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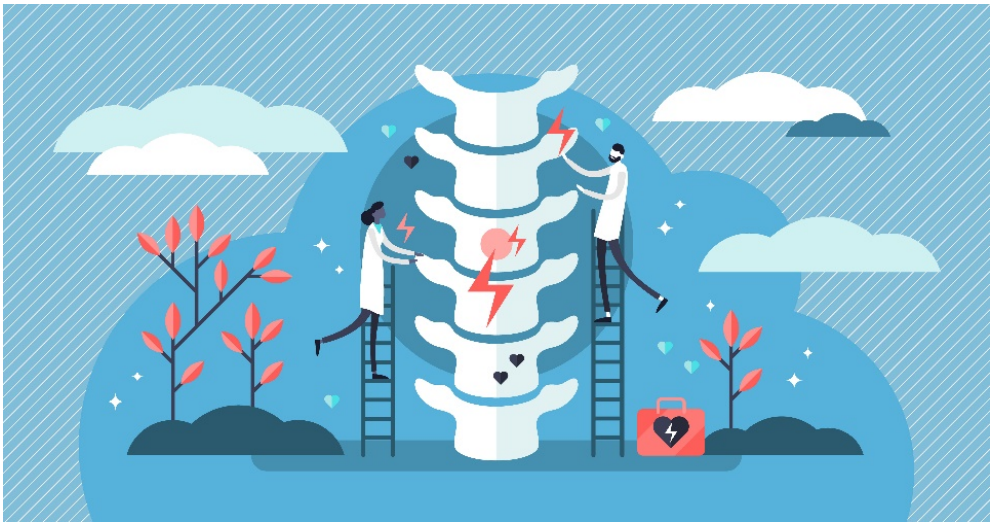
Osteopathy: effectiveness and safety for musculoskeletal pain and overview of training and quality requirements



A systematic review

Final report

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A systematic review

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Content

List of figures

List of tables

List of abbreviations

AMSTAR ..... A MeaSurement Tool to Assess systematic Reviews
AT ..... Austria
AWMF ..... Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V. (Association of the Scientific Medical Societies)
BDI ..... Beck depression inventory
CEN ..... Committee for Standardisation
CG ..... control group
CGIi ..... Clinical Global Impression Improvement Scale
CGIs ..... Clinical Global Impression Severity Scale
CH ..... Switzerland
CI ..... confidence interval
cm ..... centimetre
COME ..... Centre for Osteopathic Medicine
CPD ..... Continuing Professional Development
CROM ..... Cervical Range of Motion
DASH ..... Disabilities of the Arm Shoulder and Hand questionnaire
DE ..... Germany
DK ..... Denmark
E ..... exercise group
EASPS ..... Extended Aberdeen Spine Pain Scale
ECTS ..... European Credit Transfer and Accumulation System
EFFO ..... European Federation & Forum for Osteopathy

EFO ..... European Federation of Osteopaths
Embase ..... Excerpta Medica Database
EP ..... exercise programme
Eps ..... Education providers
EQ-5D ..... EuroQol
ERDA ..... Emotional/Rational Disease Acceptance Questionnaire
ES ..... effect size
etc. ..... et cetera
ev. ..... eventuell
FEW ..... Questionnaire for Assessing Subjective Physical Well-being
FFI ..... Foot Function Index
FI ..... Finland
FIM ..... Functional Independence Measure
FIQ ..... 10-item Fibromyalgia Impact Questionnaire
FORE ..... Forum for Osteopathic Regulation in Europe
FR ..... France
FU(s) ..... follow-up(s)
GÖG ..... Gesundheit Österreich GmbH (Austrian National Public Health Institute)
GOsC ..... General Osteopathic Council
GROC ..... Global Rating of Change
HADS ..... Hospital Anxiety and Depression Scale
HEENT ..... Head, eyes, ears, nose, and throat
IG ..... intervention group
IT ..... Italy
LKSS ..... Lysholm Knee Scoring Scale
MCID ..... Minimum clinically important difference
MET+STM ..... muscle energy technique + soft tissue massage
mg ..... milligramme
MGPQ ..... McGill Pain Questionnaire
MPQ ..... McGill Pain Questionnaire
n.s. ..... not significant
NDFG ..... number of days feeling good
NDI ..... Neck Disability Index scale
NHS ..... National Health Service
NICE ..... National Institute for Health and Care Excellence
NO ..... Norway
NPDS ..... Neck Pain and Disability Scale
NPS ..... Numerical Pain Scale
NR ..... not reported
NRS ..... Numerical Rating Scale
Ø ..... durchschnittlich
ODI ..... Oswestry Disability Index
OEGO ..... Österreichische Gesellschaft für Osteopathie (Austrian Association for Osteopathy)
OIA ..... Osteopathic International Alliance

OMT ..... osteopathic manipulative treatment
Pedro ..... Physiotherapie Evidenz Datenbank
PGI-I ..... Patients' Global Impression of Improvement
POM ..... Pain on Movement Questionnaire
PPT ..... pressure pain thresholds
Prospero ..... prospective register of systematic reviews
PSFS ..... Patient-Specific Functional Scale
PSQ ..... Perceived Stress Questionnaire
PSQI ..... Pittsburgh Sleep Quality Index
PT ..... Portugal
Pt(s). ..... Patient*in(nen), patient(s)
QBPDS ..... Quebec Pain Disability Scale
QoL ..... quality of life
QUALEFFO-41 .... Quality of Life Questionnaire of the European Foundation for Osteoporosis
RCT ..... Randomised controlled trials
RMDQ ..... Roland and Morris Disability Questionnaire
ROM ..... range of motion
RQ ..... research question
s.s. ..... statistically significant
SB ..... static baropodometry
SBC ..... Scale of Body Connection
SD ..... standard deviation
SDT ..... step-down test
SF-12 ..... 12-item Short Form Health Survey
SF-36 ..... Medical Outcomes Study Short Form-36/short form-36 health survey
SF-MPQ ..... Short-Form McGill Pain Assessment Questionnaire
SMPQ ..... Short-form McGill Pain Questionnaire
SPADI ..... Shoulder Pain and Disability Index
SRT ..... sit and reach test
STAI ..... State Trait Anxiety Inventory
tw. ..... teilweise
u. a. ..... unter anderem
UK ..... United Kingdom
US ..... United States
USA ..... United States of America
VAS ..... Visual Analogue Scale
versch. ..... verschieden(e)
WHO ..... World Health Organisation
z. B. ..... zum Beispiel

Executive Summary

Background

holistic approach

Osteopathy aims to holistically improve and support all health aspects. Mainly patients with musculoskeletal conditions and pain are treated. Internationally, there is little formal, routinely gathered information about the osteopathic practice. Osteopathy has no consistent regulation, education, and practice standards. In Austria, osteopathy is unregulated, but regulations are being discussed or have already been introduced in other countries. Currently, osteopathic services are not covered by health insurance in Austria. Due to the increasing supply and demand of osteopathic treatments for different indications, the question arises whether the public sector should pay for the services of osteopaths in the future. However, the effectiveness and safety of osteopathy in treating musculoskeletal pain remain unclear.

heterogeneous regulation, education and practice

growing profession; public sector should pay for services?

effectiveness, safety, training and quality requirements

Therefore, this systematic review aims to summarise the evidence on the effectiveness and safety of osteopathy in treating musculoskeletal pain (part 1) and to describe current training and quality requirements for European osteopaths (part 2).

Methods

part 1: systematic literature search, best available evidence for each body region and disease

For part 1, a systematic literature search for randomised controlled trials (RCTs) was conducted in five databases. 964 citations were identified and screened by two researchers independently. 35 relevant references were identified. For each body region and disease, we selected the best available evidence assessed by the 'Cochrane Collaboration's tool' version 1. We included 15 RCTs from the systematic search for the analysis and synthesis, covering the following body regions and diseases: neck, neck or (lower) back (mixed population), shoulder, knee, foot, fibromyalgia and osteoporosis. Additionally, we summarised a recent systematic review and meta-analysis for chronic non-specific low-back pain, which we critically appraised using the AMSTAR 2 tool (A MeaSurement Tool to Assess systematic Reviews).

summary of recent systematic review for chronic low-back pain

part 2: criteria forcountry selection

For the country selection of part 2, we chose the German-speaking countries Austria, Switzerland and Germany as well as other European countries that met the following inclusion criteria: existence of a national association for osteopaths, legal regulation for the practice of osteopathy existing or currently in progress, population of >5.5 million. A targeted manual search for training and quality requirements for osteopaths in the ten selected countries was conducted in different sources (e.g. PubMed, Trip medical database). Experts were contacted to further identify and complete the country's information.

targeted manual search and expert survey

Results

safe treatment

The results of this review suggest that osteopathic treatment represents a safe therapeutic choice for musculoskeletal pain in the analysed eight body regions and diseases, as only very few patients reported minor adverse events. Statistically significant inter-group improvements in favour of the osteopathic group indicate that osteopathy can be considered in patients suffering from *neck* pain as short- and mid-term (up to 3 months) effects, and some clinically meaningful reductions in pain were observed. However, long-term effects are

neck/low back pain: short- and mid-term improvements

missing, and the results for other outcomes, such as functionality or quality of life, were inconclusive. For chronic *low back* pain, a recent systematic review and meta-analysis concluded that osteopathic treatment reduced pain immediately after treatment and at the mid-term follow-up (FU) (i.e. 3 months). Functionality was improved immediately after treatment but not at the FU assessment.

foot/shoulder pain: possible improvements

It seems that *foot* pain can possibly be reduced in the mid-term by osteopathic treatment. Also, a clinically meaningful improvement was found. For *shoulder* pain, short-, mid-, and long-term inter-group effects could be observed in one study but not in the other trial. However, pre-post improvements and clinically meaningful intra-group improvements in the osteopathic treatment group were found in the other study.

other body regions and diseases: no final statement possible

The results for all other body regions and diseases (i.e. neck or (lower) back, knee, osteoporosis, fibromyalgia) are inconclusive, no or only immediate effects were found, or the evidence is insufficient to make a statement. No statistically or clinically significant deteriorations occurred due to osteopathic interventions.

legal regulation in 7/10 countires

title in 6/10 countries fully protected

Bachelor of science in 5/10 countries prescribed

2 international standards

Concerning the regulatory status and quality requirements, ten countries (Austria, Germany, Switzerland, Norway, Denmark, France, Italy, Finland, Portugal and the United Kingdom) were analysed. A legal regulation exists in seven countries, and the title 'osteopath' is fully protected in six of the ten countries. However, different training and study options for osteopathy exist in the included countries, varying in their curricula. A Bachelor of science as a minimum of education is prescribed in five countries. Osteopaths particularly work in private practices, and osteopathic therapies are mainly covered by private insurance. The European Federation & Forum for Osteopathy (EFFO), the osteopaths' lead professional associations and regulatory authorities, aims to establish regulation, standards, and recognition for osteopaths. Two international standards exist for osteopathy: the World Health Organisation (WHO) Benchmark for Training in Osteopathy and the European Standard on osteopathic healthcare provision (EN16686).

Discussion

mostly pain in the musculoskeletal system

Most patients consult osteopaths because of pain in the musculoskeletal system. Neck and low back pain represent the largest proportion. The WHO also stated in a recent report that neck and back pain is the main cause of years lived with disability worldwide.

safe treatment

neck/low back pain: improvement

The results of this review strengthen the evidence that osteopathic treatment represents a safe therapeutic choice, as only very few patients reported minor adverse events. Osteopathy can be considered in patients suffering from neck and low back pain. Further published systematic reviews and meta-analyses underline this finding. It seems that also shoulder and foot pain can possibly be reduced by osteopathic treatments.

comparison with excluded studies

short-, mid- and long-term effects

unclear to high risk of bias

To evaluate the validity of the synthesis from the 15 included studies, we compared the main results (i.e. of the primary outcome pain) with the excluded studies, which did not reveal any significant deviations. Statistically significant effects can be found in all categories of length of FUs; also in two of three studies after only one session of osteopathy. The RoB of the 15 included RCTs was unclear to high. Serious limitations of the studies were given due to the lack of patient and assessor/therapist blinding. However, the nature of osteopathy hardly allows blinding those who deliver or receive it.

The systematic review on chronic non-specific low back pain was rated with high overall confidence; however, none of the included RCTs showed a low RoB.

heterogeneity in RCTs; broad range of values for minimal clinically important difference

Heterogeneity of the included RCTs, such as professions involved, comparison, number of sessions, treatment period and FUs, might have influenced the results. Furthermore, many different outcome measurements were used for assessing the outcomes. In seven of the 15 included RCTs, clinically meaningful improvements were observed. However, in literature, the range of the minimal clinically important difference values is broad.

variability even inside the same typology of intervention

Discrepancies and variations of techniques were observed even *inside the same typology* of intervention. Though, it is essential to consider that a certain degree of variability in manual interventions is predictable in practice. This fact is even more notable in osteopathic treatment with its holistic approach because diagnosis and treatment processes are entirely based on palpatory findings. Osteopathic techniques vary in their application and frequency from country to country. It is, therefore, not known whether the treatment approaches used in different countries are comparable.

techniques perhaps not comparable

different training and quality requirements

The ten analysed European countries have different training and quality requirements for osteopaths. However, in most of these countries – in contrast to Austria – legal regulation is in force, and the title 'osteopath' is protected.

Conclusion

neck/low back pain: improvement

According to the current evidence, osteopathy can improve neck and low back pain in the short- and mid-term and possibly reduce shoulder and foot pain, while there is uncertainty about its effectiveness for pain in other body regions and diseases.

regulation before reimbursement needed

Regulations of the osteopathic profession are crucial to increase trust in osteopathy and ensure the safety of patients. However, before reimbursing osteopathic treatments, regulation is needed, and the title of osteopaths needs to be protected. Based on the set international standards, training and quality requirements must be adapted for Austria to meet the international standards for osteopathy. The information collected in this report as well as the Benchmark documents should be used to inform and guide the regulatory process in Austria.

Zusammenfassung

Hintergrund

Schmerzen schränken die Lebensqualität ein

Fast die Hälfte der Österreicher*innen leidet an chronischen Nacken-, Kreuz- oder Rückenschmerzen. Dadurch ist ihre Lebensqualität eingeschränkt. Alternative Behandlungen, wie z. B. Osteopathie, können als Ergänzung oder Alternative zu schulmedizinischen Behandlungen verstanden werden.

wachsender Berufszweig mit ganzheitlichem Ansatz

Die Osteopathie ist weltweit ein wachsender Berufszweig und zielt auf eine ganzheitliche Verbesserung und Unterstützung aller gesundheitlichen Aspekte ab. Sie umfasst die Beziehung zwischen Körper, Geist und Seele und fokussiert sich auf die Person, nicht auf die Krankheit. Der ganzheitliche Ansatz der Osteopathie basiert auf dem im 19. Jahrhundert entwickelten Konzept des amerikanischen Arztes und Chirurgen, Dr. Andrew Taylor Still.

manuelle Berührungen

Laut Weltgesundheitsorganisation (WHO) stützt sich die Osteopathie auf manuelle Berührungen, also spezielle Handgriff- und Mobilisationstechniken, zur Diagnose und Behandlung von Patient*innen. Die Wahl von osteopathischen Behandlungstechniken, Häufigkeit und Dauer der Behandlung werden auf die individuellen Bedürfnisse der Patient*innen zugeschnitten.

weltweit uneinheitliche gesetzliche Regulierungen für die Ausbildung, Ausübung und Weiterbildung

Für die Osteopathie gibt es weltweit keine einheitlichen gesetzlichen Regulierungen für die Ausbildung, Ausübung und Weiterbildung. In vielen Ländern werden gesetzliche Regulierungen diskutiert oder sind bereits eingeführt worden. Die Zulassung erfolgt durch nationale Behörden. Unter gesetzlicher Regulierung wird verstanden, dass die Berufsbezeichnung „Osteopath*in" geschützt ist und diese daher nur Personen ausführen dürfen, welche bestimmte gesetzliche Voraussetzungen hinsichtlich ihrer Ausbildung und Zulassung erfüllen.

Übernahme der Kosten?

Derzeit werden in Österreich osteopathische Leistungen nicht von der Krankenkasse übernommen. Aufgrund des steigenden Angebots und Nachfrage von osteopathischen Behandlungen bei unterschiedlichen Indikationen stellt sich die Frage, ob die öffentliche Hand in Zukunft für die Leistungen der Osteopath*innen aufkommen soll. Es ist jedoch noch unklar ob Osteopathie wirksam und sicher für Patient*innen mit Schmerzen am Bewegungs- und Stützapparat ist.

