported in the study by Wahl et al were related to Echinacea and placebo and not to OMT."	Not reported
Scholten-Peeters G. G. M. et. al (2013)	19 RCTs (626 pts in total)	Pts 'with a diversity of complaints'	Manipulative therapy (mostly SMT)	Minor aggravation of neck pain or headache, muscle soreness, stiffness, tiredness, and local discomfort No SAEs	"Only a few minor adverse events were reported in the included studies. There were no serious complications such as stroke." *(AEs reported in 4 RCTs, no AEs reported in 4 RCTs, AEs not reported in 11 RCTs)*	Not reported
Schroeder J. et. al (2013)	3 RCTs (195 pts in total)	Pts with cervical pain	Cervical SMT	Not specified SAEs: Not specified/may be none	"[Acute Neck Pain:] Reported complications were minor and were similar between manipulation therapy compared with home exercise and mobilization therapy compared with physical therapy treatment groups. [Chronic Neck Pain:] There were no significant differences in treatment complications reported when comparing subjects who underwent spine manipulation therapy to those who received exercise." *(From tables: 'Minor complications of treatments' for*	Not reported

					acute neck pain: SMT, 40% (37/91), 'Home exercise', 46% (42/91), Effect size (95% CI), 0.86 (0.61-1.20); 'Complications/side effects' for chronic neck pain: SMT, 9.4% (6/64), 'Exercise', 14.3% (9/63), Effect size (95% CI), 0.66 (0.25-1.74))	
Wynd S. et. al (2013)	24 CRs, 14 CSs, 2 surveys, 2 cohort studies, 1 commentary (901 pts in total)	Pts experiencing cervical artery dissection or stroke following cervical SMT	Cervical SMT	NA SAEs: Cervical artery dissection (901 cases), stroke (707 cases)	"This study has demonstrated that the literature infrequently reports useful data toward understanding the association between cSMT [cervical spinal manipulation therapy], CADs [cervical artery dissection] and stroke. Improving the quality, completeness, and consistency of reporting adverse events may improve our understanding of this important relation."	Not reported
Yang M. et. al (2013)	2 RCTs (39 pts in total)	Pts with any type of pneumonia	OMT (may include SMT)	Muscle tenderness No SAEs	"Only one trial reported adverse effects, as transient muscle tenderness emerged after treatment in two individuals during the period of study."	Not reported
Brantingham J. W. et. al (2012)	2 CRs, 2 CSs, 7 RCTs, 2 controlled or clinical trials, 2 single-group pretest-posttest designs (SGPPDs) (>109 pts in total)	Pts with upper extremity conditions (including hip osteoarthritis, hip strain, patellofemoral pain syndrome, acetabular anterosuperior labral tear, plantar fasciitis	SMT (may include some mobilization)	'Minor side effects', "mild posttreatment soreness after the first 1-2 treatments, which resolved in all patients." No SAEs	"Nevertheless, overall, when appraising the increasing quantity and quality of included trials, MT [manipulative therapy] for lower extremity disorders appears to be of value and, like spinal MT, fundamentally safe." *(3 studies reported 'side effects' (including one study reporting no AEs), 1 study reported no 'side effects', and AEs or 'side effects' were not mentioned for the remaining studies)*	Not reported
Dobson D. et. al (2012)	4 RCTs (116 pts in total)	Infants suffering from colic)	SMT (including one study that did not specify the chiropractic treatment)	None	"One of the studies recorded adverse events and none were encountered. However, with only a sample of 325 infants, we have too few data to reach any definitive conclusions about safety. (...) No adverse effects were found, but they were only evaluated in one of the six studies. (...) we cannot quantify any risk of adverse effects when using manipulative therapies for the treatment of infantile colic. (...) Only one study (Miller 2010; N = 102) reported findings for adverse outcomes. None were recorded. A case report was incidentally drawn to our attention during the review process. This report outlines the case history of an individual infant who died following treatment for infantile colic by a "so called CranioSacral Therapist" (Holla 2009) who appears to have used an unrecognised technique. We have not undertaken a systematic search for safety studies, although we have introduced the debate in the background section. We may consider a comprehensive search specifically for adverse effects in the update of this review."	"Not estimable" (GRADE)
Furlan A. D. et. al (2012)	2 CCs, 2 pCohorts, 22 RCTs (NA)	Pts in studies receiving SMT	SMT7	Transient increased pain *(very sparse information with respect to AEs)* SAEs: Vertebro-basilar artery (VBA) stroke, cervical artery dissection *(very sparse information with respect to SAEs)*	"Poorly and scarcely reported harms data limited our ability to meaningfully compare rates of adverse events between the treatments. (...) RCTs: The reported events in RCTs were mostly moderate in severity and of transient nature (e.g., increased pain). In one RCT, after 2 weeks of treatment, patients with neck pain receiving manipulation were not at significantly increased risk for having an adverse event compared to patients receiving mobilization (OR = 1.44, 95% CI: 0.83, 2.49). In another RCT, the proportion of patients with neck pain having	Not reported

World Confederation for Physical Therapy

and management of patients who may present with Cervical Artery Dysfunction (CAD).

Should practice in this area be restricted in Denmark, it would be the only country in Scandinavia and Western Europe to restrict practice in this way. It should be noted that practice is also not restricted in countries such as Australia, New Zealand, Canada, USA or South Africa.

WCPT urges the Danish authorities to consider the information provided and to continue to recognize the full scope of practice of Danish physiotherapists (and not to limit their future practice). Physiotherapists are well aware of the important responsibilities they hold as autonomous practitioners and that the safety of the public is paramount.

Yours sincerely

Emma K Stokes

WCPT President

Annalie Basson

IFOMPT President

Resource documents referred to in the letter:

WCPT policies and guidelines: http://www.wcpt.org/policies

WCPT Policy statement: Description of physical therapy: http://www.wcpt.org/policy/ps-descriptionPT

WCPT Guideline for physical therapist professional entry level education: http://www.wcpt.org/guidelines/entry-level-education

WCPT Ethical Principles: http://www.wcpt.org/ethical-principles

IFOMPT International Framework for Examination of the Cervical Region for potential of Cervical Arterial Dysfunction prior to Orthopaedic Manual Therapy Intervention
http://www.ifompt.org/site/ifompt/IFOMPT%20Examination%20cervical%20spine%20doc%20September%202012%20definitive.pdf

World Confederation for Physical Therapy

15th March 2016

Sundhedsstyrelsen/Styrelsen for Patientsikkerhed
Islands Brygge 67
2300 København S
Denmark

Dear Sir

The World Confederation for Physical Therapy (WCPT) is the sole international voice for the physiotherapy profession representing more than 350,000 physiotherapists through its member organisations in 111 countries. Danske Fysioterapeuter, a leading WCPT member organisation since 1951, has brought to the attention of WCPT the investigation being undertaken by the Danish health authorities of the risk of spinal manipulation and the professional competencies needed to do spinal manipulation safely.

On behalf of the physiotherapy profession, WCPT would like to provide an international perspective to the discussion by commenting on the scope of practice, knowledge, skill and competencies of physiotherapists.

Mobilization/manipulation have been core entry level skills of physical therapists since the beginning of the profession and these entry level competencies are referenced in all relevant WCPT documents including the *WCPT Policy statement: Description of physical therapy* and the *WCPT Guideline for physical therapist professional entry level education*. Physiotherapists are educated as autonomous professionals who use their professional judgment in decision making and recognise that this must occur within the physiotherapist's knowledge, competence and scope of practice wherever they practice. Physiotherapists operate as independent practitioners, as well as members of health service provider teams, and are subject to the ethical principles of WCPT and the codes of ethics and best practice in the country in which they practise.

Throughout the assessment, diagnostic and treatment processes physiotherapists have an ethical responsibility to refer the patient/client to another appropriate practitioner should they be faced with a situation that is not within the scope of their knowledge, experience or expertise.

WCPT's subgroup the International Federation of Orthopedic Manipulative Physical Therapy (IFOMPT) promotes excellence in OMT. The Danish Society for Musculoskeletal Physiotherapy is a full member of IFOMPT and its members meet the IFOMPT education criteria. IFOMPT is providing significant leadership with respect to safety in the practice of manual therapy and recently has developed a screening document for the cervical spine. This document is a consensus document based on feedback from its 22 member organisation and the latest available evidence and aims to improve safety in the treatment of the cervical spine and in particular the assessment

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Hadler et al. (1987)			x		
BenEliyahu (1996)			x		
Barrett & Breen (2000)			x		
Discussion papers					
Doyle (2011)	x				
Personal communication					
Halderman and Rubinstein					x
Letters					
Hosek et al. (1981)				x	
RCTs					
Any RCTs (number)		x (31)	x (2)		

* These systematic reviews are already included in this overview.

Abbreviations: CC, case-control study; pCohort, prospective cohort; RCT, randomized controlled trial; SR, systematic review.

Appendix 3

Table: Matrix showing the studies (left column) that the estimates (top row) are based on

Author (year)	Todd A. J. et al. (2014)	Carnes D. et al. (2010)	Gouveia L. O. et al. (2009)	Miley M. L. et al. (2008)	Chou R. & Huffman L. H. (2007)	Snelling N. J. (2006)	Oliphant D. (2004)	Gross A. R. et al. (2002)	Stevinson C. & Ernst E. (2002)	Assendelft W. J. J. et al. (1996)	Hurwitz E. L et al. (1996)	Dabbs V. & Lauretti W. J. (1995)	Shekelle P. G. et al. (1992)
SRs													
Oliphant (2004)*					x	x							
Stevinson & Ernst (2002)*					x								
Assendelft et al. (1996)*							x	x					
Hurwitz et al. (1996)*								x					
Dabbs & Lauretti (1995)*								x	x				
Shekelle et al. (1992)*							x			x			
Reviews													
Chestnut (2004)				x									
Haldeman et al. (2002)				x									
Pistolese (1998)	x												
Haldeman et al. (1993)												x	
Powell et al. (1993)							x		x				
Haldeman & Rubinstein (1992)							x						x
Patjin (1991)							x				x	x	
Wolff (1978)									x				
pCohorts													
Garner et al. (2007)		x											
Rubinstein et al. (2007)		x											
Thiel et al. (2007)		x											
Cagnie et al. (2004)		x											
Barrett and Breen (2000)		x											
Leboeuf-Yde et al. (1997)		x											
Senstad et al. (1996a)		x											
Senstad et al. (1996b)		x											
Surveys													
Rivett & Milburn (1997)								x					
Coulter et al. (1996)			x										
Klougart et al. (1996)			x						x				
Lee et al. (1995)			x									x	
Haynes (1994)			x							x			
Carey (1993)			x								x		
Michaeli (1993)			x				x			x			
Henderson & Cassidy (1988)												x	
Dvorak (1985)			x						x	x	x	x	
Gutmann (1983)			x								x	x	
Reports													
Eder & Tilscher (1990)												x	
Jaskoviak (1980)												x	
CCs													
Rothwell et al. (2001)				x					x				
Retrospective studies													
Stern et al. (1995)							x						
Community-based study													
Shekelle et al. (1991)											x		x
Prospective studies													
Nyiendo & Haldeman (1987)							x						
Senstad et al. (1997)							x						
Kirkaldy-Willis & Cassidy (1985)							x						

(1992)	study, 1 personal communication (>1500 pts in total)	SAEs: Paraplegia from meningeal hematoma, cauda equina syndrome, death *(very sparse information with respect to SAEs)*	manipulation, which in total comprised more than 1500 patients treated with manipulation. All else that is known comes from case reports, and there is concern that these represent only a fraction of the total number of complications. A review of the world's literature by Ladermann showed 135 case reports of serious complications, including 18 deaths, due to manipulation. (...) Cervical manipulation had a greater number of complications, of a more serious nature, than did lumbar manipulation. (...) Estimating the frequency with which the cauda equina syndrome occurs in patients undergoing lumbar spinal manipulation is difficult (...) we estimate the rate of occurrence of the cauda equina syndrome as a complication of lumbar spinal manipulation to be on the order of less than one case per 100 million manipulations. Even if the number of cases of the cauda equina syndrome is underestimated by tenfold, the complication rate is still low. These data suggest that the risk of lumbar spinal manipulation is small and that it may vary by the clinical condition with which the patient presents. No firm conclusions about the precise level of the complication rate may be drawn, however, because there are few available data. Systematic reports of the rate of complications of spinal manipulation are needed to help estimate better the risk of this procedure."