Osteopathie sicher und wirksam?

Wirksamkeit, Sicherheit, Ausbildungs- und Qualitätsanforderungen

Daher werden in diesem Bericht Belege zur Wirksamkeit und Sicherheit der Osteopathie bei der Behandlung von Schmerzen des Bewegungs- und Stützapparates zusammengefasst (Teil 1). Weiters wird ein Überblick über die Ausbildungs- und Qualitätsanforderungen sowie die Vorschriften für den Beruf Osteopath*in in Europa gegeben (Teil 2).

Methoden

Teil 1: Wirksamkeit und Sicherheit osteopathischer Behandlungen

systematische Literatursuche

Wir führten eine systematische Literatursuche – eine wissenschaftlich strukturierte Vorgehensweise zur Erhebung relevanter Literatur – in fünf Datenbanken durch. Gesucht wurde nach randomisiert-kontrollierten Studien (RCTs, randomised controlled trials) – die hochwertigste Form klinischer Studien um die Wirksamkeit einer Behandlung zu untersuchen – zu osteopathischen Behandlungen bei Erwachsenen mit Schmerzen des Bewegungs- und Stützapparates im Vergleich zur Standardbehandlung, keiner Behandlung oder einer

35 Studien identifiziert …

alternativen Behandlung. Von den 964 durch die systematische Literatursuche gefundenen Studien konnten wir 35 Studien identifizieren, welche unseren Einschlusskriterien entsprachen.

… und ihre Qualität bewertet

Wir bewerteten die 35 Studien hinsichtlich ihrer methodischen Qualität und ihres Verzerrungsrisikos. Ein Verzerrungsrisiko einer Studie gibt an, ob es potentielle Mängel gibt, wie etwa, dass Behandlungsgruppen nicht zufallsmäßig zugeteilt oder Ergebnisse von den Studienautor*innen selektiv berichtet werden. Es kann von hohem, unklarem (z. B. keine oder zu wenige Informationen gegeben) oder niedrigem Verzerrungsrisiko gesprochen werden.

besten verfügbaren Studien ausgewählt und analysiert

Die Studien wurden nach Schmerzregionen kategorisiert und wir wählten für jede Körperregion bzw. Erkrankung die besten verfügbaren Studien entsprechend der Qualitätsbewertung aus. Insgesamt schlossen wir 15 RCTs zu sieben Körperregionen und Erkrankungen aus der systematischen Suche ein. Zu einer weiteren Schmerzregion – Kreuzschmerzen – stand eine kürzlich publizierte systematische Übersichtsarbeit zur Verfügung, die nach einer Qualitätsbewertung zur vollständigen Darstellung sämtlicher Körperregionen herangezogen wurde.

Vergleich mit ausgeschlossenen Studien

Die Hauptergebnisse zum Endpunkt Schmerz der 20 ausgeschlossenen Studien wurden zusätzlich analysiert, um die Validität der Synthese aus den 15 eingeschlossenen Studien zu prüfen.

Teil 2: Ausbildungs- und Qualitätsanforderungen für Osteopath*innen

Auswahlkriterien der 10 eingeschlossenen Länder

Für die Analyse von Ausbildungs- und Qualitätsanforderungen für Osteopath*innen fokussierten wir uns auf europäische Länder. Von besonderem Interesse waren die Regulierungen in den drei deutschsprachigen Ländern Deutschland, Schweiz und Österreich. Zusätzlich wurden jene europäischen Länder ausgewählt, die nationale Berufsverbände und gesetzliche Regulierungen für die Ausübung der Osteopathie sowie eine Einwohner*innenzahl von >5,5 Millionen vorweisen.

Suchstrategie und Expert*innenbefragung

Wir suchten nach Ausbildungs- und Qualitätsanforderungen für Osteopath*innen in diversen Datenbanken und Webseiten. Zur weiteren Vervollständigung der Länderinformationen wurden Expert*innen der jeweiligen zehn Länder befragt. Schließlich analysierten und beschrieben wir die Informationen hinsichtlich der drei Aspekte Regulierung, Ausbildung und Ausübung der Osteopathie.

Ergebnisse

Teil 1: Wirksamkeit und Sicherheit osteopathischer Behandlungen

16 Studien zu 8 Körperregionen bzw. Erkrankungen untersucht

versch. osteopathische Techniken

In den 15 eingeschlossenen RCTs wurden sieben verschiedene Körperregionen bzw. Erkrankungen untersucht: *Nackenschmerz*, *Nacken- oder Kreuz-/Rückenschmerz* (gemischte Population), *Schulterschmerz*, *Knieschmerz*, *Fußschmerz*, *Osteoporose* und *Faser-Muskel-Schmerz* (Fibromyalgie). Zusätzlich wurde die systematische Übersichtarbeit zu *chronischen Kreuzschmerzen* zusammengefasst. In den Studien wurden verschiedene osteopathische Techniken angewandt wie beispielsweise die am häufigsten untersuchte Manipulation, Myofascial Release, welche Verhärtungen oder Verdickungen des Gewebes über das Fasziensystem, sprich Fasern des Bindegewebes, ausgleicht. Hauptsächlich Osteopath*innen, aber auch Physiotherapeut*innen und Allgemeinmediziner*innen mit osteopathischer Zusatzqualifikation führten die Behandlungen aus.

Ergebnisse zum Endpunkt Schmerz

Gruppenunterschiede und Nachbeobachtungen

Im Folgenden werden die Ergebnisse zum Endpunkt Schmerz zu den acht Körperregionen bzw. Erkrankungen beschrieben. Die Ergebnisse werden nach unmittelbaren (0-7 Tage), kurz- (1 Monat), mittel- (3-6 Monate) und langfristigen (1 Jahr) Effekten unterteilt.

Nackenschmerz: kurz- und mittelfristige Verbesserung

Bei **Nackenschmerzen** verbesserte sich die Schmerzintensität nach nur einer Behandlungseinheit nicht, jedoch unmittelbar nach fünf und acht Einheiten innerhalb eines Behandlungszeitraumes von zwei Wochen bis zwei Monaten. In zwei Studien verbesserten sich Schmerzen jeweils auch kurz- und mittelfristig. Die maximal hinnehmbaren Schmerzen (Schmerzgrenze) verbesserte sich unmittelbar nach nur einer Behandlungseinheit. In drei von vier Studien wurden klinisch relevante Ergebnisse beobachtet. Dieses Ergebnis beruht auf vier Studien mit unklarem bis hohem Verzerrungsrisiko.

Nacken- oder Kreuz-/Rückenschmerz: heterogene Ergebnisse

Bei Patient*innen mit **Nacken- oder Kreuz-/Rückenschmerzen** reduzierten sich die Schmerzen unmittelbar nach nur einer Behandlungseinheit. Jedoch verbesserten sie sich unmittelbar nach vier Einheiten im Rahmen eines Behandlungszeitraumes von zwei Monaten nicht. Es gab keine mittelfristigen Verbesserungen. Dieses Ergebnis beruht auf zwei Studien mit hohem Verzerrungsrisiko.

Schulterschmerz: mögliche Verbesserung

Schulterschmerzen haben sich im Vergleich zur Kontrollgruppe nach einer Woche nicht verbessert. Jedoch wurde ein klinisch relevanter Vorher-Nachher-Vergleich in der Osteopathie-Gruppe identifiziert. Die Anzahl der Behandlungseinheiten in dieser Studie ist unbekannt. Hingegen wurden nach vier Einheiten innerhalb von einem Monat kurz-, mittel- und langfristige Verbesserungen festgestellt. Dieses Ergebnis beruht auf zwei Studien mit unklarem bis hohem Verzerrungsrisiko.

Kreuzschmerz: mittelfristige Verbesserung

Kreuzschmerzen reduzierten sich unmittelbar nach durchschnittlich neun Behandlungseinheiten, welche innerhalb von durchschnittlich zehn Wochen stattfanden, und mittelfristig. Dieses Ergebnis basiert auf einer systematischen Übersichtsarbeit, in welche wir hohes Vertrauen in die Studienqualität haben. Diese konnte zehn RCTs mit meist hohem Verzerrungsrisiko einschließen.

Knieschmerz: heterogene Ergebnisse

Bei Patient*innen mit **Knieschmerzen** waren die Ergebnisse heterogen: Nach fünf Behandlungseinheiten wurden keine Kurzzeiteffekte hinsichtlich der körperlichen Schmerzen festgestellt. Die Knieschmerzen reduzierten sich jedoch klinisch und statistisch signifikant unmittelbar nach sechs Behandlungseinheiten, welche innerhalb von drei Wochen stattfanden, sowie kurzfristig. Dieses Ergebnis beruht auf zwei Studien mit unklarem Verzerrungsrisiko.

Fußschmerz: mittelfristige Verbesserung

Fußschmerzen wurden unmittelbar nach acht und zwölf Behandlungseinheiten innerhalb von einem Monat sowie mittelfristig reduziert. In einer der beiden Studien wurde ein klinisch relevantes Ergebnis beobachtet. Dieses Ergebnis beruht auf zwei Studien mit unklarem Verzerrungsrisiko.

Osteoporose: heterogene Ergebnisse

Bei Patient*innen mit **Osteoporose** gab es keine unmittelbare Verbesserung der Schmerzen nach sechs Behandlungseinheiten innerhalb von sechs Wochen. Jedoch reduzierten sich Schmerzen im Rahmen der Befragung zur Lebensqualität der Patient*innen. Dieses Ergebnis beruht auf einer Studie mit hohem Verzerrungsrisiko.

Fibromyalgie: nur unmittelbare Verbesserung

Bei Patient*innen mit **Fibromyalgie** verbesserten sich Schmerzen direkt nach zehn bis 50 Behandlungseinheiten, welche innerhalb von 20 und 25 Wochen stattfanden. Jedoch konnten keine eindeutigen Ergebnisse hinsichtlich der

Mittel- und Langzeiteffekte identifiziert werden. Klinisch relevante Ergebnisse konnten in einer der beiden Studien beobachtet werden. Dieses Ergebnis beruht auf zwei Studien mit unklarem bis hohem Verzerrungsrisiko.

Ergebnisse zu anderen Endpunkten

andere Endpunkte: heterogene Ergebnisse

Die Ergebnisse zu allen anderen Endpunkten (z. B. Funktionalität, Lebensqualität) waren sehr heterogen, sodass hier keine eindeutigen Tendenzen festgestellt werden konnten. Lediglich für chronische Kreuzschmerzen berichtete die systematische Übersichtsarbeit von einer Verbesserung der Funktionalität unmittelbar nach Ende der Behandlung, jedoch nicht mittelfristig.

*Sicherheit für Patient*innen*

kaum Nebenwirkungen aufgetreten

Zehn der 16 eingeschlossenen Studien berichteten über Nebenwirkungen. Davon traten in drei der zehn Studien Nebenwirkungen in Bezug auf die Körperregionen Nacken- und Kreuzschmerzen auf. Nur sehr wenige Patient*innen berichteten von verstärkten Schmerzen, Zittern, Müdigkeit, emotionalen Reaktionen, Schwindel und Krämpfen. In den anderen sieben Studien traten keine Nebenwirkungen auf.

Teil 2: Ausbildungs- und Qualitätsanforderungen für Osteopath*innen

Regulierung in insgesamt 12 Ländern

Generell ist in zwölf europäischen Ländern Osteopathie bereits gesetzlich reguliert. Der Europäische Verband und das Forum der Osteopath*innen (EFFO, European Federation & Forum for Osteopathy) vertritt die führenden Berufsverbände der Osteopath*innen. Ihr Ziel ist es, Regulierungen und Standards für Osteopath*innen zu schaffen.

2 internationale Standards: WHO und europäischer Standard

Es gibt zwei internationale Standards für die Osteopathie: Das Dokument der Weltgesundheitsorganisation (WHO) beschreibt die Berufsgrundsätze und die Art der Ausbildungsprogramme zur Standardisierung und sicheren Ausübung. Der europäische Standard beinhaltet Vorgaben für hochwertige Ausbildung, Sicherheit, klinische Praxis und Ethik. Dieser Standard wurde in 33 Ländern auf nationaler Ebene für die Öffentlichkeit bereitgestellt. Der EFFO empfiehlt gesetzliche Regulierungen der Osteopathie sowie die Einhaltung des europäischen Standards für Osteopathie. Gesetzliche Regulierungen führen zu einer Standardisierung und dadurch zu mehr Sicherheit für Patient*innen und Vertrauen in die Osteopathie.

2 Ausbildungstypen

Es lassen sich zwei Arten von Ausbildungen unterscheiden: Typ I und Typ II. Typ I richtet sich an Personen mit keiner oder nur geringer Vorbildung im Gesundheitsbereich, Typ II an Personen mit Vorbildung in einem Gesundheitsberuf. Der Lehrplan regelt für beide Typen die wesentlichen Kompetenzen in den Ausbildungsprogrammen, wobei die Behandlung individueller Patient*innen und nicht einzelner Krankheiten im Mittelpunkt steht.

Regulierung, Ausbildung und Ausübung

Im Detail wurden folgende zehn Länder im Hinblick auf die gesetzliche Regulierung, Ausbildung und Ausübung der Osteopathie untersucht: Österreich, Schweiz, Deutschland, Dänemark, Finnland, Frankreich, Italien, Norwegen, Portugal und das Vereinigte Königreich.

gesetzliche Regulierung in 7/10 Ländern

Eine gesetzliche Regulierung der Osteopathie gibt es in sieben der zehn analysierten Länder und die Berufsbezeichnung „Osteopath*in“ ist in sechs dieser Länder vollständig geschützt. Um als Osteopath*in praktizieren zu dürfen gibt es in verschiedenen Ländern unterschiedliche Ausbildungsmöglichkeiten, welche sich im Lehrplan unterscheiden. In fünf Ländern gibt es jedoch eine Mindestausbildung (Bachelor-Abschluss). In Österreich ist die Ausbildung, Ausübung und Weiterbildung von Osteopathie noch gesetzlich unreguliert und die Bezeichnung "Osteopath*in" ist ungeschützt.

Berufsbezeichnung in 6/10 Ländern gänzlich geschützt

nationale Regulierungen beruhen auf internationalen Standards in 3/10 Ländern

In drei der zehn Länder beruht die gesetzliche Regulierung auf den oben erwähnten beiden Standards. Die anderen Länder haben ihre Regulierung bereits vor der Veröffentlichung dieser Standards abgeschlossen. Eine Registrierung der Osteopath*innen erfolgt beispielsweise durch staatliche (Gesundheits-)behörden. Osteopath*innen arbeiten vor allem in Privatpraxen und ihre Behandlungen werden von Privatversicherungen übernommen. In acht der zehn einbezogenen Länder gibt es Beschränkungen für die Ausübung der Osteopathie. Nur im Vereinigten Königreich ist eine laufende berufliche Weiterbildung vorgeschrieben.

Diskussion

meist Schmerzen des Bewegungs- und Stützapparates

Die meisten Patient*innen suchen Osteopath*innen aufgrund von Schmerzen des Bewegungs- und Stützapparates auf. Nacken- und Kreuzschmerzen stellen dabei den größten Anteil dar. Auch die WHO stellte in einem Bericht fest, dass Nacken- und Kreuzschmerz weltweit die Hauptursache gelebter Jahre mit Beeinträchtigung (years lived with disability) sind.

Osteopathie ist sicher

Nacken/Kreuz: Schmerzverbesserung

Schulter/Fuß: mögliche Verbesserung

Osteopathie kann als eine sichere Behandlungsform angesehen werden, da kaum Nebenwirkungen berichtet wurden. Es traten keine statistisch oder klinisch signifikanten Verschlechterungen durch osteopathische Behandlungen auf. Die Ergebnisse des Berichts zeigen, dass Osteopathie Nacken- und Kreuzschmerzen verbessern kann. Weitere veröffentlichte systematische Übersichtsarbeiten unterstreichen dieses Ergebnis. Weiters scheint es, dass auch Schulter- und Fußschmerzen durch osteopathische Behandlungen möglicherweise reduziert werden können. Die Ergebnisse für alle anderen Körperregionen und Erkrankungen (gemischte Population mit Nacken- oder Kreuz-/Rückenschmerzen, Knie, Osteoporose, Fibromyalgie) sind nicht schlüssig, die Evidenz ist unzureichend um eine Aussage zu treffen, oder es wurden keine oder nur unmittelbare Effekte gefunden.

Studienqualität mäßig zufriedenstellend

Ein Vergleich der Hauptergebnisse mit den Ergebnissen der ausgeschlossenen Studien ergab keine erheblichen Abweichungen. Die Qualität der eingeschlossenen Studien ist mäßig zufriedenstellend, da unklare bis hohe Verzerrungsrisiken vorliegen. Die Qualitätsbewertung der systematischen Übersichtsarbeit zu Kreuzschmerzen ergab ein hohes Gesamtvertrauen in die Studie. Jedoch wies keine der darin inkludierten Studien ein niedriges Verzerrungsrisiko auf.

Verblindung in wenigen Studien (möglich)

Lediglich fünf der 15 RCTs führten eine Verblindung durch. Verblindung bedeutet, dass Personen, welche die zugeteilte Behandlung vornehmen oder sich dieser unterziehen, die Behandlung nicht kennen, sodass sie durch dieses Wissen nicht beeinflusst werden. Jedoch ist eine Verblindung von Osteopath*innen, Therapeut*innen oder Patient*innen schwer durchzuführen, da die Natur osteopathischer Behandlungen eine Verblindung kaum zulässt.

Heterogenität in RCTs

klinisch relevante Ergebnisse in 7/15 RCTs

Die Heterogenität in der im Bericht eingeschlossenen Studien könnte die Ergebnisse beeinflusst haben. Dies betrifft etwa die ausführenden Berufsgruppen, Stichprobengröße, Behandlungszeitraum, Anzahl, Dauer und Häufigkeit der Behandlungen und Dauer der Nachbeobachtung. Darüber hinaus wurden für die Bewertung der Endpunkte viele verschiedene Messinstrumente verwendet. In sieben der 15 einbezogenen RCTs wurden klinisch relevante Verbesserungen beobachtet. Allerdings wurde in der Literatur die Spanne der klinisch relevanten Schmerzreduktion unterschiedlich breit angeführt.

verschiedene osteopathische Techniken

In den eingeschlossenen Studien wurden konkrete Arten von osteopathischen Techniken angewandt. In der Praxis ist jedoch bei manuellen Behandlungen eine gewisse Abweichung oder Kombination der unterschiedlichen Behandlungstechniken vorhersehbar. Dies trifft besonders auf die Osteopathie mit ihrem ganzheitlichen Ansatz zu, wo die Diagnose und Behandlung auf Berührungen basiert.

Kurz-, Mittel- und Langzeiteffekte

Statistisch signifikante Wirkungen ließen sich in kurz-, mittel- und langfristigen Beobachtungszeiträumen feststellen. Außerdem wurden in zwei von drei Studien Verbesserungen nach nur einer Osteopathiebehandlung beobachtet. Zu berücksichtigen ist jedoch, dass wir nicht wissen, was die Patient*innen zwischen dem Ende der osteopathischen Behandlung und der Nachbeobachtung tun (Sport, manuelle Therapie, Medikamente, Massage, etc.). Diese Verzerrung müsste gemessen werden, z. B. durch Tagebücher, die dokumentieren welche Intervention(en) die Patient*innen durchgeführt haben.

Techniken in Ländern ev. nicht vergleichbar

Osteopathische Techniken sind hinsichtlich ihrer Anwendung und Häufigkeit von Land zu Land unterschiedlich. Es ist daher nicht bekannt, ob die angewandten Behandlungsansätze verschiedener Länder vergleichbar sind. Die meisten der eingeschlossenen Studien berichten über Ergebnisse aus Forschungsarbeiten, welche in Europa durchgeführt wurden. Jedoch wurden manche Studien außerhalb Europas durchgeführt. Dadurch werden die Verallgemeinerbarkeit und Übertragbarkeit der Ergebnisse auf andere Länder beeinflusst.

gesetzliche Regulierungen unterschiedlich

In den zehn untersuchten europäischen Ländern bestehen unterschiedliche Ausbildungs- und Qualitätsanforderungen für Osteopath*innen, allerdings ist in den meisten dieser Länder – im Gegensatz zu Österreich – eine gesetzliche Regulierung in Kraft und die Berufsbezeichnung „Osteopath*in“ geschützt.

Conclusio

Nacken/Kreuz: Schmerzverbesserung

Laut derzeitiger Studienlage kann Osteopathie Nacken- und Kreuzschmerzen kurz- und mittelfristig verbessern und möglicherweise Schulter- und Fußschmerzen reduzieren, während Unklarheit zur Wirksamkeit bei Schmerzen in anderen Körperregionen und Erkrankungen besteht.

Langzeit-nachbeobachtungen notwendig

Zukünftige RCTs sollten so konzipiert werden, dass sie ein geringeres Verzerrungspotenzial aufweisen und Langzeitnachbeobachtungen ermöglichen, sodass qualitativ hochwertigere Beweise zur Wirksamkeit als Grundlage für die klinische Praxis und die Gesundheitspolitik erbracht werden können.

vor Kostenrückerstattung ist Regulierung erforderlich

Eine gesetzliche Regulierung des Berufs Osteopath*in ist von entscheidender Bedeutung, um das Vertrauen in die Osteopathie zu stärken und die Sicherheit der Patient*innen zu gewährleisten. Bevor die Kosten für osteopathische Behandlungen rückerstattet werden, ist eine Regulierung und der Schutz der Berufsbezeichnung „Osteopath*in“ erforderlich. Durch eine gesetzliche Regulierung können somit nur mehr Osteopath*innen mit behördlich vorgeschriebener Ausbildung und Zulassung praktizieren. Basierend auf den gegebenen internationalen Standards müssen die Ausbildungs- und Qualitätsanforderungen für Österreich angepasst werden.

1 Background

1.1 Introduction

Osteopathie: manueller Kontakt zur Diagnoseerstellung und Behandlung …

For the World Health Organisation (WHO), osteopathy relies on manual contact for diagnosis and treatment [1, 2] and is based on the concept that the body is an integrated whole. Osteopathy is also claimed to prevent diseases and injuries (e.g. inner organs, musculoskeletal, nervous, and circulatory systems) [3] and can further be curative, palliative or adjuvant [4]. Osteopathy includes the relationship between body, spirit, and mind in health and disease [2]. It is a patient-centred primary healthcare discipline based on principles of interrelatedness between the body's integrity of function and structure [2, 4, 5]. The aim is to holistically improve and support all health aspects [4].

… mit ganzheitlichem Ansatz

The holistic approach of osteopathy to patient healing and care is based on the concept that humans are dynamic functional units, where all parts are interrelated and possess their self-healing and self-regulatory mechanisms [2]. Both, the body's ability to adopt a whole-person approach to health and the tendency for self-healing, focus on practising manual treatment [2, 5].

biopsychosoziales Modell

The osteopathic practice and philosophy are congruent with the biopsychosocial model by acknowledging that psychological factors might affect homeostasis and physiology and adopting a whole-person approach to illness. The concept of 'homeostasis' is defined as a balanced and effective integration of the body's physical, mental and chemical components. The choice of technique, frequency, and duration is tailored to each individual patient's needs [5]. Osteopathy, as a health approach, emphasises the musculoskeletal system's role in health [6]. For practice, osteopathic, medical and scientific knowledge is used [4].

Standards für Osteopath*innen heterogen

There exist the WHO benchmark for Training in Osteopathy [2] and standardisation according to the Committee for Standardisation (CEN) [7] (see Chapter 4.3). However, osteopathy has no consistent standards of education, practice, and training. This means that in some countries without regulations, e.g. Austria, unqualified practitioners can call themselves osteopaths, and all possible institutions and schools could provide courses, which can be seen as problematic for patients [7]. Large heterogeneity in regulating and recognising osteopathic practice exists across different countries [1].

politische Fragestellung

The number of osteopaths is increasing internationally, and regulations are either being discussed or have already been introduced in many countries. Among other things, the political question arises of whether the public sector should pay for the services of osteopaths in the future. There are – at least in Austria – efforts on the part of osteopaths to have the costs of therapy covered by health insurance.

1.2 Osteopathy as a medical intervention

This chapter describes the history and definition of osteopathy, different areas and techniques of osteopathy, structure-function relationship models, indications where osteopathy is applied, safety issues and contraindications, and guidelines for osteopathy.

1.2.1 History and definition of osteopathy

seit den frühen 1900-ern in Europa

Osteopathy is a patient-centred and primary healthcare discipline. It was founded by the American physician and surgeon Dr Andrew Taylor Still in the late 1800s. One of his students brought the profession to Europe in the early 1900s. According to the WHO, osteopathy is defined as follows:

Definition der WHO:

"Osteopathy provides a broad range of approaches in the maintenance of health and the management of disease. Osteopathy is grounded in the following ***principles*** *for treatment and patient management:*

3 Prinzipien

- *the human being is a dynamic functional unit whose state of health is influenced by the body, mind and spirit;*
- *the body possesses self-regulatory mechanisms and is naturally self-healing; and*
- *structure and function are interrelated at all levels of the human body.*

patientenzentrierte Gesundheitsfürsorge zur Unterstützung der körperlichen Selbstregulierungs- und -heilungsmechanismen

Within that framework, osteopathic practitioners incorporate current medical and scientific knowledge when applying osteopathic principles to patient care. Osteopathic practitioners recognise that each patient's clinical signs and symptoms are the consequences of the interaction of many physical and nonphysical factors. It emphasises the dynamic interrelatedness of these factors and the importance of the patient-practitioner relationship in the therapeutic process. It is a patient-centred, rather than a disease-centred, form of health care. Structural diagnosis and osteopathic manipulative treatment are essential components of osteopathy. Osteopathic manipulative treatment was developed to facilitate normal self-regulating/self-healing mechanisms in the body by addressing areas of tissue strain, stress or dysfunction that may impede normal neural, vascular and biochemical mechanisms [2]."

Behandlung des Körpers als Ganzes

Osteopathy is, therefore, concerned with manners in which the musculoskeletal system's biomechanics are integrated with and supports the entire body's physiology [2]. The osteopathic approach is based on diagnosing and managing altered or impaired function of related components of the neuromusculoskeletal body framework, i.e. fascia, muscle, and joint. The emphasis is on treating the patient's body as a whole using different applications [8].

Ziel: physiologische Funktion verbessern und Homöostase unterstützen

Osteopathy as a health approach is based on manual contact for diagnosing and treating somatic dysfunctions. The therapeutic aim is to improve physiological function and support homeostasis altered by somatic dysfunction. The treatment is characterised by a whole-body approach and can be applied to several body regions, also sometimes remote from the symptomatic area [9].

1.2.2 Different areas and techniques of osteopathy

osteopathische Medizin: medizinisches System zur Diagnose und Behandlung

Two main areas of osteopathy exist. **Osteopathic medicine** is a medical system of diagnosing and treating patients based on overarching principles, which give osteopathic medicine a holistic basis for practising. It is practised predominantly in countries of the global north. The practice varies from full medical profession (United States of America (USA)) to allied/adjunctive health (e.g. United Kingdom (UK) and Australia). Osteopathic medicine is a legally registered profession and allows spinal manipulative therapy, i.e. manual loading of the spine using short- or long-leverage methods [10].

osteopathische Manipulationsbehandlung: ganzheitlich und komplex; beruht auf multifaktoriellen diagnostischen Untersuchung

An essential component of osteopathic healthcare is **osteopathic manipulative treatment (OMT)**, characterised by a holistic approach. It refers to various manipulative techniques that can be combined with other advice or treatments, such as physical activity or diet [2, 6]. OMT is a complex intervention based on a multi-factorial diagnostic workup [10]. As per neuroimaging research, OMT could act in interoceptive ways (i.e. ability to feel what is happening inside the body) and, thus, has a beneficial role in sensitisation [9]. Many manipulative techniques are employed in OMT [2], such as visceral manipulations, craniosacral treatment, and myofascial release [9].

Different techniques of osteopathy

manuelle Technik verbessert physiologische Funktion, unterstützt Homöostase

A broad range of approaches to maintaining health and managing disease is provided by osteopaths. Therapeutic manual techniques are applied to improve physiological function and support homeostasis, altered by somatic dysfunction, i.e. altered or impaired function of related components of the somatic system; skeletal, myofascial and arthrodial structures; and related vascular and neural lymphatic elements.

breites Spektrum an Techniken

In German-speaking countries, osteopathic techniques are often applied to three conceptual systems: the parietal (i.e. skeletal system), visceral (i.e. organs), and craniosacral (i.e. skull, sacrum and spinal canal) systems. Although these three body systems can be distinguished, they are inseparable and become indistinct in their application [11]. The following techniques can be used as part of osteopathic treatment:

- **Myofascial (release) technique** is available to treat tension in fasciae, intended to improve tissue quality, circulation and gliding ability [12]. Myofascial release involves passive palpatory feedback to achieve a release of the myofascial tissues. Two techniques are distinguished: a direct (i.e. restrictive barrier is engaged and then loaded with a constant force by the operator until release occurs) and indirect (i.e. myofascial tissue is guided along the path of least resistance until release occurs) technique [13].
- **Structural techniques** include therapeutic work on joints of the spine and the extremities. Joint mobility is restored through mobilisation or manipulation. Stuck joint surfaces are released, and the surrounding musculature and joint capsules are treated [12].
- **Visceral osteopathy** includes therapeutic work on internal organs. Restrictions of movement or disorders are corrected [12].
- **Techniques for somato-emotional release** are used to influence energy flows in the body, and a physical-emotional release of the accumulated energy occurs through the targeted placing of the hand or individual fingers [12].

- **Craniosacral technique** includes therapeutic work on the skull, dura mater and sacrum [12]. Craniosacral involves the primary respiratory mechanism based on interdependent functions of the brain, cranial bones, spinal cord, cerebrospinal fluid, sacrum, and intracranial and intraspinal membranes [13].
- **Cranial osteopathy** includes non-invasive hands-on gentle manipulations of the skull, modifying the parameters of this mechanism. The WHO included this form of osteopathic technique among the benchmarks for training in osteopathy (see Chapter 4.3). However, some countries, e.g. France, specifically prohibit teaching cranial techniques [1].
- **Strain—counterstrain treatment** involves a passive, gentle force to inhibit inappropriate strain reflexes, which are manifested by specific point tenderness [13].
- **Muscle energy technique** involves directed patient movements from a precisely controlled position against resistance by the osteopath/ operator. This technique can be used to stretch tight muscles and fascia, mobilise restricted joints, improve local circulation, and balance neuromuscular relationships to alter muscle tone [13].
- **Soft tissue technique** involves tissues other than arthrodial or skeletal elements. It usually involves lateral/linear stretching, traction, deep pressure, or separation of muscle origin and insertion, while tissue response and motion changes by palpation are monitored [13].
- **High-velocity low-amplitude technique** involves an application of a passive force by the osteopath/operator over a short distance to mobilise restricted joints [13].
- **Osteopathic spinal manipulation** primarily involves short-level, high-velocity spinal adjustments [14]. In the USA, it is mostly provided by chiropractors. However, in osteopathy, it is only part of a philosophy of care and is regarded as an adjunct to other medical care [14].
- **Pressure release technique** is a variant of ischemic compression. This technique consists of applying pressure, which will be increased depending on the muscle response and may reduce symptoms [15].

Osteopathie: Patient*innenmanagement, Dauer, Wahl der Technik, Häufigkeit

Osteopathy is distinct from other manipulative therapy and healthcare professions, e.g. physiotherapy or chiropractic, which also utilise manual techniques despite some overlap in interventions and techniques employed. Distinctive aspects of osteopathy and its manipulative techniques are the unique integration into patient management, as well as the duration, choice of technique, and frequency [2].

1.2.3 Structure-function relationship models

5 Struktur-Funktions-Beziehungsmodelle

The practical application of osteopathy is based on five structure-function relationship models. Osteopaths use these models to gather and structure diagnostic information, followed by interpreting the significance of these neuromusculoskeletal and somatic findings for the patient's overall health. These five models are usually used in combination [2]:

biomechanisches Modell

- In the **biomechanical structure-function model,** the body is seen as an integration of somatic components relating to balance and posture mechanisms. Within this mechanism, imbalance or stress may increase energy expenditure, affect dynamic function, change the joint struc-

ture, impede neurovascular function, and alter metabolism and proprioception (i.e. one's sense of relative movement and position of neighbouring parts of the body).