*Not an exhaustive listing of all AEs observed in the included studies of the SRs. In the case of an overwhelming amount of different AEs listed by the SRs, only the SRs own summarizations of the AEs are reported in this table together with the note '(*most common*)'. 'No SAEs' includes reporting that no AEs and/or SAEs were present, or only reporting AEs which were not SAEs.

Abbreviations: AEs, adverse events; NA, no data available; CC, case-control study; CR, case report; CS, case series; HTA, health technology assessment; OMT, osteopathic manipulative treatment/therapy; pCohort, prospective cohort; pCS, prospective case series, pts, patients; rCohort, retrospective cohort; rCS, retrospective case series; RCT, randomized controlled trial; S, survey; SAEs, serious adverse events; SMT, spinal manipulation therapy; SR, systematic review.

W. J. J. et. al (1996)	SR (>1795 pts in total)	reporting 'complications' following SMT		types of complications (dislocations, factures, spinal cord compression and neglegence or nondetection of preexisting serious conditions; 56 cases). The results include residual handicap (86 cases), complete recovery (44 cases) SAEs: CRs: Vertebrobasilar accidents (165 cases), progression of radicular symptoms to cauda equina syndrome (61 cases), cerebral complications other than vertebrobasilar accidents (13 cases). The results include death (29 cases).	complications as they are probably underreported in the literature. Most non-VBA complications can be prevented by excluding patients with contraindications for SMT. (.) Refferral for SMT should not be made to practitioners applying rotatory cervical manipulation. (...) While complications of spinal manipulation have not yet been studied in prospective surveys, the incidence of serious complications is generally considered to be low. (...) Vertebrobasilar accidents occur mainly after a cervical manipulation with a rotatory component."	
Hurwitz E. L. et. al (1996)	43 CRs, 14 CSs, 10 RCTs, 1 cohort study, "and 145 articles on complications" (>935 pts in total)	Pts with cervical pain and headache	Cervical SMT	Vertebrobasilar accidents (VBA) (with consequences such as Wallenberg's syndrome), spinal cord compression, vertebrobasilar artery spasm or stenosis, other permanent functional impairment SAEs: Vertebrobasilar accidents (VBA) (with consequences such as brain stem and/or cerebellar infarction, locked-in syndrome), vertebral fracture, tracheal rupture, diaphragm paralysis, internal carotid hematoma, cardiac arrest, brain stem and/or cerebellar infarctions, vertebrobasilar artery dissection, death, serious neurologic deficit, paralysis	"Articles documenting more than 110 cases of complications allegedly arising from cervical spine manipulation have been published in English. (...) Complications occurred in patients who had received manipulation uneventfully in the past, without obvious risk factors for cerebral vascular accidents (e.g., arteriosclerosis, hypertension, heavy smoker, oral contraceptive use), without previous trauma, and with negative results on positional tests designed to assess vertebral artery sufficiency (...) Rotational manipulations were used in 45 of 55 (82%) of the cases for which the type of treatment was described. (...) In summary, of the 118 documented cases of VBA and other complications described above, 21 patients died and 52 survived with serious neurologic deficit, paralysis, or other permanent functional impairment. (...) No complications were reported among the subjects who received cervical spine manipulation in the studies reviewed for efficacy, a total of 892 patients. (...) Systematic reports of complication rates are necessary for calculation of a more precise estimate of risk. The true incidence of serious complications from cervical spine manipulation may be smaller or higher and is probably modified by clinical presentation, appropriate history taking and examination procedures, and the use of specific types of manual therapy."	Not reported
Dabbs V. & Lauretti W. J. (1995)	5 surveys, 2 report, 1 review, and data from insurance company (NA)	Pts treated for cervical pain in studies providing an estimate for the risk of SAEs or death, or pts with cervical pain in studies on cervical SMT	Cervical SMT	NA SAEs: Stroke, vertebral artery injury, death or not specified *(very sparse information with respect to SAEs)*	"The best evidence indicates that cervical manipulation for neck pain is much safer than the use of NSAIDs, by as much as a factor of several hundred times. There is no evidence that indicates NSAID use is more effective than cervical manipulation for neck pain."	Not reported
Shekelle P. G. et. al	8 CRs, 25 clinical trials, 1 review, 1 community-based	Pts with low-back pain	SMT	NA *(very sparse information with respect to AEs)*	"No systematic report of the frequency of complications from spinal manipulative therapy has been published. No complications were reported in the clinical trials of	Not reported

		suffering from phobias, dysmenorrhea)			manipulation). At present the incidence of such serious adverse events can only be estimated."	
Magee D. J. et. al (2000)	1 small uncontrolled trial (10 pts in total)	Pts with soft tissue neck injury following trauma	SMT	None	"(...) no study showed any harmful effects for physical therapy intervention. [includes the one trial on SMT]"	Not reported
Fabio R. P. D. (1999)	116 CRs (177 pts in total)	Pts experiencing 'injuries' following cervical SMT	Cervical SMT (but "The specific type of manipulation was not described in 46% (n=82)")	Wallenberg syndrome, Horner syndrome, joint dislocation, other (including visual deficits, hearing loss, balance deficits, phrenic nerve injury) *(Ordered with respect to frequency)* SAEs: Arterial dissection or spasm, brain-stem injury, cerebral/cerebellar injury, spinal cord injury, thrombosis, locked-in syndrome, brain death, death *(Ordered with respect to frequency)*	"Although the risk of injury associated with MCS [manipulation of the cervical spine] appears to be small, this type of therapy has the potential to expose patients to vertebral artery damage that can be avoided with the use of mobilization (nonthrust passive movements). The literature does not demonstrate that the benefits of MCS outweigh the risks. (...) Death occurred in 18% of the cases (n=32)."	Not reported
Haldeman S. M. et. al (1999)	115 CRs (115 pts in total)	Pts experiencing vertebrobasilar artery dissection following SMT	SMT	NA SAEs: Vertebrobasilar artery dissection	"Recent reports of specific ultrastructural aberrations in connective tissue or a unique phenotypically mild Type I collagen tissue disease in patients with spontaneous cervical artery dissection raise the possibility that certain people have either an inherited or acquired disorder of unknown origin that increases the fragility of vertebral arteries to trauma. If this is determined to be true, it may eventually be possible by means of a laboratory test to screen patients who are at risk for vertebrobasilar artery dissection before they engage in vigorous sporting activities or undergo cervical manipulation. Until that happens, vertebrobasilar artery dissection after neck movement, trauma, or manipulation should be considered a rare, random, unpredictable complication associated with these activities."	Not reported
Vernon H. et. al (1999)	6 RCTs (176 pts in total)	Pts with tension-type, and cervicogenic headache	SMT	Neck stiffness No SAEs	None *(AEs reported in 1 RCT, AEs not mentioned 5 RCTs)*	Not reported
Aker P. D. et. al (1996)	4 RCTs (NA)	Pts with mechanical neck pain	Manipulation (not further specified)	Not specified No SAEs	"Adverse effects have not been well documented. If we exclude data from the three trials in which patients with neck pain were not separated from those with low back pain [including one trial on SMT], 1254 patients were randomised in 21 randomised controlled trials. Six trials reported a total of 16 patients with increased symptoms or side effects resulting from treatment. No serious complications or deaths were reported." *(No further details provided, e g. which trials reported AEs, and if these included trials on SMT. Also the type of AEs was not stated.)*	Not reported
Assendelft	295 CRs, 3 surveys, 1	Pts in studies	SMT	CRs: Disc herniation, other	"It is difficult to estimate the incidence of SMT	Not reported

				vertebrobasilar accidents (mostly occurring after rotational cervical manipulation), dissection of the vertebral artery at the atlantoaxial joint, with intimal tear, intramural bleeding, or pseudoaneurysm leading to thrombosis or embolism. Arterial dissection and lesions of the brain stem. Cerebrovascular accidents, often with permanent neurologic deficits, including death		
Bronfort G. et. al (2001)	9 RCTs (400 pts in total)	Pts with chronic headache	SMT	Muscle soreness and neck stiffness (*most common*) No SAEs	"In the studies comparing SMT [spinal manipulative therapy] with amitriptyline [two trials], more than half the patients taking amitriptyline reported side effects such as drowsiness, dry mouth, and weight gain, and approximately 10% were withdrawn from the studies due to drug intolerance. In comparison, only 5% of the patients receiving SMT reported side effects, the most frequent being muscle soreness and neck stiffness. These effects are common and considered normal reactions to spinal manipulation. No serious complications (i.e., vertebrobasilar accidents) were reported in any of the studies included in this review. The risk of serious complications from SMT is considered low."	Not reported
Ernst E. (2001)	5 prospective investigations (>2016 pts in total)	Pts experiencing SAEs following SMT	SMT	Transient exacerbation of symptoms, discomfort, reduction in the ability to work, local discomfort, headache, fatigue and discomfort outside the area of treatment, extracranial arterial dissections No SAEs	"No reliable data exist about the incidence of serious adverse events. These data indicate that mild and transient adverse events seem to be frequent. Serious adverse events are probably rare but their incidence can only be estimated at present."	Not reported
Ernst E. & Harkness E. (2001)	8 RCTs (NA)	Pts in studies receiving SMT (includes pts with asthma, phobia, chronic LBP etc.)	SMT	Exacerbation of asthma, soreness in low-back region No SAEs	"The risks of SM [spinal manipulation] are still under-researched. In the trials reviewed above, adverse effects were not mentioned in the weaker studies [three studies]; Nielsen et al. explicitly stated that no adverse events occurred, Balon et al. only noted exacerbation of asthma symptoms, and Hondras et al. found some minor soreness at the site of SM." *(AEs reported in 2 RCTs, no AEs reported in 2 RCTs, AEs not reported in 4 RCTs)*	Not reported
Ernst E. (2000)	7 RCTs (NA)	Pts in studies receiving SMT (includes pts with chronic low-back pain, children with nocturnal enuresis, chronic asthmatic patients, pts	SMT	Exacerbation of asthma symptoms, minor soreness at the site of SMT *(very sparse information with respect to AEs)* No SAEs	"In the trials reviewed above, adverse effects were not mentioned in the weaker studies [three studies], while Nielsen et al. explicitly stated that no adverse events occurred, Balon et al. only noticed exacerbation of asthma symptoms and Hondras et al. found some minor soreness at the site of SM [spinal manipulation]. (...) Serious complications of SM seem to be very rare. They include vertebral artery dissection (upper spinal manipulation) and canda equina syndrome (lower spinal	Not reported