- The **biopsychosocial structure-function model** recognises psychological stresses and reactions affecting patients' well-being and health. This model includes socioeconomic, psychological, physiological, environmental, and cultural factors influencing disease.

biopsychosoziales Modell

- The **respiratory/circulatory structure-function model** deals with maintaining intra- and extracellular environments due to unimpeded delivery of nutrients and oxygen and removing cellular waste products.

Modell der Atemwege und des Kreislaufs

- The **neurological structure-function model** considers the influence of the proprioceptive function, spinal facilitation, autonomic nervous system, and activity of nociceptors (i.e. pain fibres) on the function of the neuroendocrine-immune network. The relationship between the visceral (i.e. autonomic) and somatic is emphasised.

neurologisches Modell

- In the **bioenergetic structure-function model**, the body seeks to balance energy production, expenditure, and distribution [2].

bioenergetisches Modell

It has been criticised that the biomedical structure-function model is still dominating in osteopathic clinical practice. Thus, osteopaths may miss opportunities to improve patients' health because they do not always identify and manage psychosocial factors, which is essential for assessing and treating physical and psychosocial factors. There may be a lack of understating of psychosocial factors and their assessment by osteopaths associated with a lack of education at an undergraduate level [16].

psychosoziale Faktoren wichtig zu identifizieren

1.2.4 Indications where osteopathy is applied

Osteopathy is applied to a wide spectrum of patients.
It is used in the fields of

Osteopathie wird in vielen versch. Bereichen eingesetzt

- osteopathic neuromusculoskeletal medicine,
- primary care (family medicine, paediatrics, general internal medicine and geriatrics),
- internal medicine subspecialties (rheumatology, cardiovascular medicine, pulmonology, neurology, oncology, and endocrinology),
- physical medicine and rehabilitation,
- psychiatry,
- end-of-life care,
- obstetrics and gynaecology,
- surgery (head, eyes, ears, nose, and throat (HEENT), orthopaedics, general surgery), and
- sports medicine [17].

Osteopathy can be prescribed for managing a variety of health conditions, such as pain in the musculoskeletal and nervous systems. It is most commonly indicated for treating painful disorders such as low back pain and headaches. Another common medical indication of osteopathy is rheumatism [18].

häufige Anwendung bei Schmerzzuständen

fast die Hälfte der Österreicher*innen leidet an chronischen Kreuz-, Rücken- oder Nackenschmerzen

In Austria, in 2019, 26% of adults suffered from chronic low back or other chronic back conditions. 20% suffered from chronic neck pain or other chronic conditions of the cervical spine [19]. Nearly half of the Austrians over the age of 16 stated having back problems as 'low back pain' and 'neck pain', respectively [20, 21]. In the UK, for example, over 5 million people develop chronic pain annually, of whom only two-thirds recover, while others live with chronic pain. Osteopaths provide musculoskeletal care and are included in the UK's national guidelines for treating chronic low back pain. Chronic pain can be treated and managed by a biomedical and psychosocial approach [22].

Beeinträchtigung des sozialen und psychischen Wohlbefindens

Chronic pain, in particular, is considered one of the most prevalent and complex problems faced by health professionals and can harm the psychological and social well-being of those affected [5]. It is one of the most challenging and pervasive health issues and is regarded as a complex diagnostic, pathophysiological, and therapeutic situation. Pain can negatively impact the social and psychological well-being of patients experiencing a high level of stress and struggling to self-manage. Furthermore, a high rate of comorbidity in the occurrence of pain and mental health exists [5].

häufig Primärursache für Beeinträchtigung

Musculoskeletal pain conditions such as low back pain substantially influence the quality of life (QoL). They are leading and also growing causes of disability. Due to the high prevalence and impact on employment, the economic burden of musculoskeletal pain is significant. It is managed in primary care by various healthcare specialists such as medical doctors, physiotherapists, chiropractors, and osteopaths. Musculoskeletal pain conditions are managed by, e.g. osteopaths via a broad range of conservative interventions (i.e. exercise therapy, manual therapy, and self-management advice) [16].

Fokus auf muskuloskelettale Schmerzen von versch. Körperregionen/ Erkrankungen

The present review focuses on musculoskeletal pain in five body regions and two diseases (i.e. osteoporosis and fibromyalgia):

- neck,
- shoulder,
- lower back,
- knee,
- foot,
- osteoporosis, and
- fibromyalgia.

Neck pain

Nackenschmerz: häufig episodisches Auftreten mit Rückfällen

Neck pain can impair QoL and functional capacity and can contribute to the development of depression and anxiety disorder [23]. According to the Global Burden of Disease study, musculoskeletal neck pain along with low back pain are ranked as the leading cause of non-fatal disability in almost all age groups [24]. Neck pain has an annual prevalence of 20-50% in the adult population [6, 19, 24] and is one of the most common musculoskeletal disorders worldwide [6].

Recurrence is frequent [24], and one-fifth of previously pain-free adults report a new episode within one year. This frequently episodic occurrence with relapses is challenging to manage. The prevalence is higher in middle-aged females and is often associated with comorbidities such as headache, back pain, and arthralgia (i.e. joint pain) [23].

Shoulder pain

Schulterschmerz: Lebenszeitprävalenz bis zu 68 %

Shoulder pain is defined as pain localised in the region of the scapula, deltoid muscle, superior part of the trapezoid muscle, and acromioclavicular joint [25]. It may lead to impaired shoulder joint function and reduce QoL [26]. The most common cause is shoulder impingement syndrome (i.e. subacromial pain/impingement syndrome) [27]. Shoulder pain is common in the general population [25]. It is the third most common musculoskeletal presentation to general practitioners, with a lifetime prevalence of 8-68% [27]. In individuals between 55-64 years, a peak prevalence of 30% can be observed. Prevalence rates range due to the different definitions of the condition in literature [25].

Shoulder impingement syndrome

Schulter-Impingement-Syndrom

Shoulder impingement syndrome is the compression of the subacromial bursa and the rotator cuff. It is characterised by pain, localised to the anterolateral acromial area, as the typical sign of this syndrome. A general loss of muscle strength may be noted. Shoulder impingement syndrome contributes to shoulder pain in up to 65% of cases [26].

Trapezius spasm

Trapezmuskel-Verkrampfung

The upper trapezius, a postural muscle, is highly susceptible to overuse. Muscle spasms keep the muscle continuously in contraction. This overload creates knots in the muscle, known as trigger points leading to pain. Tightness in muscles reduces the range of neck movements and the mobility of the cervical joints. Trapezius pain is the most common musculoskeletal disorder and a classic example of stress pain leading to severe and long disability [28].

Low back pain

Kreuzschmerz: Beeinträchtigung des körperlichen und psychischen Wohlbefindens

Chronic non-specific low back pain, referred to as the '21st-century epidemic', is located between the costal margin and buttocks. Chronic non-specific low back pain is defined as lasting three months or more. Concurrently with the pain, patients suffer from physical disabilities and psychological distress [10]. The pathophysiology remains partially unclear, and chronic non-specific low back pain is explained as a result of interactions of biological, psychological, and social factors. Neuroimaging research could show how some brain areas can be influenced by behaviours and emotions, which could induce depression, mood alterations, and maladaptive coping. This condition is one of the most common musculoskeletal health issues and has the highest prevalence in the adult population (4-26%), more relevant in women (approximately 1.5:1). Globally, it is accompanied by medical, economic, and social burdens [9, 19].

Knee pain: patellofemoral pain syndrome

patellofemorales Schmerzsyndrom: komplexes biomechanisches Verhalten

Patellofemoral pain syndrome is characterised by anterior knee pain and instability in the patellofemoral joint. The aetiology may be mainly related to joint biomechanical alterations and weakness of the knee/hip stabiliser muscles. Classic signs and symptoms of this syndrome represent pain during activities and exercise, sensitivity to palpation in the patellar region, lack of functionality, crepitation (i.e. crackling sound) during knee flexion, and joint effusion. The biomechanical behaviour of patients with patellofemoral pain syndrome is complex, and the hip joint is influenced. Patients with patellofemoral pain syndrome have decreased posterior thigh flexibility, leading to gait impairments [29].

Foot pain

Fußschmerz: Funktion und Form der Füße entscheidend

Foot pain is a common and complex issue. The risk of pain occurrence is directly related to the feet's functioning and shape. It might be that deviations from the norm, i.e. arching of the feet, affect the walking pattern resulting in excessive overloading of soft tissues and bones. Structural changes negatively impact functional efficiency. The pain appears in the course of these pathologies and weakens muscle strength or impairment of the range of motion (ROM). Foot pain is an essential problem and can negatively impact daily activities, QoL, and fitness and may increase the risk of falling [30].

Flat foot with foot pain

Plattfuß mit Fußschmerzen

A symptom of a flat foot is pain, additionally to the lowered longitudinal arch of the foot. Pain is the main reason for physiotherapeutic and medical consultations. It is suggested that decreased arching may cause adverse changes in the biomechanics of gait and foot loading parameters (static and dynamic), contributing to the overloading of bones and soft tissues [30].

Plantar heel pain

Fersenschmerzen: in 10 % der Bevölkerung

Plantar heel pain or plantar fasciitis is the most commonly reported cause of inferior heel pain. It may be characterised by non-inflammatory degenerative changes in the plantar fascia. Plantar heel pain affects as much as 10% of the general population throughout a lifetime and accounts for 8-15% of foot complaints in athletic and non-athletic populations [31].

Osteoporosis

Osteoporose: systemische Skeletterkrankung durch verminderte Knochenmasse

Osteoporosis is a systemic skeletal disease characterised by a reduced bone mass and a microarchitectural disturbance of the bone tissue. It is associated with a subsequently increased fracture risk [32]. Osteoporosis is mainly based on pathologic criteria giving special characteristics of skeletal fragility making the bone susceptible to fracture even from modest traumas. There is already a progressive loss of bone mass and a transformation causing bone deformities of bone architecture and increased susceptibility to fractures in the fourth decade of life. Patients with osteoporosis are affected by pain, functional limitations and limited QoL attributable to the musculoskeletal system [33]. According to the WHO, osteoporosis is worldwide one of the then most common diseases, increasing with age. 80% of all osteoporosis cases affect postmenopausal women [32].

Fibromyalgia

Fibromyalgie: chronische Schmerzkrankheit mit ungeklärter Pathophysiologie

Fibromyalgia is characterised by generalised pain, intense fatigue, and joint rigidity. Other frequently associated symptoms are headache, sleep alterations, craniomandibular dysfunction, depression, spastic colon, and anxiety [34]. Although fibromyalgia is not classified as a musculoskeletal disease, most symptoms manifest at this level [35]. There is no gold-standard treatment, and its pathophysiology remains unclear [36]. However, the most widely accepted hypothesis is that chronic pain in fibromyalgia is of muscle origin [34]. Fibromyalgia is a common chronic pain disorder affecting 1.5-2% of the general population [36].

1.2.5 Safety issues and contraindications

Überweisung zu anderen Gesundheitsberufen

Osteopaths must refer patients to other health professionals if the therapeutic intervention falls outside their competencies. Specific osteopathic techniques and approaches also may be contraindicated in particular conditions. These contraindications are regrouped in the function of osteopathic techniques considered, which can be:

Kontraindikationen

- direct,
- indirect,
- combined, and/or
- fluid.

bei welcher Indikation welche Technik nicht anwenden?

Direct techniques (e.g. thrust, muscle contraction/energy, impulse, passive ROM, fascial loading) pose different risks from indirect and fluid. Unfortunately, little evidence has been published on which techniques should be avoided in specific conditions [2].

Contraindications to direct techniques

erzielen Gewebereaktion

Direct techniques are used to achieve tissue response and can be applied to a specific joint or non-specifically to a larger body area. Absolute and relative contraindications to direct methods are distinguished:

absolute und relative Kontraindikationen

- Systemic conditions that constitute *absolute* contraindications to direct techniques (e.g. bleeding disorders, tissue diseases)
- Systemic conditions that constitute *relative* contraindications to direct techniques (e.g. osteopenia)
- *Absolute* contraindications to direct techniques specifically applied at a local site (e.g. open wounds, recent surgeries, abdominal pain)
- *Absolute* contraindications to direct techniques that specifically involve thrust or impulse applied at a local site (e.g. acute fracture, compromised bone or joint stability)
- *Relative* contraindications to direct techniques that specifically involve thrust or impulse applied at a local site (e.g. strained ligaments, acute injury of the neck) [2]

Contraindications to indirect, fluid, and balancing techniques

Techniken für z. B. Weichteile, Faszien, Atem, Schädel

Indirect, fluid, or balancing techniques can also be applied to a specific joint or non-specifically to a larger body area. These techniques may include soft-tissue and fascial loading or unloading, phases of respiration, hydraulic pressures, and postural or cranial adjustments. Absolute and relative contraindications can be distinguished:

absolute und relative Kontraindikationen

- *Absolute* contraindications to indirect, fluid, or balancing techniques applied at a local site (e.g. acute cerebral bleed, recently closed head injury)
- *Relative* contraindications to any indirect, fluid, or balancing technique applied at the local site (e.g. metastatic disease, neoplasm) [2]

1.2.6 Guidelines for osteopathy

keine Europäischen Leitlinien für Osteopathie …

No European guideline for osteopathy was identified in the Trip medical database, Guidelines International Network database and the German Association of the Scientific Medical Societies (AWMF, Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V.) database.

… jedoch für Schmerz

Many guidelines for pain have been published. However, osteopathy is not mentioned. For example, in Austria and Germany, guidelines for non-specific low back pain [37] and non-specific low back pain [38] exist. In the UK, for instance, the National Institute for Health and Care Excellence (NICE) published a guideline (NG59 [39]) in 2016 entitled 'Low back pain and sciatica in over 16s', which was updated in 2020. In a commentary on this NICE guideline, it is stated that osteopathy is not directly mentioned in the guideline; however, it directly relates to osteopaths working for the National Health Service (NHS) and privately in the UK. Private practitioners are able to evaluate their practice against the guideline. For osteopaths working in the NHS, the guideline gives a clear context for osteopathic treatment and an opportunity for osteopaths being part of a clear pathway in back pain management. As the resultant recommendations are produced for different types of practitioners and settings, the importance of this guidance varies for osteopathic practice depending on the context of individual practitioners and their patients [40].

z. B. Leitlinien für Kreuzschmerzen, jedoch Osteopathie nicht direkt erwähnt

US Leitlinie für Osteopathie

In the USA, in 2016, the American Osteopathic Association published a guideline for OMT in patients with low back pain. The guideline focused on the necessity to identify somatic dysfunction as the more probable cause of pain [41].

1.3 Osteopathy as a health profession

international in Gesundheitssystemen unterschiedlich vertreten

Internationally, osteopathic healthcare has a very diverse representation across the health systems ranging from semi-integration as complementary and allied healthcare therapists (i.e. many European and Australasian countries) to full integration within conventional healthcare systems (i.e. USA). Depending on the country's regulatory and medico-legal standards and the scope of osteopathic training and practice, osteopaths may also prescribe other medical therapies (including pharmaceuticals). However, osteopathic practitioners share the understanding of osteopathy as the relationship between the structure and function of the human body [18].

gesetzlich geschützt und reguliert vs. ungeschützt und unreguliert

In many countries throughout the world, osteopathy is practised [2]. In some countries (e.g. the UK, Australia, Portugal, and Denmark), the title 'osteopath' is legally protected and statutorily regulated. Osteopaths need a minimum standard of education and training and must be formally registered to practise osteopathy legally [42]. In some countries, manual therapists, who have not received proper training, use osteopathic techniques and claim to provide osteopathic treatment [2]. However, in many countries, the osteopathic profession is unregulated and emerging [6].

1.4 Project aims and research questions

Osteopathie als wachsender Beruf

Osteopathy is a growing profession [3]. The Osteopathic International Alliance (OIA) published a report in 2020 summarising that osteopaths mainly treat patients with musculoskeletal conditions and pain in primary care. They further highlighted that, internationally, there is little formal, routinely gathered information about osteopathic practice [3]. In Austria, osteopathy is currently not a social insurance benefit, but the supply and demand steadily increase.

Schmerzbehandlung des Bewegungs- und Stützapparates:

Therefore, this report aims to systematically review published data regarding the effectiveness and safety of osteopathy in treating musculoskeletal pain and describe current training and quality requirements for osteopaths in Europe. The overall project's objective is to provide decision support for the reimbursement of osteopathy. The project aims

Wirksamkeit, Sicherheit, Ausbildungs- und Qualitätsanforderungen

- to summarise the evidence on the effectiveness and safety of osteopathy in treating musculoskeletal pain (part 1) and
- to provide an overview of the training and quality requirements and regulations of the osteopathic profession in Europe (part 2).