					including chiropractic treatment (SMT))	
Gross A. R. et. al (2002)	6 surveys, 7 RCTs, 6 SRs (NA)	Pts with mechanical neck disorders, neck disorders with headache of cervical origin or neck disorders with radicular signs or symptoms	SMT (including a few studies on mobilization)	Minimal benign reaction lasting less than 24 h, some/more/new discomfort, dizziness, visual disturbances and ear symptoms, headache, nausea, myelopathies, radiculopathy, disc prolapse and increased pain, dizziness, nausea, headache, nystagmus, vomiting, brachalgia, brachalgia with neurological deficit, loss of consciousness, acute wry neck, tiredness, hot skin, local discomfort, radiating discomfort SAEs: Cerebral vascular accident (CVA), neurological complications (moderate to severe nature, and death)	"The true risks are unclear. Available estimates are as follows: the lowest reported estimate for risk of irreversible injury when applying manipulation is one in 20,000 (...) The accuracy of the rate is limited, as a result of the poor quality of the literature on which it is based. However, the weight of the evidence suggests that there is some risk."	"The accuracy of this estimate [estimate from the SRs] is low, as it is based on level V evidence" (NA)
Gross A. R. et. al (2002)	10 RCTs (NA)	Pts with mechanical neck disorders	Manipulation (may be entirely SMT)	Increased neck or headache pain, increased radicular pain, severe thoracic pain, persistent acute pain, "customary reaction of minimal benign reactions" No SAEs	"Seven trials reported on adverse events [including two trials not using SMT]. The adverse events reported include more pain, discomfort, dizziness, visual disturbances and ear symptoms. Most studies did not appear to have any systematic method for recording adverse reactions. (...) Adverse events were inconsistently reported in trials. When reported, they were categorized as benign transient side-effects. There was no report of reversible or irreversible serious complications."	Not reported
Stevinson C. & Ernst E. (2002)	1 CR, 1 CS, 1 CC, 3 rCohorts, 5 surveys, 1 SR, 3 reviews, 1 retrospective analysis (>2357 pts in total)	Pts in studies reporting AEs associated with SMT	SMT	Local discomfort, headache, tiredness, radiating discomfort, dizziness, nausea, hot skin, disk herniation, arterial spasm *(the seven first AEs, is the most common, ordered with respect to frequency)* SAEs: Vertebrobasilar accidents (some causing death), progression of radicular symptoms to cauda equina syndrome, cerebral complications, dislocations and fractures (often accompanied by spinal cord compression), progression to cauda equina syndrome (mostly occurring with manipulation to the lumbar region),	"In conclusion, serious complications of spinal manipulation seem to be rare, whereas less serious adverse events occur frequently. (...) However, without reliable data about the incidence of specific risks, it is difficult to achieve the correct balance between providing adequate information and causing unnecessary alarm."	Not reported

					be caused by the neck manipulation, was found and resected. A 3-month-old girl was seen by a German physiotherapist who treated her with forced rotation and retraction of the head. As a result, both vertebral arteries dissected causing ischaemia of the caudal brain stem with subarachnoid haemorrhage. The diagnosis was confirmed with MRI and the child died."	
Ernst E. J. (2002)	4 CRs, 3 SRs (>4 pts in total)	Elderly in studies reporting AEs following SMT	Cervical SMT	Bone fracture, pain and swelling in temporomandibular joint for one month, myelopathy, paresthesias in all extremities *(very sparse information with respect to AEs)* **SAEs**: Multiple spinal compression fractures, thoracic epidural hematoma, bilateral vertebral artery dissections, brainstem stroke *(very sparse information with respect to SAEs)*	"A recent review of the published literature (1925-1997) located 177 case reports of serious complications after manipulations of the cervical spine. The age range of the patients thus affected was 4 months to 87 years. Osteoporosis should be regarded as a contra-indication to spinal manipulation. In addition to these probably rare events, spinal manipulation is associated with frequent (~50%) transient mild adverse effects."	Not reported
Ernst E. (2002)	31 CRs (42 pts in total)	Pts experiencing SAEs following cervical SMT	Cervical SMT	Paraesthesiae, pain and reduced mobility of right arm, diaphragmatic palsy, intimal tear of right vertebral artery, retinal artery occlusion, disc herniation, cervical myelopathy, spinal stenoses, spinal epidural haematoma, dissection of carotid artery, profuse vomiting, vertigo and Horner's syndrome, Brown–Séquard syndrome, radiculopathy of right arm, Dural tear, lesions of the cervical nerve root, cervical myelopathy, subdural haematoma **SAEs**: Arterial dissection (usually of the vertebral arteries, causing stroke), serious sequelae (such as permanent visual field loss), permanent neurological deficit, dissection of right intracranial artery, cerebral infarct, cerebellar infarction, emboli, death	"In conclusion, serious complications of cervical spine manipulation appear to occur regularly. Their incidence is essentially unknown and should be established as a matter of urgency through adequately designed investigations. (...) Arterial dissection, usually of the vertebral arteries, causing stroke was the most common serious adverse event (at least 18 cases). In most instances, the acute onset of symptoms after the manipulation made a causal relationship likely. Symptoms often developed quickly — after or during therapy — and varied widely according to the exact nature of the injury. The eventual outcome was often not reported, but included serious sequelae, such as permanent visual field loss, permanent neurological deficit and death (serious sequelae in at least 17 cases)."	Not reported
Gerritsen A. A. M. et. al (2002)	1 RCT (45 pts in total)	Pts with carpal tunnel syndrome	SMT	"Minor side effects" No SAEs	"Minor side effects (e. g. nausea, abdominal discomfort, headache) were reported for diuretics, NSAIDs, oral steroids and chiropractic treatment." *(Not specified which of the side effects are from the trial*	Not reported

					of these adverse effects were self-limiting."	
Oliphant D. (2004)	2 surveys, 8 review articles, 9 prospective/retrospective studies (NA)	Pts in studies reporting AEs from lumbar SMT	Lumbar SMT	"Mild aggravation of symptoms", radiculopathy, disk prolapse, or not specified *(very sparse information with respect to AEs)* SAEs: Worsening of lumbar disc herniation, cauda equina syndrome, or not specified	"The apparent safety of spinal manipulation, especially when compared with other accepted treatments for LDH, should stimulate its increased use in the conservative treatment plan of LDH. (...) Spinal manipulation for the treatment of LDH appears to be very safe, and there is no sound basis to recommend against a trial of spinal manipulation of patients with LDH, although limited lumbar flexion and gentle technique are suggested to further reduce the risk. (...) Disk herniation is the number one claim against chiropractors; yet, it appears likely that lumbar disk prolapse could occur only in an already fissured and fragmented disk. Even in patients presenting with LDH, the risk of spinal manipulation appears minimal, especially compared with other common treatments for LDH, such as NSAIDs and surgery, and spinal manipulation may be no more dangerous than activities of daily living, such as a cough or stumble. More research is needed to determine accurately the incidence of disk injury/increased disk symptoms following spinal manipulation; under what conditions, if any, spinal manipulation can actually cause a disk herniation; the benefit of spinal manipulation in the treatment of LDH compared with natural history, other conservative treatments, and surgery; and which patients will benefit most from which type of treatment. (...) In Koes et al review of trials of effectiveness of manipulation for acute and chronic low back pain, few papers specifically mentioned the absence of adverse effects, but most did not mention adverse effects at all. This may be because none occurred during these trials involving over 1500 patients or simply they were not recorded as part of the data. However, if any significant complications had been known to occur, they would probably have been mentioned, at least as a reason for dropout. (...) The numbers that these calculations have been based on can be argued to be rough estimates at best, and therefore with each calculation, the accuracy of this risk estimate may have been reduced. However, there has been an increased emphasis on evidence-based care. This risk was calculated according to the best evidence available, and the numbers used err in favor of overestimating the risk."	Not reported
Ernst E. (2003)	2 CRs, 1 SR (2 pts in total)	Children and adolescents experiencing SAEs following SMT	SMT	Holocord astrocytoma, respiratory distress, holocord astrocytoma with excessive acute necrosis *(very sparse information with respect to AEs)* SAEs: Cerebrovascular accident, quadriplegia and seizures, vertebral arteries dissected causing ischaemia of the caudal brain stem with subarachnoid haemorrhage, death	"At present, it is impossible to provide reliable incidence figure (for the risk of unconventional therapies). (...) Chiropractic upper spinal manipulation (e.g. high-velocity thrusts) has been repeatedly associated with serious adverse events, e.g. cerebrovascular accidents. A recent systematic review summarised 177 published cases of injury. The age range of the patients thus affected was 4 months to 87 years. American paediatricians described the case of an infant with congenital torticollis treated with chiropractic spinal manipulation. Within a few hours of this therapy the child began suffering from respiratory distress, quadriplegia and seizures. A holocord astrocytoma with excessive acute necrosis, believed to	Not reported

	(340 pts in total)	associated with spinal manipulation		nausea, vomiting, diplopia, throbbing headache, instant pain followed by headache nausea vomiting double vision and dural tear SAEs: Dissection of arteries (carotid and vertebral and intracranial) basilar artery infarction, Wallenberg's syndrome, transitory neurological deficits, emboli partial and complete loss of vision, ischaemic lesion in medulla oblongata, 'signs suggesting brain stem dysfunction', loss of consciousness, epidural haematoma, acute infarctions, stroke, cauda equina syndrome, radiculopathy, subarachnoid haemorrhage, dural tear, , Horner's syndrome, subdural haematoma, incomplete cervical cord injury, paralysis, disc herniation, 'locked-in syndrome', myelopathy, radiculopathy, loss of hearing, epileptic fit, rip fracture, paresthesiae, paraplegia, bone fractures, 'nerve damage', disk prolapse, paraparesis, spinal cord compression, vertebral artery occlusion, death	manipulative therapies, the overall incidence of such complications is probably low; however, no reliable figures can be generated through this or any other data available to date. It is concluded that serious cerebrovascular complications of spinal manipulation continue to be reported. Their incidence is unknown. Large and rigorous prospective studies are necessary in order to define the risks of spinal manipulation accurately."	
Lenssinck M.-L. B. et. al (2004)	5 RCTs (NA)	Pts with tension-type headache	Manipulation (SMT or not specified)	Neck soreness and stiffness No SAEs	"Only two studies reported side effects [one of these did not include SMT]. The study of Boline et al. (1995) provided information on the side effects of chiropractic spinal manipulation and amitriptyline. In proximally 4% of the patients receiving spinal manipulation side effects like short-term neck soreness and stiffness were reported after the first treatment."	Not reported
Oduneye F. (2004)	2 RCTs (128 pts in total)	Pts witch chronic cervical pain	SMT	Increased neck pain or headache, severe thoracic pain, increased radicular pain No SAEs	"We found inadequate evidence to assess reliably, any adverse effects of spinal manipulation in people with chronic neck pain. (...) The first study did not report on the adverse effects of treatment. The second study reported that no permanent injuries occurred in any treatment group, and there was no significant difference between groups in the incidence of adverse effects at 12 month follow up (P=0.49). Increased neck pain or headache was experienced in 12% of participants (6/64 with spinal manipulation alone v 8/64 with spinal manipulation plus exercise v 9/63 with machine-assisted exercise). One participant receiving spinal manipulation alone experienced severe thoracic pain, and one participant receiving spinal manipulation plus exercise experienced increased radicular pain. Both	Not reported

Brown A. et. al (2005)	2 RCTs, 14 SRs, 2 non-randomized controlled trials (NA)	Pts with low-back pain	SMT (including some studies on chiropractic care or manipulation, not further specified)	Not specified SAEs: Cauda equina syndrome *(very sparse information with respect to SAEs)*	"The results of the review suggest that serious adverse events are unlikely to occur with chiropractic treatment for LBP. (...) Another systematic review noted that the development of cauda equina syndrome can be a serious complication of lumbar spinal manipulation, yet the incidence was low."	Not reported
Ernst E. (2005)	14 CRs (14 pts in total)	Pts with ophthalmological AEs following SMT	SMT of the upper spine	Ptosis, the ophthalmological consequences (nystagmus, Wallenberg's syndrome, loss of vision, hemianopsia, ophthalmoplegia, diplopia, Horner's syndrome, ptosis). SAEs: Vertebral artery dissection, basilar artery infarction, stroke, dissection of carotid artery, cerebellar infarction, epidural haematoma	"Upper spinal manipulation is associated with ophthalmological adverse effects of unknown frequency. Ophthalmologists should be aware of its risks. Rigorous investigations must be conducted to establish reliable incidence figures. (...) The ophthalmological consequences included nystagmus, Wallenberg's syndrome, loss of vision, hemianopsia, ophthalmoplegia, diplopia, Horner's syndrome and ptosis. In many cases, visual deficits were the first signs. The onset of symptoms was frequently instant. In several instances, the eventual clinical outcome entailed a permanent deficit. In the majority of cases, the causality between USM and the ophthalmological adverse effect was certain or likely."	Not reported
Hondras M. A. et. al (2005)	2 RCTs (NA)	Pts with asthma	SMT	None	"One of the included studies (Nielsen 1995) reported data on adverse events. (...) Adverse events: stated that no side-effects were reported by patients as a result of the manipulation."	Not reported
Lisi A. J. et. al (2005)	7 CRs, 5 CSs, 1 RCT, 2 cohort studies, 1 controlled clinical trials (183 pts in total)	Pts with symptomatic lumbar disk diseases	SMT	Worsening of pain *(very sparse information with respect to AEs)* No SAEs	"Consistent descriptions of adverse effects among the included studies were lacking. This is summarized in Table 6. Consequently, no conclusions regarding safety could be made. (...) Moreover, several studies commonly cited as describing significant adverse effects after lumbar HVLASM in cases of disk pathology did not meet our inclusion criteria." *(From table 6. 2 trials "stated that no adverse effects occurred", 4 trials "clearly described any worsening of pain during treatment period", 3 trials "clearly described no worsening of pain during treatment period")*	Not reported
Rubinstein S. M. et. al (2005)	2 CCs (7 pts in total)	Pts in studies reporting cervical artery dissection following cervical SMT	Cervical SMT	NA SAEs: Cervical artery dissection	"A strong association was found for manipulative therapy (ORadj , 3.8; 95% CI, 1.3 to 11). However, although an important confounder (ie, neck pain before the onset of stroke) was adjusted for in regression analysis, selection and information bias were most probably present. The study by Rothwell et al lacked control for confounding and included cases of occlusive stroke along with unconfirmed dissections. The number of cases identified in both studies were few (n=7) and in only 57% (n=4/7) of the cases was there a clear temporal association between the treatment and the onset of dissection (using 24 hours after the treatment as the cutoff point)."	Not reported
Brønfort G. et. al (2004)	2 RCTs (85 pts in total)	Pts with tension-type headache	SMT	Neck soreness and stiffness No SAEs	"The results of the trials included in this review [on non-invasive physical treatments, including SMT] do not suggest that any of these therapies are associated with important risks of severe adverse reactions. Side effects have been addressed mostly for spinal manipulation."	Not reported
Ernst E. (2004)	33 CRs, 14 retrospective investigations	Pts experiencing cerebrovascular complications	SMT	Headache, confusion, stupor vertigo, visual disturbances, left-sided tinnitus, vertigo,	"The most frequently reported complication was stroke due to arterial dissection after cervical spinal manipulation. Considering the popularity of spinal	Not reported

	(nonrandomized) designs, single-group interventions and other small experimental or pre-experimental designs) (NA)			No SAEs		
Luijsterburg P. A. J. et. al (2007)	2 RCTs (175 pts in total)	Pts with lumbosacral radicular syndrome	Manipulation (not further specified)	None	None *(One trial reported no AEs and the other trial did not report AEs)*	Not reported
Vernon H. & Humphreys B. K. (2007)	14 RCTs (701 pts in total)	Pts with cervical pain	SMT (including a few studies on manipulation, not further specified)	Increased neck pain or headache, "minor side effects" No SAEs	"There were no adverse reactions to any of the therapies [for acute neck pain] reported in any of these studies. This could be interpreted to mean that no adverse reactions actually occurred or that they were not monitored and, therefore, not reported (...) There were no major adverse events reported in any of these trials [for chronic neck pain]."	Not reported
Vernon H. et. al (2007)	9 RCTs (593 pts in total)	Pts with chronic mechanical neck pain	SMT	"Minor side effects" No SAEs	"In none of these trials were any major adverse reactions reported." *(From table, reported for one of the included studies: "No major side effects in either group. For minor side effects in the first 4 wk: Manip: 16% Mob = 8.7% P = .051".)*	Not reported
Gemmell H. & Miller P. (2006)	4 RCTs, 1 randomized trial with a 2x2x2 factorial design (>79 pts in total)	Pts with non-specific cervical pain	SMT	Not specified/may be none SAEs: Not specified/may be none	"Only one paper reported on adverse effects from manual therapy." *(No further details provided (e.g. which kinds of AEs or if any AEs were observed))*	Not reported
Proctor M. et. al (2006)	3 RCTs (>162 pts in total)	Women with dysmenorrhea	SMT	Not specified SAEs: Not specified/may be none	"Only one trial (n = 138) reported the number of adverse effects experienced. Results showed no significant differences in the adverse effects experienced by participants in the HVLA and sham treatment groups after one cycle of treatment (Peto OR 1.51, 95% CI 0.25 to 8.95)."	Not reported
Snelling N. J. (2006)	1 survey, 4 RCTs, 1 SR, 3 reports, 1 retrospective study (>214 pts in total)	Pts with disc herniation	SMT	Additional disc herniation, radiculopathy *(very sparse information with respect to AEs)* SAEs: Cauda equina syndrome, spinal cord injury *(very sparse information with respect to SAEs)*	"A review on safety of spinal manipulation in the treatment of disc herniation has recently been published, therefore this will be dealt with in less depth. (...) Evidence for harms is based primarily on case reports, and incidences would appear to be rare, though underreporting may be a significant problem. No data was available from the insurance companies on incidences of adverse events. (...) The most recent comprehensive review specific to this question, which draws together much of the published literature, estimates that the risk of causing further disc herniation or cauda equina syndrome by spinal manipulation in patients presenting with a herniated lumbar disc to be one in 3.7 million. (...) With respect to harms, none of the included trials suggested greater complications in the manipulation groups, however when an adverse event occurs rarely, data from trials are not very useful, as they would need to involve huge numbers of patients in order to demonstrate any increase in adverse events."	Not reported

				(very sparse information with respect to SAEs)	event was estimated as less than 1 per 1 million patient visits."	consistency of results within and between study designs, directness of evidence)
Ernst E. (2007)	28 CRs, 5 rCSs, 2 pCSs, 3 CCs, 3 surveys, 1 SR, (>924 pts in total)	Pts in studies reporting AEs following SMT	SMT	CRs: Oedema, nerve injury, disc herniation, haematoma, bone fracture. rCSs: Vertigo, disc prolapse, bone fractures, worsening of symptoms, radiculopathy, spinal cord injuries (myelopathy). pCSss: headache, stiffness, local discomfort, radiating discomfort, fatigue, radiating pain, tiredness. CC: NA. Surveys: Radiculopathies. SR: NA. SAEs: CRs: Dissection of the vertebral arteries, dural tear. rCSs: Stroke, vertebral artery dissection, cerebrovascular accidents, worsening of symptoms, spinal cord injuries (quadriparesis, central cord syndrome or paraparesis), cauda equina syndrome. pCSs: None CCs: Carotid artery dissection, vertebral artery dissection, vertebrobasilar accidents, vascular accidents. Surveys: Cerebrovascular accidents. SR: Cervical artery dissection.	"Spinal manipulation, particularly when performed on the upper spine, is frequently associated with mild to moderate adverse effects. It can also result in serious complications such as vertebral artery dissection followed by stroke. Currently, the incidence of such events is not known. (...) The case reports confirm previous reports associating upper spinal manipulation with a range of complications. The most serious problems, which some experts now describe as 'well-recognized', are vertebral artery dissections due to intimal tearing as a result of overstretching the artery during rotational manipulation. This seems to occur most commonly at the level of the atlantoaxial joint. Intimal injury can be followed by intramural bleeding or pseudoaneurysm formation, which can result in thrombosis, embolism or arterial spasm. The retrospective case series confirm that spinal manipulation is associated with risks such as vascular accidents and non-vascular complications. (...) Most of the incidents reported in case series or surveys had not been previously reported, indicating that under-reporting may frequently be high. The two prospective case series corroborate the results from several earlier investigations showing that mild to moderate adverse effects occur in a large proportion of patients receiving spinal manipulation. These adverse effects are transient and non-serious but nevertheless seriously affect many patients. (...) Case-control and other studies confirm that upper spinal manipulation is associated with risks and that spinal manipulation is an independent risk factor for vertebral artery dissection. (...) The three surveys disclose more complications. They suggest that many therapists are now becoming aware of the risks of spinal manipulation. Two of the surveys also confirm that under-reporting is frequently close to 100%. (...) Dissection of the vertebral arteries was the most common problem [in the CRs]; other complications included dural tear, oedema, nerve injury, disc herniation, haematoma and bone fracture."	Not reported
Gross A. R. et. al (2007)	4 RCTs (NA)	Pts with mechanical neck disorders, neck disorders with headache or neck disorder with radicular findings	Manipulation	NA No SAEs	"We found that minor, transient, and reversible side effects consisting of increased symptoms were occasionally reported. A valid estimate of clinically significant, uncommon, and rare adverse events cannot be made from these trials. Adverse effects of longterm steroid therapy and manipulation have been well described." *(Does not specify in which studies the AEs were observed, or if these studies included SMT)*	Not reported
Hawk C. et. al (2007)	93 CRs, 29 CSs, 14 RCTs, 9 SRs, 1 cohort, 33 "other" (pilot studies, quasi-experimental	Pts with non-musculoskeletal conditions	Chiropractic care (including SMT in majority of the studies)	Lumbar soreness, muscle soreness, irritability, headache, neck pain, low-back pain, joint and muscle soreness	"The adverse effects reported for SMT for all age groups and conditions were rare and, when they did occur, transient and not severe."	Not reported