Forschungsfragen

For that purpose, the following research questions (RQs) are answered:

- RQ1: How effective and safe is osteopathy compared to standard care, no therapy or alternative therapy (e.g. sham therapy, physiotherapy, massage) in treating musculoskeletal pain in adults?
- RQ2: What are the current training and quality requirements for osteopaths in Europe? Who is allowed to offer osteopathy, and what qualifications do osteopaths need?

2 Methods

Übersichtsarbeit für chronische Kreuzschmerzen

The topic for this report was suggested by the Austrian health insurance fund (Österreichische Gesundheitskasse). They identified beforehand a recent systematic review and meta-analysis covering chronic non-specific low back pain [9]. Therefore, the focus of the report was on osteopathic treatment for patients in all other body regions and diseases. However, to give an overall picture, this report also describes the systematic review of low back pain.

2.1 Protocol registration

Studienregistrierung

The protocol of the current systematic review has been recorded on PROSPERO (https://www.crd.york.ac.uk/prospero/ registration number: CRD42022330778).

2.2 Part 1: Evidence of efficacy and safety of osteopathy for pain in the musculoskeletal system

2.2.1 Search process

systematische Suche in 5 Datenbanken

The systematic literature search was conducted on the 18th and 19th of May 2022 in the following databases:

- Embase
- Medline via Ovid
- The Cochrane Library
- PEDro
- INAHTA

Sucheinschränkungen

The systematic search was limited to randomised controlled trials (RCTs) published in English or German from inception until May 2022. Furthermore, conference abstracts were excluded. The specific search strategy employed can be found in the Appendix (see "*Literature search strategies for part 1*").

2.2.2 PICOS question

Einschlusskriterien für relevante Studien

Inclusion criteria for relevant studies are summarised in Table 2-1.

Table 2-1: PICOS question for research question 1 (all body regions and diseases except for lower back)

Population	Adults (male, female; over 18 years) with musculoskeletal pain in various body regions and diseases **Inclusion:** e.g. musculoskeletal pain (back/neck/cervical/shoulder/pelvic/ankle pain etc.), osteoarthritis, shoulder impingement syndrome, epicondylopathia, epicondylitis, rheumatic conditions in the musculoskeletal system (ankylosing spondylitis, fibromyalgia etc.), postoperative pain, chronic/persistent pain, adhesive capsulitis, piriformis syndrome **Exclusion:** e.g. neurological pain (e.g. migraine/headache, carpal tunnel syndrome), neurofibromatosis, cancer patients/survivors, pregnant/postpartum women, patients with dysmenorrhea, prostatitis, hemophilic arthropathy, bruxism, suboccipital tenderness, temporomandibular disorder

Intervention	**Osteopathy** *Operational definition: Any osteopathic technique (i.e. single technique or in combination with other techniques) alone or in addition to other interventions delivered by osteopaths or other therapists (i.e. osteopaths or non-osteopaths)* **Inclusion**[1]**:** craniosacral therapy/treatment, osteopathic manipulative treatment/medicine, cranial osteopathy, myofascial release, osteopathic visceral manipulation, dry needling, strain—counterstrain technique, high-velocity low-amplitude (spinal) manipulation, thrust manipulation, (Spencer) muscle energy technique, soft tissue technique, pressure release technique, spinal manipulative treatment, lumbopelvic manipulation **Exclusion:** proprioceptive neuromuscular facilitation, chiropractic, electrotherapy treatment[2], self-applied interventions/techniques (e.g. self-myofascial release)
Control	Standard care, no therapy or alternative therapy (e.g. waiting list, no care, sham treatment, massage, physiotherapy, conservative therapy, pharmacological treatment, other non-surgical treatment) **Exclusion:** surgical treatment
Outcomes	
Effectiveness	*Primary outcome:* ■ Pain[3] *Secondary outcomes:* ■ Physical/Mental/General health ■ Functional status ■ Mobility restriction ■ Range of motion (ROM)/Stiffness ■ Symptom improvement ■ Quality of life (QoL) ■ Fatigue ■ Body awareness ■ Depression/Anxiety
Safety	■ Adverse events[4] ■ Side effects[5]
Study design	RCTs
Publication period	From inception until May 2022
Languages	English, German
Sample size	Abstract screening: ≤25 patients excluded; full texts assessment: ≤50 patients excluded[6]

Abbreviation: PICOS, Population, Intervention, Control, Outcomes, Study design

1 In the introduction, only interventions are described which are applied by operators in the included studies.

2 Electrotherapy treatment involves the application of a therapeutic electrical current to the area of injury, inflammation, dysfunction, or pain.

3 All outcome measurements were taken into account.

4 An adverse event is defined as "a harmful or undesirable outcome that occurs during or after the use of a drug or intervention but is not necessarily caused by it. When causality is uncertain or the purpose of the relative effectiveness assessment is to establish causality, "adverse event" should generally be the default term over "adverse effect" or "adverse reaction/adverse drug reaction" [43].

5 This unintended effect "does not necessarily imply harm, as some side effects may be beneficial. Furthermore, it tends to understate the importance of harms because "side" may be perceived as denoting secondary importance" [44].

6 Generalisability from small samples is problematic and may produce inconsistency and overestimation of effects.

2.2.3 Flow chart of study selection

964 Referenzen identifiziert

After deduplication, overall, 964 citations were identified through the systematic literature search. Two researchers (LG, VH) independently screened the references, and in case of disagreement, a third researcher (IR) was involved in solving the differences. The selection process is displayed in Figure 2-1.

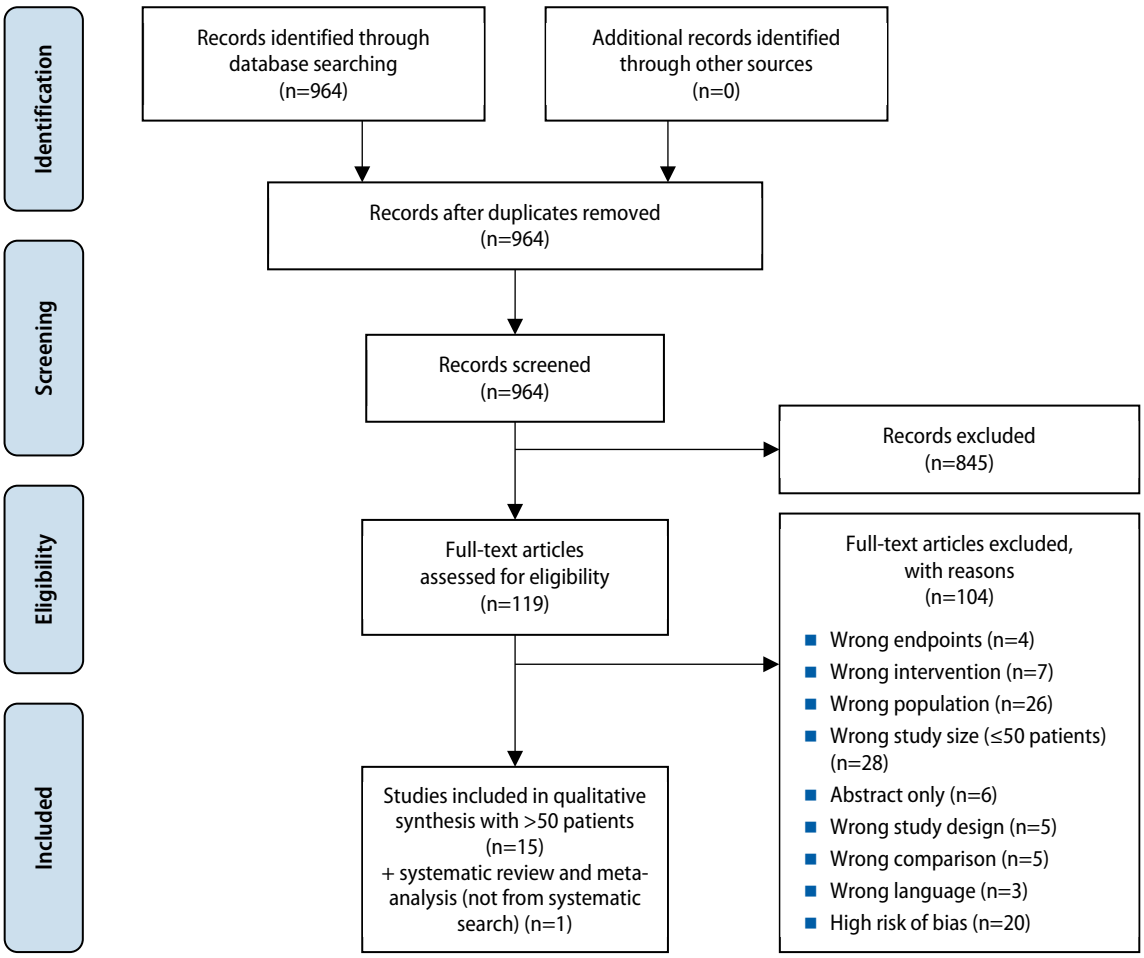

Figure 2-1: Flow chart of study selection (PRISMA flow diagram)

15 RCTs aus systematischer Suche + 1 systematische Übersichtsarbeit zu 8 Körperregionen/ Erkrankungen eingeschlossen

From the systematic search, we identified 35 RCTs covering seven body regions and diseases (i.e. neck, neck or (lower) back, shoulder, knee, foot, osteoporosis, fibromyalgia). Initially, we planned to exclude all RCTs with high RoB (see Chapter 2.2.4). However, this procedure would not have covered all regions and diseases. Therefore, we revised the inclusion strategy to cover all seven regions and diseases. For that purpose, we selected two studies for each region or disease according to the best available evidence[7] assessed by the 'Cochrane Collaboration's tool' version 1 (see Chapter 2.4) for data analysis and synthesis. This methodological path resulted in 13 studies from the systematic search included in the analysis. Furthermore, we additionally includ-

[7] Best available evidence i.e. studies rated with many ‚yes' (low risk) and less ‚no' (high risk) and ‚unclear' (unclear risk).

ed studies rated by the Cochrane tool with a maximum of 1x 'no' and 1x 'unclear' in all domains. This strategy resulted in two additional studies concerning the region of the neck. In conclusion, the analysis and synthesis included 15 studies from the systematic search. The region of the lower back was covered by a systematic review and meta-analysis [9]. As a result, eight regions and diseases covered by 16 studies are reviewed in this report.

Einschlussbegründung bei Fibromyalgie

For fibromyalgia, there were two articles with the same RoB rating. We decided to choose the article from Castro-Sanchez 2011a [35] instead of Castro-Sanchez 2011b [45], so we could compare two different osteopathic techniques, i.e. craniosacral therapy [46] and myofascial release [35], in our analysis. The study from Castro-Sanchez 2011b [45] also assessed craniosacral therapy.

ausgeschlossene Studien: Extraktion des Endpunktes Schmerz

Additionally, we extracted the primary outcome of interest (i.e. pain) from the 20 excluded studies with lower quality to compare the main results of the included with the excluded studies. The extraction tables' results of the excluded studies (see Appendix Table A-22 to Table A-27) were compared to the main results of the included studies in the discussion section (see Chapter 5.1.1).

2.2.4 Quality appraisal

Bewertung von Studienqualität und Verzerrungsrisiko

Two independent researchers (LG, VH) critically appraised all studies (n= 35) at a study level. They assessed the first three studies in a blinded manner to ensure high inter-rater reliability in assessing the risk of bias (RoB). The other 32 studies were divided between the two researchers for evaluation. However, all studies rated with a high RoB (n=25) were discussed before exclusion. For the RCTs, the 'Cochrane Collaboration's tool' version 1 [47, 48] was used to systematically assess internal validity and RoB, as presented in the Appendix (Table A-2). The systematic review and meta-analysis from 2021 concerning chronic non-specific low back pain [9] was critically appraised using AMSTAR 2 (A MeaSurement Tool to Assess systematic Reviews) [49] (see Appendix Table A-3). Disagreements were solved through consensus. The results of the appraisal have informed data synthesis.

2.2.5 Data extraction and analysis

Datenextraktion und Kontrolle

The data from the selected studies were systematically clustered in terms of the region of pain or disease and extracted into data extraction tables (see Appendix Table A-4 to Table A-21). The single-data extraction method with verification by another researcher was used: One researcher (LG) extracted the data, and one further researcher (VH) controlled the extracted data.

2.2.6 Data synthesis

qualitative Evidenzsynthese

A qualitative synthesis of the evidence was conducted. After extracting data in data extraction tables, data were interpreted according to the statistical values extracted. For that purpose, the means or confidence intervals together with the exact p-values were reported in a narrative form. All data from the extraction table were synthesised.

2.3 Part 2: Overview of current training and quality requirements for osteopaths in Europe

2.3.1 Inclusion criteria

Einschlusskriterien für relevante Studien

Inclusion criteria for relevant studies are summarised in Table 2-2.

Table 2-2: Inclusion criteria for research question 2

Description	Project scope
Interest	Regulation of the osteopathic profession in Europe
Countries	Selected European countries (e.g. Germany, Switzerland)
Categories of interest	■ *Regulation:* e.g. osteopathy located in primary healthcare, protected title ‚osteopath', existing national associations of osteopathy, available official documents related to regulation ■ *Education:* e.g. education level required to practise, type of education offered ■ *Practice of osteopathy:* e.g. reimbursement, private practice, restrictions to practise
Study design	Any kind of publication (e.g. evaluation reports, curricula, educational/study programmes)
Language	English, German

2.3.2 Country selection

Kriterien für Länderauswahl

For the country selection, we focused on European countries, with the German-speaking countries Austria, Switzerland and Germany as a fixed part of the analysis. In the further selection process, we considered the existence of national associations for osteopaths, the existence of legal regulations for the practice of osteopathy or whether a legal regulation is currently in progress, as well as a population of >5.5 million. Finally, in addition to Austria, Switzerland and Germany, Norway, Finland, Denmark, France, Portugal, Italy and the UK were included in the analysis. An overview of the selection process of the seven countries can be found in the Appendix (Table A-28).

2.3.3 Search process

gezielte manuelle Suche und Expert*innen-Befragung

A targeted manual search for training and quality requirements for osteopaths in ten selected countries was conducted in different sources (e.g. in PubMed, Google Scholar, Trip medical database, and osteopathic institutions). Experts were contacted to further identify and complete the country's information. The experts contacted were persons and/or members of organisations listed on the European Federation & Forum for Osteopathy (EFFO) website for the respective country[8].

[8] See https://www.effo.eu/membership/member-organisations/ [cited 03.10.2022]

2.3.4 Data extraction and analysis

Datenextraktion und Kontrolle

The data from the selected countries were systematically clustered in terms of regulation, education and the practice of osteopathy and extracted into data extraction tables (see Appendix Table A-29 to Table A-38). The single-data extraction method with verification by another researcher was used: One researcher (VH) extracted the data, and one further researcher (LG) controlled the extracted data.

2.3.5 Data synthesis

qualitative Synthese

A qualitative synthesis of the evidence was conducted. After extracting data in data extraction tables and tabular presentation, data were interpreted according to the three aspects of regulation, education and practice of osteopathy. For that purpose, the aspects were reported in a narrative form. All data from the extraction table were synthesised to describe the identified training and quality requirements at a country level within Europe.

2.4 Quality assurance

Begutachtung durch 1 interne & 2 externe Reviewer*innen

This report was reviewed by one internal and two external reviewers (see Project Support). The external reviewers were primarily asked to assess the following quality criteria:

- *Technical correctness:* Is the report technically correct (evidence and information used)?
- Does the report *consider the latest findings* in the research area?
- *Adequacy and transparency of method:* Is the method chosen adequate for addressing the research question, and are the methods applied in a transparent manner?
- *Logical structure and consistency of the report:* Is the structure of the report consistent and comprehensible?
- *Formal features:* Does the report fulfil formal criteria of scientific writing (e.g. correct citations)?

The AIHTA considers the external peer review by scientific experts from different disciplines as a method of quality assurance of the scientific work. The responsibility for the report content lies with the AIHTA.

Teil 1: Wirksamkeit und Sicherheit; Teil 2: Ausbildungs- und Qualitätsanforderungen

In the following, the results of the current report are divided according to the two research questions. Part 1 gives information regarding the evidence of the efficacy and safety of osteopathy for pain and other outcomes in the musculoskeletal system. Part 2 provides an overview of the current training and quality requirements for osteopaths in Europe.

3 Results of part 1: Evidence of efficacy and safety of osteopathy for pain in the musculoskeletal system

This chapter describes, first, the study characteristics and interventions of the included studies (n=16) and, second, the outcome measures, quality of evidence and the results regarding the effectiveness and safety of the osteopathic interventions. Finally, the effectiveness of osteopathic interventions focusing on the primary outcome of pain, the professions involved, the types of osteopathic interventions, and safety aspects are summarised in separate chapters.

Teil 1: Effektivität & Sicherheit von Osteopathie

3.1 Description of study characteristics and interventions of included studies

The following eight regions and diseases are covered: neck, neck or (lower) back, shoulder, lower back, knee, foot, osteoporosis, and fibromyalgia. The presentation of the regions and diseases follows the order from the upper to the lower body.

8 Körperregionen/ Erkrankungen

3.1.1 Neck

Four of 15 identified studies were chosen to examine the indication of chronic [50], acute [51], and subacute-chronic [52] neck pain; one study did not report if the cervical myofascial pain is chronic or acute [15]. The RCTs from Germany [50, 51] and Spain [15, 52] randomised 54 [50, 52] to 75 [15] patients. The patients' mean age was between 42 and 48 in two studies [50, 51], and the age range was between 20 and 60 years in the other two studies [15, 52]. The majority of patients were female (48% [52] to 82% [50]). Dropouts only occurred in one study [50], where three patients were lost to the assessment at week eight and nine patients to the assessment at week 20.

4/15 RCTs eingeschlossen

54 und 75 Patient*innen (Pts.), Ø 42-48 Jahre alt, bzw. Altersrange 20-60, mehrheitlich weiblich

Craniosacral therapy [50], strain—counterstrain treatment [51], pressure release [15], or myofascial releases [52] were compared to (light-touch) sham treatment [50, 51], kinesiotaping and placebo [15], or standard physical therapy [52]. Between one [15, 51] and eight [50] osteopathic sessions were applied with a duration of each session of 45 minutes reported in two [50, 52] of the four studies within a treatment period between one session [15, 51] and eight weeks [50].

versch. angewandte Techniken, 1-8 Behandlungen im Zeitraum von max. 8 Wochen

The interventions were applied by physiotherapists with advanced craniosacral therapy qualifications [50], a general practitioner with additional qualifications in sports medicine, manual therapies and osteopathy [51], and a therapist with nine years of experience and certified in the myofascial release therapy technique [52]. One study did not report the operator [15]. The follow-up (FU) in two studies was at one month [52] and three months after the treatment [50]. Two studies did not conduct a FU assessment [15, 51] (see Appendix Table A-4 and Table A-5).

(Physio)therapeut*in/ Hausarzt/-ärztin, jeweils mit osteopathischer Ausbildung

kein bis max. 3 Monate Nachbeobachtung (FU)

3.1.2 Neck or (lower) back

2/2 RCTs, 120 und 201 Pts. im Alter von 16-65 Jahren;

Fascial Release & osteopathische spinale Manipulation

Two studies could be identified concerning the indication of acute/chronic [53] and (sub)acute [54] neck or (lower) back pain. The results were not reported separately for neck and (lower) back pain. The RCTs from Italy [53] and the UK [54] randomised 120 [53] and 201 patients [54]. The age range was 16 to 65 years [53, 54]. One study reported that 30% were female [53]. Eighteen patients dropped out [54]; the other study did not report any drop-outs [53]. Fascial release [53] or osteopathic spinal manipulation [54] was compared to sham treatment [53] or usual care [54].

Osteopath*in & Hausarzt/-ärztin mit osteopathischer Ausbildung

An osteopath applied one session (4-8 minutes per session) of fascial release [53]. A general practitioner registered as an osteopath performed three to four sessions of osteopathic spinal manipulation (0.5-1x/week) for two months [54]. Only one study conducted a FU assessment at six months [54] (see Appendix Table A-6).

3.1.3 Shoulder

2/6 RCTs mit 60 und 75 Pts. im Alter von 20-53 Jahren; Myofascial Release & Muskelenergietechnik

Physiotherapeut*in & Osteopath*in; Behandlungszeitraum 1-4 Wochen

Six studies were identified for the region of the shoulder, and two were selected for analysis. The two RCTs from India [28] and Australia [27] investigated patients with upper trapezius spasm [28] or shoulder impingement syndrome [27]. The studies involved 60 [28] to 75 patients [27] between 20 [28] and 53 [27] years. 38% [27] and 52% [28] of them were female. Eighteen patients dropped out until the last FU in the Australian study [27] and none in the Indian study [28]. The authors investigated the effectiveness of myofascial release compared to an active release technique applied by physiotherapists within a treatment period of seven days [28] and muscle energy technique compared to muscle energy technique + soft tissue massage and placebo [27]. The latter was applied by an osteopath in four sessions for 15 minutes each, once a week, within a treatment period of four weeks [27].

1 Jahr FU in 1 RCT

The FU assessments were examined four weeks after discharge (test point week 7), at six months (test point week 29), and one year (test point week 55) [27], while there was no FU assessment in the other study [28] (see Appendix Table A-7).

3.1.4 Lower back

1 systematische Übersichtsarbeit mit 10 RCTs (1.160 Pts.)

A systematic review and meta-analysis from 2021 covered the indication of chronic low back pain. This review from Italy included ten RCTs with a total of 1,160 patients (mean age 43). The dropout rate was between 0-77% [9].

Techniken: hauptsächlich osteopathische manipulative Behandlung, Myofascial Release

Ø 9 Behandlungen in 10 Wochen; FUs 4-24 Wochen

Osteopathic interventions, i.e. OMT (n=6), myofascial release (n=2), craniosacral treatment (n=1) or osteopathic visceral manipulation (n=1) were compared to no active treatment (sham therapy or no intervention; n=5) or active treatment (standard exercise, classic massage; n=5). The systematic review and meta-analysis did not report who applied the interventions. The total number of sessions was between one and 24 sessions (mean 9 sessions) within a treatment period between two and 24 weeks (mean 10 weeks). Each session lasted between 15 and 60 minutes (mode: 45 minutes) with a treatment frequency between twice a week to once a month. FU assessments ranged from four to 24 weeks (in 6/10 studies; there was no FU in the 4 other studies) [9] (see Appendix Table A-8).

3.1.5 Knee

2/2 RCT: in einem RCT gemischte Population mit Hüft- oder Knieschmerzen

Two studies could be identified, however, one RCT included a mixed population of patients with hip or knee pain; the results were not reported separately. This RCT from the USA assessed acute (postoperative) knee or hip osteoarthritis or hip fracture [13]. A second study from Brazil could be identified regarding the indication of chronic patellofemoral pain syndrome [29].

60 und 82 Pts. im Alter von 19-69 Jahren

Sixty [13] and 82 [29] patients were randomised with a mean age of 69 [13] and an age range of 19-35 [29] years. Thereof, 59% [29] and 10% [13] were female. Five eligible patients withdrew from the study [29], and eight patients were lost to the 4-week post-discharge FU [13].

Techniken: z. B. Myofascial Release, Muskelenergie, Soft Tissue, Cranio-Sacral

Myofascial release, strain—counterstrain, muscle energy, soft tissue, high-velocity, low-amplitude (not at the surgical site), or craniosacral manipulation were compared to sham treatment (i.e. range-of-motion activities, light touch) [13]. In the other study, OMT was compared to an exercise programme and a waiting list [29].

Osteopath*in & Medizinstudent*innen des Institutes für Osteopathie

Medical students of the Department of Osteopathic Manipulative Medicine [13] and an osteopath [29] applied five sessions (10-30 minutes each session) 2.4 times a week [13] and six sessions (40 minutes each) in a treatment period of three weeks, twice a week [29]. FU assessment was four weeks after discharge (only SF-36 (Medical Outcomes Study Short Form-36) assessment) [13] and at 30 days [29] (see Appendix Table A-9).

3.1.6 Foot

2/4 RCTs mit 66 und 70 Pts., ca. 75 % weiblich

Four studies could be identified regarding the region of the foot, of which two were selected to examine the effectiveness of myofascial release [30, 31]. The RCTs were conducted in Poland [30] and Qatar [31], assessing the indications of flat foot with foot pain [30] or unilateral plantar heel pain [31]. Seventy (age range 20-49) [30] and 66 patients (mean age 42) [31] were randomised. The majority (78% [30] and 74% [31]) of them were females. Ten [30] and one patient(s) [31] dropped out of the study.

zertifizierte (Physio)therapeut*in, angewandte Technik: Myofascial Release, 8-12 Behandlungen innerhalb 4 Wochen, FU nach 12 Wochen in 1 RCT

The intervention was applied by a therapist [30] and physiotherapists certified in myofascial release [31]. A total number of eight (40 minutes each session twice a week) [30] and 12 (30 minutes each session three times a week) [31] sessions of myofascial release were compared to an exercise programme, myofascial release and exercise programme or no intervention [30] and sham ultrasound therapy [31] within four weeks. A FU was conducted 12 weeks after randomisation in only one [31] of the two studies (see Appendix Table A-10).

3.1.7 Osteoporosis

1/1 RCT mit 72 Pts., Ø 77 Jahre alt

One RCT from Italy was identified, covering pain in the elderly with osteoporosis [33]. In this study, 72 patients with osteoporosis (71% female) with a mean age of 77 years were assessed; no dropouts occurred. OMT was compared to sham manipulative treatment [33].

Osteopath*in, 6 Behandlungen in 6 Wochen, kein FU

An osteopath applied six sessions (30 minutes each) once a week for a treatment period of six weeks. There was no FU assessment [33] (see Appendix Table A-11).

3.1.8 Fibromyalgia

2/5 RCTs mit 94 und 104 Pts. im Alter von 34-65 Jahren; Cranio-Sacral & Myofascial Release

Five studies could be identified to indicate fibromyalgia, of which two studies from Spain were selected for analysis. The two RCTs randomised 94 [35] and 104 [46] patients between 34 and 65 years, whereof 96% [46] were female reported in one of the two studies. Craniosacral therapy was compared to placebo [46], and myofascial release was compared to sham therapy [35]. Eight [35] and 20 [46] patients dropped out of the studies.

zertifizierte (Physio)therapeut*in, 10-50 Behandlungen in 20-25 Wochen, FU 1 Jahr

An expert craniosacral therapist applied 50 sessions, one hour each, twice a week within a treatment period of 25 weeks [46]. In the other study, a physiotherapist applied ten sessions, one hour each, twice a week within a treatment period of 20 weeks [35]. Both studies assessed six months and 1-year post-treatment [35, 46] (see Appendix Table A-12).

3.2 Description of the outcome measurements and effectiveness of the osteopathic interventions

8 Körperregionen/ Erkrankungen, 16 RCTs

This chapter describes the mainly used outcome measurements for the primary outcome of pain and the effectiveness of the osteopathic interventions in the eight regions and diseases, including 16 studies.

3.2.1 Outcome measurements for the primary outcome of pain

Messinstrumente für Schmerz

Various outcome measurements were used to assess the outcome of pain. The three most frequently scales used in the included RCTs were the Visual Analogue Scale (VAS; n=7), the (short form) McGill Pain Questionnaire (MGPQ/MPQ; n=3), and the Numeric Pain Rating Scale (NPS/NPRS/NRS; n=3).

Visual Analogue Scale (VAS)

Visuelle Analogskala (VAS)

The VAS of sensory intensity and affective magnitude is validated as a ratio scale to measure pain [55]. It consists of a 10-cm line (0-10 or 0-100) with two end-points representing ‘no pain’ and ‘pain as bad as it could possibly be’. Patients are asked to rate their pain by placing a mark on the 10-cm line below to indicate the current level of pain (see Figure 3-1 [56]).

Figure 3-1: Visual Analogue Scale [56]

McGill Pain Questionnaire (MGPQ/MPQ)

McGill Schmerz-Fragebogen

The McGill Pain Questionnaire is a validated multidimensional pain questionnaire designed to measure the affective, sensory, and evaluative aspects of the present pain and pain intensity. The Pain Rating Index contains 78 pain descriptor items categorised into 20 subclasses, each containing two to six words that fall into four major subscales: affective, sensory, evaluative, and miscellaneous. For each subclass of words, the patient is instructed to select one word that fits the present pain. If none of the words describes the pain, no word is selected. The score is based on the rank order or position within the word set [57].

Numeric Pain Rating Scale (NPS/NPRS/NRS)

Numerische Schmerz-Bewertungsskala

The validated Numeric Pain Rating Scale is a segmented numeric version of the VAS in which patients select a whole number that best reflects pain intensity. Similar to the VAS, it is anchored by terms describing pain severity extremes. The Numeric Pain Rating Scale is a single 11-point numeric scale with 0 representing one pain extreme ('no pain') and 10 representing the other pain extreme ('worst pain imaginable'). Most commonly, patients are asked to report their pain intensity in the last 24 hours or average pain intensity [57].

3.2.2 Minimum clinically important difference

VAS: minimaler klinisch bedeutsamer Unterschied in versch. Studien mit 1,4 bis 5,2 cm Reduktion

The minimum clinically important difference (MCID) is the smallest benefit of value to patients [58]. Seven of the 15 included RCTs used the validated VAS for measuring pain. A mean reduction in the VAS of *3 cm* represents an MCID in pain severity corresponding to patients' perception of adequate acute pain control [59]. In the literature, other studies could be found regarding thresholds for the MCID. In these studies, the MCID was between *-1.4 and -5.2 cm*, although the differences were calculated for various diseases (i.e. rotator cuff disease, joint arthroplasty, hallux valgus, and rheumatism) [60-63].

McGill Schmerz-Fragebogen: MCID bei Reduktion um 1 bis 2,3 Punkte

Three RCTs rated pain by the validated McGill Pain Questionnaire. However, thereof two studies used the short form, of which we could not find an MCID value. In the literature, the range of MCID values was a reduction of *1-2.3 points* in patients with chronic pain [64].

Numerische Schmerz-Bewertungsskala: MCID bei Reduktion von 1 bis 3,3 Punkten

Three of the 15 RCTs used the validated numeric pain rating scale (NPS/NPRS/NRS) to measure pain. A mean reduction of *3.3 points* on the scale represents an MCID in pain based on data from adult rheumatology populations [63]. Based on a population with chronic musculoskeletal pain, *one* point reduction represented an MCID for the patient. A change score of *-2.0 points* was best associated with 'much better' improvements [65].

3.2.3 Effectiveness of the osteopathic interventions

Zusammenfassung von Verzerrungsrisiko, Messinstrumenten, Ergebnissen zu Wirksamkeit und Sicherheit

This chapter summarises, for each indication, the applied osteopathic interventions, the risk of bias in the included studies, the assessed outcome measurements and the respective effectiveness and safety results. Results for the primary outcome of interest (i.e. pain), with a focus on those assessed with the before mentioned scales (e.g. VAS), are reported with the corresponding effect sizes or mean group differences. Other results are reported verbally, with reference to statistically significant group differences.

Neck

4 RCTs: Cranio-Sacral, strain—counterstrain, Pressure/Myofascial Release

Four RCTs compared craniosacral therapy [50], strain—counterstrain treatment [51], pressure [15] or myofascial [52] release to light-touch sham treatment [50], sham treatment [51], kinesiotaping and placebo [15], or standard physical therapy [52].

Risk of bias

unklares bis hohes Verzerrungsrisiko

The RoB was unclear in two studies [50, 51] due to unclear allocation concealment [50] and selective outcome reporting [51]. In the other two studies [15, 52], the RoB was rated high mainly due to a lack of blinding [15, 52] and also due to unclear outcome reporting [15] and unclear allocation concealment [52]. The RoB table can be found in the Appendix (see Table A-2).