	cohort study, 1 'small non-randomized static-group comparison study (preexperimental design)' (>297 pts in total)	symptoms	OMT)	(pt. had an underlying undetected spinal tumor, fracture resolved without residual effects)	pregnancy. The majority of studies, including case reports, did not include reporting of adverse effects in their manuscript. Two narrative reviews discussed possible contraindications to SMT during pregnancy and 3 clinical studies formally reported that no adverse events occurred. (...) high quality clinical trials on safety and effectiveness should be a priority."	
Reiman M. P. et. al (2009)	2 CSs, 3 pCohorts, 1 RCT, 1 descriptive study, 1 prognostic cohort (>76 pts in total)	Pts with lumbar spinal stenosis	SMT (including one study on 'manual physical therapy to the thoracic and lumbar spine')	Not specified SAEs: Not specified/may be none	"Initial group characteristics (C) and adverse effects (K) were also either not often described or difficult to ascertain." *(From table: one study including SMT describes adverse events. No further details provided (e.g. which kinds of AEs or if any AEs were observed))*	Not reported
Miley M. L. et. al (2008)	4 CRs, 3 CCs, 1 survey, 1 SR, 8 prospective and retrospective case series studies, 5 reviews, 4 opinion and expert commentary pieces (NA)	Pts in studies reporting vertebral artery dissection and ischemic stroke following cervical SMT	Cervical SMT	NA SAEs: Vertebral artery dissection and ischemic stroke	"The evidence that both supports and negates a causal association between VAD [vertebral arterial dissection] and CMT [cervical manipulative therapy] has been thoroughly reviewed and appraised. The evaluated evidence includes case-control studies, prospective and retrospective case series, case reports, surveys, and expert commentaries, which comprises a weak to moderately strong platform from which to draw our conclusions. In summary, we have found the burden of evidence to support a cause-and-effect relationship between CMT with VAD and subsequent stroke. Although we confidently make this assertion based on the evidence presented, we agree that a comprehensive prospective study must be conducted in a collective effort between all CMT practitioners to further examine this causal relationship, the incidence of VAD and stroke caused by CMT and the therapeutic efficacy of CMT. (...) Published estimates of the incidence of VAD and stroke after CMT range from 1 in 5.8 million to 1 in 500018,20. The best available estimate is from the case-control study by Rothwell et al, which concludes that for every 100,000 persons 45 years of age who receive CMT, approximately 1.3 cases of vertebral artery dissection or occlusion attributable to CMT would be observed within 1 week of manipulative therapy."	"Weak to moderately strong evidence exists to support causation between CMT and VAD and associated stroke." (Sir Bradford Hill's criteria for causation and the strength of the research designs)
Stuber K. J. & Smith D. L. (2008)	2 CSs, 1 rCS, 1 survey, 1 single-group pretest-posttest (285 pts in total)	Women with pregnancy-related low-back pain	Manipulation	None	"None of the studies indicated any adverse effects or evidence of harm to either the pregnant woman or unborn child from the treatments rendered. However, only the study by Lisi formally reported that there were no adverse events; the remaining studies did not comment one way or the other."	Not reported
Vernon H. & Humphreys B. K. (2008)	6 RCTs (178 pts in total)	Pts with chronic mechanical neck pain	SMT	"New discomfort" in neck, superficial phlebitis, more pain, mild exacerbation of pain No SAEs	"Mild, temporary pain-related adverse effects were reported in 6–17% of subjects in three studies. No major adverse reactions (defined as any reaction requiring additional medical intervention at any time) were reported in any of these studies."	Not reported
Chou R. & Huffman L. H. (2007)	16 SRs, 2 trials (NA)	Pts with low-back pain	SMT	Worsening lumbar disc herniation *(very sparse information with respect to AEs)* SAEs: Cauda equina syndrome	"Five systematic reviews consistently found that serious adverse events after spinal manipulation (such as worsening lumbar disc herniation or the cauda equina syndrome) were very rare. One systematic review found no serious complications reported in more than 70 controlled clinical trials. Including data from observational studies, the risk for a serious adverse	"good" (based on the type, number, size and validity of studies, strength of association,

				SAEs: Not specified	experienced serious adverse events."	
Boudreau R. & Spry C. (2009)	1 CR (1 pts in total)	Pts with syringomyelia	SMT	None	"No adverse effects were observed."	Not reported
Brurberg K. G. et. al (2009)	1 CS, 1 RCT (>695 pts in total)	Infants suspected with kinematic imbalance due to suboccipital strain	SMT and osteopathy	Mild bradycardia No SAEs	"In a large patient series it was reported about mild bradycardia following manual therapeutic KISS-treatment. The effect on heart rate was short-lived (3 to 25 seconds), and can hardly be defined as pathological."	Not reported
Gouveia L. O. et. al (2009)	100 CRs, 2 CCs, 3 rCohorts, 6 pCohorts, 12 surveys, 1 RCT (>2838 pts in total)	Pts in studies reporting AEs associated with chiropractic interventions	Chiropractic interventions (almost entirely SMT or cervical SMT)	RCT: Increased neck pain or stiffness, headache. CC: NA. pCohorts: local discomfort, exacerbation of pain, and radiation and headaches. (occurred most commonly in the first 24 hours after manipulation, were transient, mild, and benign). rCohorts: myelopathies, radiculopathies, vertigo, diminishment or loss of consciousness, radiculopathy, sudden onset of new and unusual headache and neck pain. CRs: herniated disc, radiculopathy, myelopathy. SAEs: RCT: None CC: vertebrobasilar accidents, cervical artery dissection. pCohorts: None. rCohorts: strokes, transitory ischemic accidents, acute subdural hematoma, death, spinal cord injury (including myelopathy, tetraparesis, central cord syndrome, or paraparesis), cauda equina syndrome, Brown-Séquard syndrome, vertebral artery occlusion, strokes. CRs: strokes, spinal fluid leak presented as intracranial hypotension, spinal epidural hematoma, cauda equina syndrome, diaphragmatic palsy, pathologic fractures of vertebra.	"Adverse reactions are frequent after spinal manipulation ranging from 33% to 60.9%, mostly increased pain or stiffness. However, the frequency of serious adverse events is not established varying between 5 strokes/100,000 manipulations to 1.46 serious adverse events/10,000,000 manipulations and 2.68 deaths/10,000,000 manipulations, with stroke being the most frequent. (...) There is no robust data concerning the incidence or prevalence of adverse reactions after chiropractic. Further investigations are urgently needed to assess definite conclusions regarding this issue."	Not reported
Hunt K. J. et. al (2009)	1 RCT (NA)	Pts with carpal tunnel syndrome	Chiropractic care (including SMT)	Sore neck No SAEs	"In the intervention group, adverse effects were noted for one patient who complained of a 'temporary sore neck at the end of the treatment'. It is unclear from the report whether this was resolved at the end of the study."	Not reported
Khorsan B. et. al (2009)	6 CRs, 6 CSs, 2 CCs, 9 surveys, 1 RCT, 2 SRs, 4 narrative reviews, 1	Pregnant women with back pain and other related	SMT (including some mobilization and	NA SAEs: Cervical spine fracture	"Case reports and narrative reviews were included in Table 4 to describe the nature and severity of reported adverse events related to SMT or OMT during	Not reported

					Combining all the data from the cohort studies (Table 1) we estimated, an upper 95% CI incidence risk rate of major adverse events (as per our definition) of 0.007% (0/42,451) after treatment or 0.01% (0/22,833) per patient. (...) There were no reports of any major adverse events in any trial [RCTs]. The 31 RCTs included 2281 participants who received manual therapy and 2779 who received other therapies. Fifteen trials reported that no adverse events occurred regardless of the intervention administered. We estimated an upper incidence rate of major adverse events of ~0.13% (0/2301) after manual therapy treatment."	
Ernst E. (2010)	23 CRs (26 pts in total)	Pts who died following treatments from a chiropractor	Treatments from a chiropractor (including SMT)	NA SAEs: Death (including vascular accident leading to thrombosis and cerebral infarction)	"In conclusion, numerous deaths have been associated with chiropractic neck manipulations. There are reasons to suspect that under-reporting is substantial and reliable incidence figures do not exist. The risks of chiropractic neck manipulations by far outweigh their benefits. (...) The type of complication associated with death frequently related to a vascular accident leading to thrombosis and cerebral infarction."	Not reported
Hahne A. J. et. al (2010)	3 RCTs (NA)	Pts with lumbar disc herniation with associated radiculopathy	Manipulation (may be entirely SMT)	None	"Three trials [including one trial on SMT] reported at least 1 adverse event in conservative treatment groups. (...) In 1 trial [on SMT compared with mechanical traction], 2 of the 50 participants receiving mechanical traction fainted. (...) A further 4 trials reported that there were no adverse events associated with conservative treatment [including one trial on SMT]. (...) Six trials made no mention of adverse events [including one trial on SMT]. (...) no adverse events related to manipulation were reported by the trials in our review."	Not reported
Kaminsky] A. et. al (2010)	8 RCTs (NA)	Pts with asthma	SMT (including a few studies on chiropractic care or chiropractic manipulation, not further specified)	Exacerbations of asthma No SAEs	"None of the studies indicated any adverse effects or evidence of harm (other than exacerbations of asthma) to patients treated by chiropractors. Studies by Balon and Nielsen were the only ones to mention adverse effects/reactions as part of the article and to formally state that there were no adverse events. All other articles included in this study did not mention adverse effects. None of the included articles included a comprehensive list of possible adverse effects from the intervention."	Not reported
Shin B.-C. et. al (2010)	12 CRs (18 pts in total)	Pts experiencing AEs following SMT	SMT	Herniated discs SAEs. Cauda equina syndrome, dural tear, vertebral fracture, vertebral subluxation, stroke	"In conclusion, adverse effects after spinal manipulation have been reported in the Korean literature with some regularity. Their true incidence, however, remains unknown. (...) In cases in which the lumbar region had been manipulated, the adverse effects usually pertained to herniated discs or cauda equina syndrome. In cases in which the cervical region had been manipulated, the most serious complications were dural tear, vertebral fracture, vertebral subluxation and stroke. In the majority of cases, the onset of symptoms was soon after treatment. Most patients made full recoveries but, in several instances, lasting neurological deficits remained."	Not reported
Boudreau R. et. al (2009)	1 RCT, 3 SRs, 1 HTA (>52 pts in total)	Pts with acute or chronic lower back pain	SMT	Headache, tiredness (*most common; very sparse information with respect to AEs*)	"Evidence on adverse events was minimal, but the literature consistently reported that patients commonly experienced mild adverse events, and rarely	Not reported