Outcome measurements

viele versch. Instrumente zur Messung von Schmerz-Endpunkten z. B. VAS

For assessing the outcomes, several measurements were used. The VAS [50], NPRS/NPS [15, 52], and Neck Pain and Disability Scale [51] were used to evaluate pain intensity and level of pain. Pain on movement was assessed by the Pain on Movement Questionnaire [50] and the point of maximum pain and pressure pain sensitivity with pressure pain thresholds [50]. Pain acceptance was rated by the Emotional/Rational Disease Acceptance Questionnaire [50], cervical joint range (objective pain) and cervical active ROM were measured by a goniometry [15, 52], myofascial trigger points (objective pain) were measured by an algometry [15] and pressure pain thresholds by a pressure algometer [52].

weitere Messinstrumente z. B. für Funktionalität, Lebensqualität (LQ), körperliches/psychisches Wohlbefinden

Mobility restriction was assessed by the Cervical ROM [51], and the 12-item Short Form Health Survey was used to assess QoL [15, 50]. Functional disability was measured using the Neck Disability Index [50], physical well-being by the Questionnaire for Assessing Subjective Physical Well-being [50], and anxiety and depression by the Hospital Anxiety and Depression Scale [50]. The Perceived Stress Questionnaire was used to assess stress perception [50], the Scale of Body Connection to assess body awareness/dissociation [50], and the Patients' Global Impression of Improvement to assess global improvement [50].

Primary outcome

Schmerzintensität: statistisch und klinisch relevante Verbesserungen (2/3 RCTs)

Two studies reported mean between-group differences regarding **pain intensity**, assessed on a 100mm VAS (after 8 sessions: -21.0 [95% CI -32.6, -9.4], $p=0.001$; at 20 week FU[9]: -16.8 [-27.5, -6.1], $p=0.003$) [50] and an 11-point NPRS (after 5 sessions: -1.04 (-1.71, -0.36), $p<0.01$, 'medium ES'); at 1 month FU: -1.56 [-2.3, -0.81], $p<0.001$, 'large ES') [52]. In both studies, a statistically and clinically meaningful improvement could be found regarding the primary outcome of pain measured by the VAS and NPRS. In another study, pain intensity, measured by NPDS, improved from baseline to post-treatment in the intervention group after one treatment session (IG: mean 0.7 (SD 0.7), $p<0.0001$, CG: 0.3 (0.9), n.s.), but the group difference was not statistically significant [51]. One study also assessed the **level of pain** (subjective pain) by the 11-point NPS and reported mean pre-post differences for each of the three groups (IG: pre 5.36 (SD 0.37), post 4.24 (0.38), $p<0.001$; placebo: pre

Schmerzgrad nach einer Behandlungseinheit statistisch und klinisch relevant verbessert

[9] "Outcomes were assessed before and after treatment (week 8) and again 3 months later (week 20) [52]".

5.04 (0.48), post 4.4 (0.41), p>0.05; kinesiotaping: pre 5.32 (0.42), post 2.92 (0.52), p<0.001), that were statistically significant in the intervention and kinesiotaping group but not in the placebo group. Furthermore, clinically meaningful intra-group improvements measured by the NPS in the pressure release group could be identified [15].

Bewegungsschmerz, maximaler Schmerzpunkt, Druckschmerzempfindlichkeit, myofasziale Trigger-Punkte: heterogene Ergebnisse

A statistically significant between-group improvement in favour of the intervention group could be observed regarding the **pain on movement** assessed after eight sessions (p<0.01) and at the 20 weeks FU (p<0.05) [50]. The **point of maximum pain** was statistically significantly improved after eight sessions (p<0.05) but not at the 20 weeks FU. No statistically significant improvement could be found for **pressure pain sensitivity** at the anatomical sites of musculus levator scapulae and musculus semispinalis capitis. However, pressure pain sensitivity was statistically significantly reduced at the musculus trapezius assessed after eight sessions (p<0.05) but not at the 20 weeks FU [50]. **Myofascial trigger points** of the **right** (p<0.05) and **left** (p<0.001) sternocleidomastoid muscle **(objective pain)** comparing pressure release with placebo improved after one session [15].

Druckschmerzgrenzen: heterogene Ergebnisse

Pressure pain thresholds statistically improved after five sessions at the sites suboccipita left, thoracic right (p<0.05, respectively), and suboccipita right (p<0.01), but not at the thoracic left side. At the one-month FU, pressure pain thresholds were statistically significantly improved at the sites suboccipita left/right and thoracic right (p<0.05, respectively) but not at the thoracic left side [52].

Secondary outcomes

körperliche/mentale Gesundheit, Körperbewusstsein, globale Verbesserung: heterogene Ergebnisse

Analysing the between-group differences, ***physical health*** regarding **functional disability** and **physical QoL** statistically significantly improved after eight sessions (p<0.05, respectively) and at the 20 (p<0.01 and p<0.001) weeks FU, but not **physical well-being**. ***Mental health*** only improved concerning **anxiety** at the 20 weeks FU (p<0.05), but not after eight sessions. Furthermore, **mental QoL**, **depression**, **stress perception**, and **pain acceptance** did not improve in any of the two test points. **Body awareness** improved after eight sessions (p<0.01), but at the 20 weeks FU; **body dissociation** did not improve at any test point. **Global improvement** was enhanced after eight sessions (p<0.001) and at the 20 weeks FU (p<0.05) [50].

Bewegungseinschränkung, -umfang, LQ: heterogene Ergebnisse

The **cervical active ROM** improved when rotating to the left (p<0.05) but not at flexion, extension, side bending left/right, and rotation to the right after five sessions. At the one-month FU, cervical active ROM when rotating to the left (p<0.01) and right (p<0.05) side was still improved. However, the ROM did not improve when flexing, extending, or side bending [52]. Also, the **cervical joint range** (objective pain) and **QoL** did not statistically significantly improve between the groups after one session [15]. However, no statistically significant between-group differences in **mobility restriction** were found after one session [51].

Safety

nicht schwerwiegende unerwünschte Ereignisse aufgetreten

No serious adverse events occurred. However, six patients had minor adverse events during or subsequent to the treatment [50] and in four patients, mild transient adverse effects occurred [51]. They reported pain [50, 51], shivering, tiredness, strong emotional reactions, weeping [50], and dizziness [51]. In the other two studies, no adverse events occurred [52] or were reported[10] [15]. No side effects were reported in all four studies.

Conclusion

Verbesserungen: Schmerzintensität, funktionelle Einschränkung, LQ …

To conclude, in the studies assessed, craniosacral therapy was effective and safe in reducing neck **pain intensity** and may improve **functional disability** and the **QoL** up to three months after intervention [50]. However, strain—counterstrain as a single intervention did not immediately affect **mobility** and **pain** compared to a sham treatment [51].

… Schmerz, Druckschmerzgrenze

Pressure release reduced pain in patients with neck pain compared to the control group [15]. Myofascial release therapy could be better than a standard physical therapy program for improving **pain** and **suboccipital pressure pain thresholds** in patients with neck pain. However, the difference between both treatments is less than the minimum detectable change[11] on the numerical pain rating scale [52] (see Appendix Table A-13 and Table A-14).

Neck or (lower) back

gemischte Population

Two studies included both patients with neck or (lower) back pain and did not report the results separately [53, 54].

Risk of bias

hohes Verzerrungsrisiko

The risk of bias in both studies was high mainly due to a lack of blinding [53, 54] but also because of unclear generation of randomisation sequence, allocation concealment, outcome data addressed, outcome reporting [54], unclear allocation concealment and outcome reporting [53].

Outcome measurements

McGill Schmerz-Fragebogen

Both studies used the Short-Form McGill Pain Assessment Questionnaire (SF-MPQ/SMPQ) to investigate pain outcomes [53, 54]. Furthermore, spinal pain and disability were assessed by the Extended Aberdeen Spine Pain Scale (EASPS), physical and mental health by the SF-12, and the EuroQol (EQ-5D) measured QoL [54].

Primary outcome

Schmerz, Wirbelsäulenschmerzen: Verbesserung in 2/3 Schmerz-Endpunkten

When comparing fascial release with sham treatment, a statistically significant between-group difference regarding the outcome of **pain** (measured by SF-MPQ) could be found after one session (IG: pre: mean 24.7 (SD 8.6), post: 15.5 (9.8), vs CG: pre: 24.9 (9.2), post: 25.1 (8.9); $p<0.0001$) [53]. However, osteopathic spinal manipulation compared to usual care did not statistically significantly improve pain (assessed with SMPQ) after two months of treat-

[10] That means that adverse events were not reported at all (i.e. there may have been some, but the authors did not say one way or the other).

[11] "Minimal detectable change is defined as the minimal change that falls outside the measurement error in the score of an instrument used to measure a symptom [66]."

ment (IG: mean change 4.6 (SD 8.0) vs CG: 2.1 (7.0); n.s.), but there is a trend for improvement at the six months FU (IG: 6.6 (8.8) vs CG: 3.7 (8.1); p=0.05). **Spinal pain and disability** (measured by EASPS) statistically significantly improved after two weeks of treatment (IG: 13.9 (12.8) vs CG: 8.6 (14.2); p<0.05) but not after six months FU [54].

Secondary outcomes

Mental health statistically significantly improved after two months of treatment and at the six-month FU (p<0.01 and p<0.05, respectively). **Physical health** and **QoL** did not improve at both test points [54].

mentale/körperliche Gesundheit, LQ: heterogene Ergebnisse

Safety

No adverse events occurred [54] or were reported [53]. No side effects were reported in both studies.

keine unerwünschten Ereignisse (berichtet)

Conclusion

In the included studies, manual fascial techniques are effective manual techniques for improving **pain perception** over a short-term duration in people with non-specific neck or low back pain [53]. Furthermore, **spinal pain and disability** (only after 2 months) and **mental health** could be improved due to osteopathic spinal manipulation [54] (see Appendix Table A-15).

Verbesserungen: Schmerzwahrnehmg., Wirbelsäulenschmerz, mentale Gesundheit

Shoulder

For the region of the shoulder, two studies were included. Myofascial release [28] and muscle energy technique [27] were compared to an active release technique [28] and muscle energy technique + soft tissue massage and placebo [27].

Myofascial Release, Muskelenergietechnik

Risk of bias

The RoB was high mainly due to a lack of blinding but also selective outcome reporting [27] and unclear due to unclear allocation concealment, blinding, and outcome reporting [28].

unklares bis hohes Verzerrungsrisiko

Outcome measurements

Both studies measured pain by the VAS. Various further outcome measurements were used to assess other outcomes: Cervical ROM was measured by a neck ROM and neck disability by the Neck Disability Index scale [28]. The Disabilities of the Arm Shoulder and Hand questionnaire assessed arm, shoulder and hand disability, the Shoulder Pain and Disability Index measured shoulder pain and disability, and the Global Rating of Change evaluated changes in activities [27]. Furthermore, activity/functionality was assessed using the Patient-Specific Functional Scale), and the ROM was measured by an inclinometer [27].

u. a. VAS

Primary outcome

Both studies used the VAS to measure pain. One study found a statistically significant between-group difference *in favour of the control group* (i.e. active release technique) regarding **pain** after a treatment period of seven days (IG: mean of the difference -2.48 (SD 0.86), CG: -4.79 (1.13); p<0.001). However, statistically significant pre-post differences in both groups (p<0.001) were found. Furthermore, a clinically meaningful improvement in both groups

Schulterschmerz: Vorher-Nachher-Effekt und klinisch (1 RCT) und statistisch (1 RCT) relevante Verbesserungen

could be identified regarding the primary outcome of pain measured by the VAS [28]. The other study, a 3-arm single-blind RCT, found that the muscle energy technique and placebo group statistically significantly differed concerning the two outcomes **'pain'** and **'shoulder pain and disability'** at week 3 (i.e. at discharge) ($p<0.01$, respectively), and the FUs at week 7 ($p<0.05$, respectively), 29 ($p<0.05$, respectively), and 55 ($p<0.05$ and $p<0.01$) favouring the osteopathic intervention group [27].

Secondary outcome

Bewegungsumfang, Nackeneinschränkung: keine Verbesserungen

There was a statistically significant between-group difference *in favour of the control group* (i.e. active release technique) regarding **ROM** and **neck disability** after a treatment period of seven days. However, statistically significant pre-post differences in both groups ($p<0.001$, respectively) in all measurements were found [28]. Also, the **ROM** did not differ between the two groups at the only test point at week 3 (i.e. at discharge) [27].

Arm-/Schulter-/Hand-Einschränkung, Aktivitätsänderung, Funktionalität: heterogene Ergebnisse

Arm, shoulder and hand disability statistically significantly differed at week 3 (i.e. at discharge) and at the FUs at week 29 ($p<0.01$, respectively) and 55 ($p<0.05$) in favour of the osteopathic intervention group (i.e. muscle energy technique), but not at week 7. **Changes in activities** statistically significantly differed between the two groups only at week 3 (i.e. at discharge) ($p<0.001$) and at the FU at week 7 ($p<0.05$), and **activity/functionality** only at the FU at week 3 ($p<0.05$) and 55 ($p<0.01$) favouring the osteopathic group [27].

Safety

keine unerwünschten Ereignisse (berichtet)

No adverse events occurred [27] or were reported [28]. Side effects were not reported in both studies [27, 28].

Conclusion

Active Release besser als Myofascial Release; Verbesserung: Schmerz(einschränkung)

To conclude, active release therapy (i.e. control group) gave better results in all outcomes than myofascial release (i.e. intervention group). However, pre-post improvements were found in both groups and a clinically meaningful effect in the intervention group [28]. Muscle energy technique of the thoracic spine with or without soft tissue massage improved the **pain and disability** in individuals with shoulder impingement syndrome [27] (see Appendix Table A-16).

Lower back

systematische Übersichtsarbeit

A systematic review and meta-analysis covers the indication of chronic low back pain. Different osteopathic interventions were compared to active or no active treatment [9].

Methodological quality of the study

hohes Vertrauen in Studienqualität

The systematic review and meta-analysis was critically appraised in AMSTAR 2 [49], resulting in high overall confidence. Here, a limitation was given as the review authors did not report on the sources of funding for the studies included in the review (see Appendix Table A-3). In the systematic review and meta-analysis [9], the RoB was assessed in the ten included RCTs. No RCT showed low RoB in all 13 items of the Cochrane Collaboration RoB tool [48]. The RoB summary (i.e. review authors' judgements about each RoB item for each included study) can be found in Figure A-1 in the Appendix [9].

Outcome measurements

The outcome pain was measured by the VAS, NRS, and MGPQ. The Oswestry Disability Index, Roland and Morris Disability Questionnaire, and Quebec Pain Disability Scale rated the functional status [9].

VAS, Numerische Schmerz-Bewertungsskala, McGill Schmerz-Fragebogen

Primary outcome

The analysis found that **pain** statistically significantly reduced in all ten studies involving 1,049 patients after, on average, nine sessions, compared to control interventions (ES -0.59 [95% CI -0.81, -0.36], p<0.00001). Also, at the FU assessments at 12 weeks, a statistically significant improvement (ES -0.73 [95% CI -1.09, -0.37], p<0.0001) in pain could be observed (2 studies, 128 patients) [9].

Schmerz: statistisch signifikante Verbesserung

Secondary outcomes

Functional status statistically significantly improved involving 1,055 patients (10 studies) after, on average, nine sessions (ES -0.42 [95% CI -0.68, -0.15], p<0.01). However, the FU assessment at 12 weeks did not yield statistically significant results (4 studies, 676 patients) [9].

funktioneller Status: Verbesserung nur unmittelbar nach Behandlung

Safety

Adverse events occurred in two of ten studies, while seven studies did not report on those events. One study reported that there was no data collection. Increased pain arose in ten subjects during the first week of myofascial release treatment (1/10 study) and increased back muscle spasticity occurred on one occasion (1/10 study). Side effects were not reported (10/10 studies) [9].

unerwünschte Ereignisse aufgetreten

Conclusion

To conclude, osteopathy effectively improves **pain** levels immediately after the osteopathic treatment and at the 12-week FU. **Functional status** was only improved immediately after the treatment. The overall quality of evidence was very low to moderate [9] (see Appendix Table A-17).

Verbesserungen: Schmerzgrad, funktioneller Status

Knee

One study included both patients with knee and hip pain and did not report the results separately. The study compared one or a combination of different osteopathic techniques with sham treatment [13]. The other study assessed OMT compared to an exercise programme and a waiting list in patients with chronic patellofemoral pain syndrome [29].

gemischte Population; u. a. osteopathische manipulative Behandlung

Risk of bias

The RoB was unclear in both studies due to the unclear generation of randomisation sequence and allocation concealment, as well as outcome reporting [13] and an unclear blinding process [29].

unklares Verzerrungsrisiko

Outcome measurements

Pain was assessed by the VAS, functionality by the Lysholm Knee Scoring Scale, and dynamic knee valgus by the step-down test. Furthermore, a static baropodometry rated the plantar pressure, the sit and reach test assessed the posterior thigh flexibility, and hip ROM was evaluated by a fleximetry [29]. Various measurements were used to investigate the outcomes in the other study: Functional independence was rated by the Functional Independence

versch. Messinstrumente verwendet, u. a. VAS

Measure, rehabilitation efficiency by its total score change per rehabilitation unit day, and general health by the Medical Outcomes Study Short Form-36. Furthermore, daily analgesic medication use (mg/day) and length of stay (days) were assessed [13].