			No SAEs	was statistically significant in the SMT group (p<0.005)."	
Posadzki P. & Ernst E. (2011)	6 SRs (NA)	Pts suffering from headaches	SMT (may include some mobilization and other manual therapies)	Not specified/may be none SAEs: Not specified/may be none	"Several of the included SRs fail to mention the important issue of adverse effects after SM." *(incomplete descriptions, 3 trials mention AEs, 3 trials do not mention AEs)*	Not reported
Posadzki P. & Ernst E. (2011)	16 RCTs (NA)	Pts with musculoskeletal pain	OMT (including SMT in some of the trials)	Tiredness, "mild adverse effects" No SAEs	"In four trials only adverse effects were reported. Given the fact that 12 trials did not report adverse reactions at all safety of OMT remains unclear."	Not reported
Rubinstein S. M. et. al (2011)	26 RCTs (2435 pts in total)	Pts with chronic low-back pain	SMT (including a few studies on mobilization)	Muscle soreness, stiffness, transient increase in pain, aggravated conditions, tiredness, increased pain No SAEs	"Slightly more than one-third of the studies reported on adverse events. Adverse events in the SMT group were limited to muscle soreness, stiffness, and/or transient increase in pain. None of the studies registered any serious complications in either the experimental or control group."	Not reported
Walker B. F. et. al (2011)	10 RCTs (NA)	Pts with nonspecific low-back pain	SMT	"Minor, transient, exacerbations of symptoms" No SAEs	"Adverse effects were reported in only two of the included studies [one of these trials included SMT]. From these two studies, 16 out of a total of 106 participants who received the chiropractic interventions reported minor, transient, exacerbations of symptoms. None of the included studies reported any serious adverse effects in participants that received the chiropractic interventions. However, relatively small and short-term RCTs included in this review are not the best study design for detecting adverse events, and longer term large observational studies are needed to provide a valid evaluation of adverse effects, particularly those that are uncommon or rare."	Not reported
Carlesso L. C. et. al (2010)	3 CSs, 14 RCTs (NA)	Pts with cervical pain or cervicogenic headache	Cervical SMT (including three studies on cervical mobilization)	Transient neurological symptoms, increased neck pain, headache, fatigue No SAEs	"Seventeen of 76 identified citations resulted in no major AE. Two pooled estimates for minor AE found transient neurological symptoms [RR 1.96 (95% CI: 1.09-3.54) p<0.05]; and increased neck pain [RR 1.23 (95% CI: 0.85-1.77) p>.05] (both estimates are based on two trials, that used only SMT of the neck as intervention, n=285 and n=389 respectively). Forty-four studies (58%) were excluded for not reporting AE. No definitive conclusions can be made due to a small number of studies, weak association, moderate study quality, and notable ascertainment bias."	Major/ catasthropic adverse events - ; Minor adverse events - transient neurological symptoms: low, Minor adverse events - increased neck pain: low. (GRADE)
Carnes D. et. al (2010)	8 pCohorts, 31 RCTs (25179 pts in total)	Pts in studies reporting AEs following manual therapy	Manual therapy (including SMT in the majority of the trials)	Headaches *(very sparse information with respect to AEs)* SAEs: Serious neurological complaints', 'unbearably severe side effects', 'significant adverse events', 'alarming' adverse events *(very sparse information with respect to SAEs)*	"Nearly half of patients after manual therapy experience adverse events that are short-lived and minor; most will occur within 24 h and resolve within 72 h. The risk of major adverse events is very low, lower than that from taking medication. We suggest that risk is inherent in all health interventions and should be weighed against patient-perceived benefit and alternative available treatments. (...) Of the eight studies [prospective cohorts], one (Thiel et al., 2007) reported 14 cases of `unbearably severe side effects' in 4712 treatments (0.13%). Thiel et al. (2007) reported an upper risk rate for `serious adverse events' using Hanley's `rule of three' (Hanley and Lippman-Hand, 1983) of approximately 0.01% (3/28,109 consultations).	Not reported

		disorders, and/or pain, shoulder impingement syndrome, rotator cuff injuries, disease or disorders, acromioclavicular injury, osteoarthritis, frozen shoulder, neurogenic shoulder pain, glenoid hypoplasia)				
Cross K. et. al (2011)	6 RCTs (187 pts in total)	Pts with mechanical neck pain	Thoracic SMT	Aggravation of symptoms, muscle spasm, headache. (a duration of no greater than 24 hours) No SAEs	"Only 2 of the included studies presented complications or adverse events as a result of the interventions. Cleland et al reported no significant differences in the number of side effects experienced by individuals in the thrust manipulation versus nonthrust group. (...) In a later study by Cleland et al, no adverse events in either group throughout the trial were reported."	Not reported
Huang T. et. al (2011)	2 RCTs (131 pts in total)	Children with nocturnal enuresis	SMT (chiropractic adjustments of the spine)	Headache, stiff neck, acute pain in lumbar spine No SAEs	"Adverse effects identified in eight of the 24 RCTs were generally mild and self-limiting. However, the adverse effects could not be attributed to the trial treatments with certainty. Furthermore, the majority of the trials (15) failed to mention whether or not there were adverse effects. (...) However, judged on the evidence available adverse effects of these therapies seemed to be generally mild." *(This conclusion applies to all 24 included RCTs - no conclusion was available for only the two RCTs on SMT. For two RCTs on SMT, only one RCTs reported AEs, the other did not mention AEs)*	Not reported
Lystad R. P. et. al (2011)	6 pCohorts, 3 RCTs (NA)	Pts with cervicogenic dizziness	SMT	"Minor adverse reactions" No SAEs	"Only three studies commented on adverse reactions. Two RCTs [did not include SMT] reported no adverse reactions, and one prospective cohort study [included SMT] found minor adverse reactions associated with the interventions in eight of nineteen participants."	Not reported
Posadzki P. & Ernst E. (2011)	9 RCTs (NA)	Pts with cervicogenic headache	SMT	Hot skin, dizziness, headache, "minimal benign reactions lasting less than 24 hours" No SAEs	"The majority of RCTs failed to provide details of adverse effects. (...) Four of the 9 RCTs reported adverse effects (AEs). Five RCTs failed to provide that information. The non-reporting of AEs is in violation of all guidelines of reporting clinical trials and, arguably, of medical ethics. It is also worth noting that several hundred severe complications after upper spinal manipulations have been reported (e.g., Ernst and Terrett). A particular concern relates to vascular accidents caused by arterial dissection after upper spinal manipulation. The estimates as to the incidence of these complications vary hugely. Underreporting of AEs in RCTs is likely to generate a false impression about the safety of SM."	Not reported
Posadzki P. & Ernst E. (2011)	3 RCTs (NA)	Pts with migraine headache	SMT	Neck pain and soreness. *(very sparse information with respect to AEs)*	"Two studies (out of three) reported adverse effects; and one RCT failed to provide such information. In the study by Parker et al. the likelihood of adverse effects	Not reported

		spondylosis)		manipulation in treating neck pain was not clear."	
Posadzki P. & Ernst E. (2012)	5 RCTs (NA)	Pts with tension-type headache	SMT	Neck stiffness, minor aggravations of neck pain or headaches No SAEs	"Three studies reported adverse effects (AEs) and two RCTs failed to provide that information. Several hundred severe complications after upper spinal manipulations have been reported. The estimates as to the incidence of these complications vary hugely. Not reporting AEs is unhelpful and distorts the overall picture about AEs after SM. It also is also not in line with generally accepted research ethics."	Not reported
Puentedura E. J. et. al (2012)	93 CRs (134 pts in total)	Pts experiencing AEs following cervical SMT	Cervical SMT	Disc herniation, weakness, paresthesias, and increased pain **SAEs**: Arterial dissection, cerebrovascular accident, vertebral dislocation or fracture, death	"This review showed that, if all contraindications and red flags were ruled out, there was potential for a clinician to prevent 44.8% of AEs associated with CSM [cervical spine manipulation]. Additionally, 10.4% of the events were unpreventable, suggesting some inherent risks associated with CSM even after a thorough exam and proper clinical reasoning. (...) Four of the [seven] deaths were determined to be preventable, one unpreventable and two unknown. (...) Arterial dissection was the most common AE reported, being present in 37.3% of the cases (n=550). Other common AEs included disc herniation (18.7%, n=525), CVA [cerebrovascular accident] (13.4%, n=518), and vertebral dislocation or fracture (6.7%, n=59)."	Not reported
Rubinstein S. M. et. al (2012)	20 RCTs (1195 pts in total)	Pts with acute low-back pain	SMT	Aggravation of symptoms, stiffness (*most common*) No SAEs	"Importantly, there was no evidence of serious adverse events demonstrated in any of the trials, although all RCTs were too small to give any reliable and precise estimate of these types of events (...) Six studies, with a total of 1195 participants, reported on adverse events. One study reported four serious adverse events, occurring equally in both the experimental and control groups; however, "neither of the events appeared to be related to the allocated treatment strategies" (Juni 2009). In another study 25% of the participants reported at least one side effect of treatment; however, there were no differences between the groups and all symptoms resolved within 48 hours of onset (Cleland 2009)."	"Not estimable" relative effect for SAEs and no grading given (GRADE)
Stuber K. A. et. al (2012)	4 CRs, 1 pCohort, 2 SRs (NA)	Females who are pregnant or postpartum (period from giving birth to six weeks after) and experiencing AEs following SMT	SMT	Vertigo, paresthesias **SAEs**: Right cerebral infarct, occlusion of the left vertebral artery and thrombus in basilar artery, pathological type II odontoid fracture with ventral displacement producing spinal cord compression and paravertebral hematoma, epidural hematoma	"There are only a handful of reported cases of adverse events following spinal manipulation during pregnancy and the postpartum period in the literature with the severity ranging from mild increases in pain that resolved quickly to significant life-threatening injuries. While improved reporting of such events is required in the future, it may be that such injuries are relatively rare. Clearly future research into efficacy of this treatment for these populations and the rates of occurrence of adverse events is necessary to determine whether or not this is true."	"lower levels of evidence" (the hierarchy of evidence)
Brantingham J. et. al (2011)	2 CRs, 1 CS, 5 RCTs, 1 controlled trial (CT), 1 single-arm trial, 1 investigational study (>266 pts in total)	Pts with shoulder pain and disorders (including shoulder complaints, dysfunction,	SMT	None	None *(4 studies reported no AEs, 2 studies did not report AEs, and AEs was not mentioned for the 5 remaining studies)*	Not reported

					adverse events was similar in manipulation versus Diazepam groups (9.5% versus 11.1%). Nonrandomized Studies: In two case control studies, subjects younger than 45 years of age with vertebro-basilar artery (VBA) stroke were more likely to visit a chiropractic or primary care physician than subjects without VBA stroke. This association was not observed in older subject visiting the chiropractic clinic. In the first case-control study, the excess risk of vascular accident was observed for both, subjects undergoing chiropractic care and subjects undergoing primary care treatments. In the second case-control study, subjects with cervical artery dissection were more likely to have had spinal manipulation within 30 days (OR = 6.62, 95% CI: 1.4, 30.0). In one cohort study, rate of complications did not differ between subjects with low-back pain receiving manipulation plus mobilization versus no treatment. In another prospective cohort study of 68 subjects with chronic LBP, treatment with medication-assisted manipulation or spinal manipulation alone for at least 4 weeks did not lead to any complications requiring institutional review board notification."	
Gleberzon B. J. et. al (2012)	1 CS, 1 pCS, 6 RCTs, 2 pilot RCTs, 1 randomized feasibility study, 1 controlled clinical trial, 2 prospective study, 1 retrospective evaluation, 1 retrospective study (NA)	Pts below 18 years	SMT	Not specified SAEs: May be none	"SMT was safely used, with only two transient, self-limiting adverse reactions reported. [from the feasibility pilot study] (...) No adverse effects were reported in any of the clinical trials reviewed."	Not reported
Haynes M. J. et. al (2012)	5 CCs (NA)	Pts in studies reporting craniocervical artery dissection associated with cervical SMT	Cervical SMT	NA SAEs: Cranio-cervical artery dissection, vertebrobasilar occlusive stroke, vertebral artery dissection	"All of the extracted studies yielded inconclusive evidence regarding a strong association or no association between cSMT [cervical spinal manipulative therapy] with CAD [carotid artery dissection] related stroke."	Not reported
Kuczynski J. J. et. al (2012)	6 RCTs (268 pts in total)	Pts with low-back pain	SMT	Aggravation of symptoms and stiffness (*most common*) No SAEs	"Physical therapy spinal manipulation appears to be a safe intervention that improves clinical outcomes for a variety of patients with LBP. (...) Only one study reported the presence of adverse effects. Cleland et al found that 25 percent of patients within the study reported these side effects. Nine patients in each spinal manipulation group reported side effects, whereas 10 patients in the nonthrust manipulation (comparative) group reported such effects. Although no serious complications were reported, the most common side effects included aggravation of symptoms and stiffness. All adverse effects were reported to be resolved within 48 hours of onset."	Not reported
Lin J. H. et. al (2012)	4 RCTs (283 pts in total)	Pts with mechanical neck pain (cervical spondylotic radiculopathy or cervical	Chinese manipulation	None	"No adverse events were reported in the four studies. (...) Only one study mentioned adverse events and none was observed in that study. The other studies did not report whether adverse events had been measured in the trials. (...) The adverse event rate of Chinese	Not reported

SAB
-dit alternativ
SAMMENSLUTNINGEN AF ALTERNATIVE BEHANDLERE
www.sabnyt.dk

Kalundborg den 15. marts 2016

Til

Styrelsen for Patientsikkerhed
Embedslægeinstitution Øst og Tilsyn
Islands Brygge 67
2300 København S

Vedr. Høringssvar om Manuel behandling og Kiropraktorers forbeholdte virksomhedsområde.

Sammenslutningen af Alternative Behandlere (SAB) har gennemgået den udsendte høringsversion om Manuel behandling og Kiropraktorers forbeholdte virksomhedsområde.

Vi vedlægger høringssvar og forventer at blive løbende orienteret om forslag, ændringer og tiltag m.m., der kan påvirke vores medlemmer.

Idet vi regner med forståelse af vores synspunkter,

med venlig hilsen

Peter Madsen
Formand for Sammenslutningen af Alternative Behandlere
Kåstrupvej 1
4400 Kalundborg

Tlf. 70207045

Indholdsoversigt høringssvar fra Sammenslutningen af Alternative Behandlere (SAB)

1. Høringssvar SAB og høringssvar Body-sds samt Fakta og Spørgsmål
2. Bilag til høringssvar: Baggrundsdokument med bilag udleveret i forbindelse med foretræde for Sundhedsudvalget.
3. Bilag til høringsvar: Baggrundsdokument med bilag til beretning afgivet af Sundheds- og forebyggelsesudvalget den 14. april 2015
4. Bilag til høringssvar: artikelsamling fra DR.dk

Høringssvar fra Sammenslutningen af Alternative behandlere (SAB).

Sammenslutningen af Alternative Behandlere (SAB) er af Sundhedsstyrelsen og Styrelsen for patientsikkerhed blevet bedt om at levere et høringssvar i forbindelse med styrelsernes udarbejdelse af en anbefaling til Sundheds- og ældreministeriet omkring kiropraktorernes behandlingsområde.

Vi takker for henvendelsen og vil naturligvis gerne indgive et høringssvar til brug for styrelsernes og ministeriets videre arbejde.

Sammenslutningen af Alternative behandlere er en frivillig brancheorganisation med 550 medlemmer. Ud af dem skønner vi, at omkring 275 er berørt af den bestemmelse i loven, der nu er til diskussion, da de arbejder med behandlingsteknikker, der ifølge lovteksten kan risikere at bliver karakteriseret som kiropraktisk behandling.

SAB er en af de af Sundhedsstyrelsen godkendte brancheorganisationer, der er en del af den brancheadministrerede ordning Registrerede Alternative Behandlere (RAB).

Det betyder, at SAB står for RAB-godkendelsen af vores medlemmer, og vi er dermed ansvarlige for, at de RAB-godkendte behandlere, der er medlemmer hos os, lever op til de krav, RAB-ordningen indebærer.

Det er krav, der blandt mange andre krav betyder, at de berørte RAB-godkendte behandlere - udover 650 timers undervisning i deres primære fag, også skal have gennemgået mindst 100 timers patologi/sygdomslære, og 200 timers anatomi/fysiologi. Herudover skal de som udøvende behandlere have en forsikring, der sikrer, at deres klienter kan indklage eventuelle skader og, hvis sådanne anerkendes, få erstatning herfor.

Ifølge den nyeste undersøgelse fra Statens Institut For Folkesundhed gik 27 pct. af den danske befolkning eller 1,2 million danskere alene i 2013 til en eller anden former for alternativ behandling. Og antallet har været konstant stigende i mange år og er det stadig. Da man i sin tid indførte RAB-systemet var det netop for at sikre at de mange danskere, der benytter sig af alternativ behandling, kunne sikres et ens højt uddannelses- og kompetenceniveau hos behandleren, samt at klienterne fik mulighed for at klage over behandlingen og i forlængelse heraf opnå erstatning, hvis behandleren kunne gøres ansvarlig for en skade.
(note: RAB-registrerede behandlere skal i øvrigt også bede klienter om at opsøge læge, hvis de skønner, at der er lidelser eller sygdomme tilstede, der kræver lægebesøg.)

Det er vigtigt at understrege at langt fra alle alternative behandlere, er RAB-registrerede. Det bestemmer den enkelte behandler selv.

RAB-registrerede behandlere har altså en grundlæggende viden om kroppen og derudover en meget detaljeret viden om netop de teknikker, den enkelte er uddannet i, som for de flestes vedkommende i øvrigt er "håndværk". Mange af dem bygger på gamle og gennemprøvede – i

nogle tilfælde tusindår gamle - behandlingsteknikker, hvor den opsamlede viden om og erfaring med kroppen og dens muskler og led gives videre til behandlerne, når de uddanner sig.

Kiropraktorer var indtil 1991 med i gruppen af alternative behandlere. Og før 1991 var der ingen restriktioner, ingen begrænsninger og ingen forbehold for, hvilke manuelle teknikker, massageteknikker eller manipulationsbehandlinger alternative behandlere måtte udføre.

Så op til 1991 var der rigtig mange, behandlergrupper, der anvendte teknikker og behandlinger, der svarer til beskrivelsen af de behandlinger, der altså nu er forbeholdt læger og kiropraktorer.

Det har aldrig været en problem eller et emne, der har været diskuteret politisk.

Det har ikke været nødvendigt.

Der har aldrig være et skadesbilleder, der har betydet, at man skulle tage op til revision om der foregik "farlige" behandlinger.

Det har aldrig været et "lægeligt område", sikkert fordi det har fungeret fint som det var.

Nemlig et alternativ til den etablerede lægeverden. I øvrigt et alternativ som den enkelte klient selv vælger og selv betaler. Altså behandlinger, som den danske stat ikke har udgifter til.

Det var derfor heller ikke, som alle der sætter sig ind i historikken og bemærkningerne til loven fra 1991 vil kunne se, hverken patientsikkerhed eller frygt for skader, der var baggrunden for at kiropraktorerne i 1991 opnåede den for dem længe ønskede autorisation.

Baggrunden for det var rent politisk, da et flertal ønskede "at gøre noget godt for de mennesker, der har glæde af den alternative behandling". Som ophavsmanden til loven, tidligere folketingsmedlem Erling Christensen (s) har formuleret det: " Vi vedtog loven, fordi vi mente at mennesker fik gavn af behandlingen, men vi havde ikke nogen lægefaglig evidens for, at det virkede".

Det har man stadig ikke.

Danmark var i 1991 det første land i verden til at autorisere kiropraktorerne.
Vi var dengang og er stadig også det eneste land, hvor manuelle behandlinger og manipulationer er forbeholdt kiropraktorer og læger.

I andre lande er behandlinger af kroppens led og manipulationer ikke forbeholdt bestemte behandlergrupper. I Frankrig er det osteopaterne, der er flest af. I Tyskland heilpraktikerne og i Sverige er naprapater meget populære. Men selvom de nævnte behandlere i de nævnte lande altså er langt mere kendte end kiropraktorernes, så har de ikke monopol på at udføre dem.

Det skal også tilføjes, at behandlingerne i de nævnte lande godt kan være tilskudsberettigede, uanset hvem der udfører dem.

I 1991 har der helt sikkert siddet mange andre, fra andre alternative behandlingsformer end kiropraktikken og været misundelige og med et hemmeligt ønske om at opnå det samme muligheder som kiropraktorerne.

Men én ting er misundelse og ærgrelse. Noget andet er rimelighed og retfærdighed, som hænger uløseligt samen med disse få sætninger i loven: *" Ved kiropraktisk behandling forstås manuel behandling af kroppens led"*.

Det var denne formulering, der utilsigtet gjorde op med den hidtidige virkelighed på behandlerområdet og pludselig gjorde en stor gruppe af de eksisterende alternative behandlere lovløse og kriminelle, og det er ikke bare noget, man kan være ærgerlig over. Det er forkasteligt – uretfærdigt.

Hverken de, der nu har en særstilling og som de eneste må behandle lovligt – altså kiropraktorer og læger - eller nogen andre bør kunne glæde sig over det – endsige forsvare det.

Siden loven blev indført, har den pågældende formulering i loven egentlig ikke skabt problemer.

Men kun fordi ingen har forholdt sig til den.

Det er der så nu, hvor man 25 år efter loven blev lavet, er i en situation, hvor man anvender de nævnte beskrivelser i loven til at retsforfølge en bestemt behandler der, hvis han dømmes, givetvis vil blive løftestangen til at fratage hundredevis af behandlere deres levebrød, fordi de ligeledes vil kunne anklages for at lave kiropraktik, selvom ingen af dem gør det.

Realiteterne er jo, at alle de behandlingsformer, der inden 1991 benyttede sig af manuelle teknikker og lignende stadig gør det. Ergo har loven ikke ændret en tøddel på, hvem der udfører de beskrevne behandlinger – ligesom den heller ikke har begrænset dem til nogen, der kun udføres af læger og kiropraktorerne.

Det er simpelthen at smide blår i øjnene på folk, at påstå andet.

Og sådan er det fordi de teknikker, der anvendes i diverse alternative behandlingsformer netop ikke er kiropraktik . Teknikkerne er anderledes.

Men "ens" er de blevet med den beskrivelse, der er i loven.

Man lavede – ved en fejl må man antage – en monopolstilling for kiropraktorerne (og lægerne).

Og hvorfor er der så ingen, der har reageret på det tidligere?

Fordi de teknikker som heilpraktikere, thaimassører, massører, Body-sds-terapeuter og diverse andre alternative behandlere anvender, som nævnt ganske enkelt ikke er de samme teknikker, som dem kiropraktorerne anvender. Derfor har man bare fortsat med at anvende dem og behandle efter samme principper som før 1991. Fordi ingen har skænket det en tanke, at nogen kunne finde på at påstå, at deres behandlinger var "kiropraktiske behandlinger".

Særlig ikke når man tænker på, at den etablerede behandler-verden ofte har haft travlt med lige præcis det modsatte – nemlig at understrege, at alternative behandlinger netop IKKE kunne sammenlignes med såkaldte "anerkendte behandlingsmetoder".

Ingen alternative behandlere har derfor indtil nu frygtet, at de faktisk brød loven – for de ved jo alle selv, at deres teknikker, netop ikke er kiropraktik – og at de selvfølgelig ikke kalder sig for kiropraktorer. Derfor har der ikke været grund til at ændre praksis – og slet ikke til at frygte for domme for lovovertrædelser.

Som det fremgår af den fremsendte høringsrapport, mener styrelserne heller ikke, at fysioterapeuterne må anvende de nævnte teknikker. Og det på trods af, at loven ellers umiddelbart giver udtryk for, at denne behandlergruppe har lov til at udføre de nævnte behandlinger. Som det også fremgår af rapporten, så er realiteten – også på det område – at fysioterapeuterne anvender teknikkerne i deres behandlinger. Så også for den behandlergruppe, ser man allerede i dag det realistiske skadesbillede med kun et par skader indenfor de sidste år. Og der er altså over 16.000 fysioterapeuter, der potentielt anvender teknikkerne dagligt.

Så situationen er altså, at behandlingerne af muskler og led finder sted i samme omfang i dag, som de altid har gjort. Og derfor er det realistiske skadesbillede ved at lade RAB-godkendte kropsterapeuter, og fysioterapeuter LOVLIGT udføre manuelle behandlinger, led-frigørelser og manipulationer altså allerede tilstede i dag. Fordi behandlingerne allerede finder sted, da ingen af behandlergrupperne har haft den fjerneste anelse om, at nogen kunne finde på at betegne deres behandlinger som "kiropraktisk behandling", når de nu ikke selv gør det.

Og der er næppe nogen, der vil påstå, at det vrimler med erstatningssager mod hverken alternative behandlere eller fysioterapeuter.

I SAB har vi ingen statistik over anmeldte skader hos vores medlemmer. Men da RAB-godkendelsen indebærer, at man tegner en ansvarsforsikring så ens klienter netop har muligheden for at klage og opnå erstatning, så ville billedet have tegnet sig allerede, hvis der var en skadeshistorik, der gav anledning til bekymring. Kontakt til Forsikringsoplysningen og en række forsikringsselskaber viser klart, at man ikke engang fører statistik over den slags skader. For der er ganske enkelt for få.

Hvad angår skader der er registreret som følge af manuelle behandlinger af led og manipulationer tegner kiropraktorerne sig for den største del. Det vil vi i SAB ikke forholde os til, men kan blot konstatere, at argumentet om at man får en bedre skadestatistik ved at lade læger og kiropraktorer have behandlingsmonopol altså ikke holder.

Her er det virkelig interessant at erindre sig, at Sundhedsstyrelsen før 1991 i årevis afviste en autorisation af kiropraktorer og også fagligt anbefalede ikke at gennemføre den. I bund og grund jo et ganske fornuftigt synspunkt i betragtning af, at der hverken dengang eller i dag er videnskabelig bevis for at behandlingerne virker endsige udgør nogen betydende risiko for patienterne.

Alligevel har man i Styrelsen for Patientsikkerhed og Sundhedsstyrelsen svinget 180 grader rundt og i markant modsætning til de faktiske forhold er det nu argumentet om patientsikkerheden, der ligger til grund for at kiropraktorer og læger har opnået monopol på at behandle kroppens led. Og ingen vil åbenbart forholde sig til, at baggrunden for at give autorisationen på ingen måde var og stadig ikke er – fagligt og videnskabeligt funderet.

Så tilbage står i dag lovens bogstav. Og det kan desværre læses, som fanden læser bibelen. Og når man gør det – og samtidig lader sig rive med at skrækscenarier om farlighed der ganske enkelt ikke har hold i hverken virkelighed eller forskning – og som man endda selv må beskrive som teoretiske, så ender man i den situation vi er i nu.

Hvor en, skal vi kalde det "uautoriseret" autorisation af en alternativ behandlergruppe ender med at blive svanesangen for de resterende alternative behandlere, fordi der i lovprocessen laves en formulering, som ingen bemærker eller tillægger større betydning på det tidspunkt.

Godt 20 år senere har nogen pludselig fået øje på, at der findes et alternativ til kiropraktiske behandlinger, som en hel enorm klient-gruppe i dag foretrækker og har stor gavn af.

Det resulterer i en anmeldelse af en behandler, der har været med i et tv-indslag.

Sagen ruller – og manden anklages af Sundhedsstyrelsen for at bryde autorisationsloven ved at udøve kiropraktiske behandlinger.

Manden er Bengt Valentino Andersen. Stifter af det danske behandlingssystem Body-SDS. Sagens detaljer skal ikke oprulles her. Den skal for i august 2016. Hvis den da ikke udskydes igen, hvad den er blevet flere gange.

Body-SDS er den af de behandlergrupper Sundhedsstyrelsen selv har givet SAB bemyndigelse til at RAB-godkende, når den enkelte Body-SDS-behandler lever op til RAB-kravene.

Så Body-SDS-terapeuter kan altså på den ene side være godkendt at Staten igennem RAB-systemet – og på den anden side måske blive dømt som kriminelle.

SAB har ikke være involveret i den proces, der går forud for den forespørgsel om høringssvar vi nu har fået fra Styrelsen for Patientstikkerhed og Sundhedsstyrelsen.

Men det har repræsentanter for det danske behandlingssystem Body-SDS.
Body–SDS er ikke blevet bedt om at indgive et høringssvar på trods af dette og på trods af det omfattende materiale de har leveret til styrelsen.

Da Body-SDS er en af de største behandlergrupper i SAB og repræsenterer det problem loven skaber for alle andre RAB-behandlere med speciale i behandling af kroppen, har SAB derfor bedt Body-SDS om det materiale og den information de igennem de seneste år har samlet.

Materialet indeholder en lang række fakta samt en række henvisninger til relevant forskning. Ligesom den går i dybden med den del af det, der berøres i nærværende skriv. Materialet indgår derfor i dette høringssvar fra SAB. Det skulle også sikre, at der senere vil være aktindsigt i det pågældende materiale, hvis nogen skulle ønske det.

Som alternative behandlere, er vi vant til, at det vi arbejder med ikke kan evidensunderbygges og bevises videnskabeligt.

Men i den etablerede lægeverden, er det normalt ikke et diskuterbart parameter.

Desværre har SAB ikke mange midler. Ej heller adgang til en hær af læger og forskere, der kan underbygge, udtale sig og fremlægge argumenter.

Men Sundhedsstyrelsen og Styrelsen for Patientsikkerhed burde også selv være i stand til at levere en objektiv vurdering af de fakta, der findes.

Indtil nu er partsudtalelser og svar fra de adspurgte neurologer og neurokirurger blevet anvendt som objektiv sandhed af Styrelsen for Patientsundhed og Sundhedsstyrelsen som samtidig har tilsidesat fakta og forskningsresultater.

Man må håbe og formode at styrelserne efter de nuværende høringssvar tager deres egne udsagn og anbefalinger op til fornyet revision.

For evidens og videnskab vægtes jo højt, når der skal diskuteres patientrisiko.
Og sådan skal det vel være, for at man kan sikre klinisk validitet i rådgivning og vejledning. Behovet for at kunne referere til en videnskabelig rapport eller en klinisk test er jo nok en god vej, når man bruge milliarder af danskernes penge på et offentligt sundhedssystem.

Derfor er det faktisk chokerende, trist og skræmmende at Sundhedsstyrelsen og Styrelsen for Patientsikkerhed i denne sag tilsidesætter netop de kriterier, for at stå fast på en argumentation, der er opstået på et helt fejlagtigt grundlag. Nemlig den forkerte tese, at manipulation og manuel behandling af kroppens led skal være forbeholdt læger og kiropraktorer fordi det udgør en patientrisiko.

For vores klienter betyder det ikke så meget, at der ikke kan påvises evidens for de behandlinger de vælger at få foretaget. Vi har den holdning, at det enkelte individ selv bestemmer over, hvad de vil have gjort ved deres krop – og vi lever fint med, at lade resultaterne tale for sig selv. Og med den store procentdel af den danske befolkning, der mener at alternativ behandling har en effekt for dem, har vi egentlig ikke behov for forskningen blåstemplinger. Derfor betyder det ikke noget for os, at forskningen påviser, at der ikke er evidens for effekten af manipulation. Vi skal jo ikke have forskningsmidler og penge til at holde en universitetsuddannelse i gang, som kiropraktorerne skal.

Men evidens og forskning er alligevel på vores side i den her sag. For når det kommer til om de – ifølge forskningen ikke evidensbaserede behandlinger - udgør en risiko, der betyder at de bør være forbeholdt læger og kiropraktorer, så har vi de hårde fakta på vores side.

For forskningen viser, at sandsynligheden for at komme til skade ved en manipulationsbehandling er forsvindende lille. Også selvom neurokirurger, neurologer, kiropraktorer og muligvis andre, gerne vil udlægge fakta anderledes.

Så når det nu er forskning og evidens og selvfølgelig patientsikkerhed, der er måleparameteret for Sundhedsstyrelsen og Styrelsen for Patientsikkerhed, så er de argumenter der præsenteres i den tilsendte rapport ganske enkelt ikke valide.

I SAB tror vi på, at styrelserne ikke har bedt os komme med en udtalelse, hvis man allerede havde lagt sig fast på de konklusioner, der er draget i den tilsendte rapport. For så ville det her jo blot være en skin-proces uden mening.

I SAB er vi ikke i tvivl om, at hvis Sundhedsstyrelsen og Styrelsen for Patientsikkerhed ikke finder en løsning, der følger fornuften, virkeligheden og den faktuelle situation, sådan som det politiske flertal før sommerferien også var kommet frem til og derfor krævede, at alle fysioterapeuterne og de RAB-godkendte alternative behandler, der er udannet indenfor diverse kropsterapeutiske behandlingsteknikker bliver afkriminaliseret, så vil det skabe kaos og uoverskuelige konsekvenser for hele den alternative behandlerverden og for fysioterapeuterne. Og dermed for både behandlerne og deres hundredetusinder af klienter og patienter, der er dem, der i sidste ende vil blive ramt.

Det har vi i SAB ikke fantasi til at forestille os, at styrelserne ønsker.

For hvis det ene og alene er argumentet om beskyttelse af patienterne, som styrelserne bliver ved med at vende tilbage til, så bør de, bare ved selv at gennemgå al tilgængelig forskning og det materiale de nu har fået tilsendt – kunne se, at der ikke er valide, faglige og saglige argumenter for at kalde manuelle behandlinger og manipulationer for "farlige". Det er dermed ikke patientsikkerhed, der kan bruges som argumentet for at de nævnte behandlinger skal være forbeholdt læger og kiropraktorer.

Faktisk er der absolut ingen argumenter for, hvorfor man som patient/klient skulle føle sig mere sikker på en sådan behandling udført af en læge eller kiropraktorer, fremfor af en fysioterapeut eller RAB-godkendt Body-SDS-terapeut, massør eller lignende.

I SAB tror vi også på, at selvom vi ikke har store forskerhold, læger og professorer til rådighed, så bliver vi taget lige så alvorligt, som de andre aktører styrelserne har bedt komme med høringssvar.

Ikke mindst fordi de argumenter vi bringer til torvs netop har baggrund i videnskab, virkelighed og fakta. Så vi håber og tror, at styrelserne vil lade fornuften råde – og springe ud af den onde cirkel af ikke underbyggede argumenter, der bliver ved med at bide sig selv i halen.

- Loven blev ikke indført for at afholde andre behandlere fra at udføre de nævnte behandlinger.
- Loven blev ikke indført fordi man frygtede for patienters sikkerhed.
- Loven blev ikke indført på baggrund af faglige argumenter.

Loven blev indført for at "gøre noget godt" for en gruppe alternative behandlere og deres klienter.
Loven blev indført på baggrund af politik.
Og uanset, hvor mange gange man forsøger at udlægge det til andet end det, så bliver det aldrig rigtigt.

Hvis Sundhedsstyrelsen og Styrelsen for Patientsikkerhed også efter denne høringsproces fastholder den tilgang de giver udtryk for i den tilsendte rapport og endda anbefaler at lovteksten kun skal ændres for at gøre det endnu mere tydeligt, at læger og kiropraktorer skal opretholde deres behandlingsmonopol, så håber vi i SAB inderligt, at politikerne i det mindste vil være fornuftige som de var før sommerferien sidste år, og så træffer en politisk beslutning, der reelt har fagligheden og videnskaben i ryggen – og som retter op på den uholdbare situation, man skabte i 1991.

Som en del af dette høringssvar indgår omfattende materiale udarbejdet af Body-SDS a/s.

Materialet skal ses i sammenhæng og alle dele bedes medtaget som en del af SABs høringssvar.