Primary outcome

Schmerz: statistisch und klinisch relevante Verbesserungen

After a treatment period of three weeks and at the 30-day FU, the difference between groups improved statistically significantly in **pain** (assessed by an 11-point VAS scale) comparing OMT with the waiting list group (at 30-day FU: IG: mean -6.56 (SD 2.03), CG: -0.5 (1.03)). A clinically meaningful improvement could be found regarding the primary outcome of pain measured by the VAS [29]. The primary outcome of pain was not investigated in the other study [13].

Secondary outcomes

Schmerzmittel, funktionelle Unabhängigkeit, Aufenthaltsdauer: keine Verbesserungen; Wirksamkeit der Rehabilitation verbessert

No statistically significant changes from admission to discharge could be observed in the **daily analgesic medication use**. No statistically significant differences from admission to discharge could be found concerning **functional independence** and **daily analgesic medication use**. At rehabilitation unit discharge, a statistically significant enhancement in the **rehabilitation efficiency** ($p<0.05$) was observed, but not in the **length of stay**. There were no statistically significant changes from admission to four weeks after discharge in **general health** [13].

Oberschenkelflexibilität, Funktionalität, Schiefstellung des Knies, Sohlendruck, Bewegungsumfang in Hüfte: heterogene Ergebnisse

After a treatment period of three weeks, the change between the two groups improved statistically significantly in **posterior thigh flexibility** ($p<0.05$). **Functionality** was statistically significantly enhanced compared to OMT with the exercise programme group. **Dynamic knee valgus** and **plantar pressure in the middle foot** statistically significantly improved when comparing OMT with the exercise and the waiting list group. The outcome of **hip ROM** was not statistically significant, comparing OMT with the exercise and the waiting list group. At the 30-day FU, statistical differences and effect sizes could only be found in the variables functionality and plantar pressure in the middle foot. Not all data were reported in this study [29].

Safety

nicht berichtet

Adverse events and side effects were not reported in both studies [13, 29].

Conclusion

heterogene Ergebnisse

To conclude, in the study assessed, OMT effectively reduced knee **pain** in patients with patellofemoral pain syndrome [29]. The authors of the other RCT stated that OMT does not appear to be efficacious in acute rehabilitation patients who recently underwent surgery for knee or hip osteoarthritis or a hip fracture [13] (see Appendix Table A-18).

Foot

Myofascial Release

Two studies were selected to examine the effectiveness of myofascial release compared to exercise programme, myofascial release and exercise programme or no intervention [30] and sham ultrasound therapy [31].

Risk of bias

unklares Verzerrungsrisiko

The RoB was unclear in both studies due to the unclear generation of randomisation sequence, allocation concealment, blinding process, and outcome reporting [30, 31].

Outcome measurements

The NRS assessed pain intensity [30], pain, disability and activity restriction was rated using the Foot Function Index, and a pressure algometer evaluated pressure pain thresholds [31]. Furthermore, foot load distribution and selected static/dynamic foot indicators were measured by the FreeMed ground reaction force platform [30].

Numerische Schmerz-Bewertungsskala

Primary outcome

The 4-arm RCT [30] found statistically significant differences before and after the interventions (i.e. myofascial release (left foot: mean -3.26 (SD 2.54), $p<0.01$; right foot: -2.66 (1.63), $p<0.01$), exercise (left foot: -1.93 (2.12) $p<0.05$; right foot: -1.66 (1.79), $p<0.05$)) concerning the outcome **pain intensity** (measured by NRS scale) for both feet. The control group did not statistically significantly improve on any side of the feet. A statistically significant enhancement in a between-group comparison could only be observed after a treatment period of four weeks by comparing the myofascial release group with the control group by assessing the left ($p<0.05$) and right ($p<0.05$) foot but not comparing myofascial release with the exercise group. A clinically meaningful intra-group improvement in the osteopathic intervention group measured by the NRS could be found [30].

Schmerzintensität: statistisch und klinisch relevante Verbesserungen

The double-blind RCT [31] measured the effectiveness of 12 sessions of myofascial release after a treatment period of four weeks and a FU at week 12 after randomisation. After 12 sessions, in the intervention group, a 72% reduction in **pain, disability and activity restriction** could be found, whereas in the control group, the outcomes were only reduced by 7%. At the FU at week 12 after randomisation, there was still a 61% reduction measured in the intervention group but only a 2% reduction in the control group. A statistically significant improvement after 12 sessions and at the FU assessment ($p<0.001$, respectively) comparing the two groups could be observed, favouring the myofascial release group. **Pressure pain thresholds** improved in the intervention group over the gastrocnemius, soleus, and calcaneus muscle after 12 sessions and at the FU assessment ($p<0.001$, respectively) [31].

Schmerz, Aktivitäts(einschränkung), Druckschmerz: statistisch signifikante Verbesserungen

Secondary outomes

No secondary outcomes were assessed in both studies.

nicht untersucht

Safety

No adverse events occurred [31] or were reported [30]. Furthermore, both studies did not report any side effects.

keine unerwünschten Ereignisse (berichtet)

Conclusion

To summarise, a limited influence of both exercises and myofascial release techniques on **pain** and selected **static and dynamic indicators** of a flat foot could be observed [30]. Myofascial release was more effective than sham ultrasound therapy regarding **pain, disability and activity restriction**, and **pressure pain** [31] (see Appendix Table A-19).

Verbesserungen: (Druck)schmerz, statische/dynamische Indikatoren, Aktivitäts(einschränkung)

Osteoporosis

osteopathische manipulative Behandlung

One study compared OMT with sham manipulative treatment [33].

Risk of bias

hohes Verzerrungsrisiko

The RoB was high mainly due to a lack of blinding but also because of unclear allocation concealment and outcome reporting [33].

Outcome measurements

VAS

The outcome pain was assessed with the VAS and QoL with the QoL Questionnaire of the European Foundation for Osteoporosis [33].

Primary outcome

Schmerz: heterogene Ergebnisse

After a treatment period of six weeks, there was no statistically significant mean between-group difference regarding **pain** measured by the VAS (IG: pre 4.4 (SD 2.6), post: 4.1 (1.9), CG: pre 4.8 (2.5), post 4.6 (2.7), n.s.). However, in the **subscale pain** of the QUALEFFO-41, the OMT group statistically significantly improved ($p<0.01$) [33].

Secondary outcomes

LQ: heterogene Ergebnisse in Subskalen

QoL statistically significantly enhanced ($p<0.01$) due to OMT after a treatment period of six weeks; also, the subscales perception of health ($p<0.01$) and path/mobility ($p<0.05$) improved, but not mental well-being, daily activities, housework, and leisure activities [33].

Safety

nicht aufgetreten/berichtet

No adverse events occurred, and side effects were not reported [33].

Conclusion

Verbesserung: LQ

In conclusion, the authors of the RCT stated that in a group of elderly subjects affected by osteoporosis, OMT was able to increase self-reported **QoL**, while the effect on **body pain perception** is unclear [33] (see Appendix Table A-20).

Fibromyalgia

Cranio-Sacral, Myofascial Release

Two studies investigated the effects of craniosacral therapy [46] and myofascial release [35] compared to placebo/sham in patients with fibromyalgia.

Risk of bias

unklares bis hohes Verzerrungsrisiko

The RoB was unclear due to the unclear generation of randomisation sequence, allocation concealment and outcome reporting [46] and high mainly due to inadequate generation of randomisation sequence and a lack of blinding but also because of unclear allocation concealment and outcome reporting [35].

Outcome measurements

VAS, McGill Schmerz-Fragebogen

The VAS was used for measuring pain in both studies. In one study, pain was also rated by the MPQ [35]. The 10-item Fibromyalgia Impact Questionnaire evaluated physical functioning, fatigue, tiredness on walking, and stiffness [35]. Clinical severity/improvement was assessed by the Clinical Global Impression Severity/Improvement Scale, postural stability by a stabilometer plat-

form, and the number of days feeling good provided information about the mood [35]. QoL was rated by the short form-36 health survey, sleep quality by the Pittsburgh Sleep Quality Index, depression by the Beck depression inventory, and anxiety by the State Trait Anxiety Inventory [46].

Primary outcome

Schmerz: statistisch und klinisch relevante Verbesserungen *nur* unmittelbar nach Behandlung

Diskrepanzen bei FUs

After a treatment period of twenty-five weeks, there was a statistically significant between-group difference in favour of the craniosacral therapy group in **pain** (measured by the VAS) (baseline: IG: mean 9.13, CG: 8.9; post-treatment: IG: mean 8.18, CG: 8.88; $p<0.05$) but not at the six months and one year FU [46]. In the second study, the two groups statistically significantly differed in the outcomes of **pain** (measured by MPQ and VAS) and **pain**[12] **(sensory, affective and 'sensory + affective')** after a treatment period of 20 weeks and at the six months FU ($p<0.05$, respectively) (e.g. pain measured by VAS: mean between-group difference post-treatment: IG: 7.98 (SD 1.03); CG: 8.87 (SD 1.01); at 6-months FU: IG: 8.25 (1.13), CG: 8.94 (1.34)). There was also a clinically meaningful improvement (measured by the MPQ and VAS) in the osteopathic intervention group. At the one-year FU, only **'pain sensory' and 'pain sensory + affective'** statistically significantly differed ($p<0.05$, respectively), but not pain (MPQ, VAS) and pain affective [35].

Secondary outcomes

LQ, Angst, Depression/Stimmung, Schlafqualität: heterogene Ergebnisse

After a treatment period of twenty-five weeks, there was a statistically significant between-group difference in favour of the craniosacral therapy group in **QoL** (i.e. physical function ($p<0.01$); physical role, body pain, general health, vitality, and social function ($p<0.05$, respectively)). In the subscales of emotional role and mental health, the between-group differences did not statistically significantly differ. Furthermore, the between-group difference in **trait anxiety** and **sleep quality** ($p<0.05$, respectively) statistically significantly improved but not **state anxiety** and **depression** [46]. However, in the second study, **mood** differed statistically significantly between the two groups after a treatment period of 20 weeks and at the FU at six months and one year ($p<0.05$, respectively) [35].

LQ, Vitalität, Schlafqualität: heterogene Ergebnisse

At the six months FU, the two groups statistically significantly differed in the outcomes **QoL** (only items physical function and vitality), **vitality**, and **sleep quality** (only items sleep duration/disturbance, habitual sleep efficiency) ($p<0.05$, respectively). No difference could be observed for all other items. At the 1-year FU, only **sleep quality** (only items sleep duration, habitual sleep efficiency, daily dysfunction) statistically significantly improved ($p<0.05$) due to craniosacral therapy [46].

Erschöpfung (beim Gehen), klinische Verbesserung/ Schweregrad, körperliche Funktionsfähigkeit/ Stabilität, Steifheit: heterogene Ergebnisse

Fatigue and **clinical improvement** differed statistically significantly between the two groups after a treatment period of 20 weeks and at the FU at six months and one year ($p<0.05$, respectively). **Physical functioning**, **stiffness**, and **clinical severity** statistically significantly differed after a treatment period of 20 weeks and at the FU at six months but not at the 1-year FU ($p<0.05$, respectively). However, there was a statistically significant improvement in the outcome of **tiredness on walking** only at the 20 weeks assessment, and **postural stability** did not differ between the two groups at any test point [35].

[12] The authors assessed pain in three different dimensions (i.e. sensory, affective, and sensory + affective) of fibromyalgia syndrome.

Safety

nicht aufgetreten/ berichtet

In both studies, no adverse events occurred, and side effects were not reported [35, 46].

Conclusion

Verbesserungen: Schmerz, Angst, LQ, Erschöpfung, Schlaf, körperliche Funktionsfähigkeit, klinischer Schweregrad

To conclude, approaching fibromyalgia through craniosacral therapy improves **anxiety** and **QoL** levels in the studies assessed. Craniosacral therapy reduces the perception of **pain** and **fatigue** and improves their **night rest**, increasing **physical function** [46]. Myofascial release techniques can be seen as a complementary therapy for **pain** symptoms, **physical function** and **clinical severity** but did not improve **postural stability** in patients with fibromyalgia syndrome [35] (see Appendix Table A-21).

3.3 Summary of effectiveness outcomes, test points, number of sessions, treatment period, professionals involved, type and safety of osteopathic interventions

Tabelle mit Übersicht zu Wirksamkeits-Ergebnissen, Testzeitpunkten, Behandlungseinheiten, -zeiträumen und -techniken

An overview of effectiveness outcomes, test points, number of sessions, treatment period, professionals involved, and type of osteopathic interventions can be found in Table 3-1. In this table, ✓ stands for statistically significant improvements (inter-group differences) favouring the intervention group, **X** for no statistically significant differences, and ‡ for clinically meaningful improvement in the osteopathic intervention group. Test points were summarised into four categories:

- Immediately after intervention (0-7 days after the end of treatment)
- Short-term effects (1-month FU)
- Mid-term effects (3-6 months FU)
- Long-term effects (1-year FU)

Abbildung zeigt Ergebnisse zu Endpunkt Schmerz

Figure 3-2 summarises the effectiveness of osteopathic interventions on the primary outcome of pain. Finally, the safety aspects of osteopathic interventions are summarised.

3.3.1 Effectiveness outcomes, test points, number of sessions and treatment period

Zusammenfassung fokussiert auf statistisch signifikanten Gruppenunterschieden

The following summary focuses on statistically significant between-group differences and statistically non-significant differences. Details on mean group-differences and effect sizes (if available) can be found in the respective chapters and in the data extraction tables (see Table A-13 to Table A-21).

Neck pain

4 RCTs zu Nackenschmerzen …

Regarding the region of the neck (n=4 with unclear to high RoB), two RCTs assessed only one session of osteopathic treatment and had no FU. The other two RCTs applied five to eight sessions within two to eight weeks and assessed outcomes at short-term and mid-term FUs. Pain intensity and level of pain improved in three of four studies immediately after the intervention. The

study without improvement assessed the effect of only one session of osteopathic treatment. Statistically significant between-group differences regarding pain intensity/level of pain could be found at the short- or mid-term FU in one study each. Furthermore, a clinically meaningful intra-group difference in the osteopathic group could be observed in three of four studies regarding pain intensity and level of pain.

… Schmerzintensität: Verbesserung direkt nach Behandlung in 3/4 RCTs, kurz- bzw. mittelfristige Effekte in jeweils 1 RCT

Other pain outcomes, such as pain on movement, myofascial trigger points, and pressure pain thresholds, partly improved after the treatment or at short-/mid-term FUs. However, other pain outcomes (e.g., pressure pain sensitivity, cervical joint range (i.e. objective pain)) showed no statistically significant between-group improvements.

heterogene Ergebnisse bei weiteren Schmerz-Endpunkten

Regarding functionality outcomes, such as ROM, functional disability and mobility restriction, the results were heterogeneous, with mid-term improvements in one RCT but no differences in another RCT. Results regarding QoL were also heterogeneous.

heterogene Ergebnisse bei Funktionalität und LQ

Neck or (low) back pain

For the regions with a mixed population of neck or (low) back pain (n=2 with high RoB), one RCT applied one session of osteopathy and had no FU. The other RCT assessed four sessions within two months and immediate and mid-term results. Pain was only significantly reduced in one RCT, however, the outcome 'spinal pain and disability' improved immediately after the treatment in the other RCT. There were no statistically significant pain improvements at the mid-term FUs. Mental health improved significantly in one study after the treatment and at mid-term FU. The other outcomes (physical health, QoL) did not show statistically significant group differences.

2 RCTs zu Nacken- oder Kreuz-/Rückenschmerzen

teilweise (tw.) Verbesserung der Schmerzen direkt nach der Behandlung

Shoulder pain

For shoulder pain (n=2 with unclear to high RoB), one RCT assessed four sessions of osteopathic treatment in a period of four weeks and had FUs until one year. The other RCT did not specify the number of sessions assessed within seven days and had no FU. Pain and 'shoulder pain and disability' were improved at all test points at short-, mid- and long-term FUs in one study and showed no significant group difference immediately after treatment in the other RCT. However, a statistically and clinically meaningful intra-group improvement in the osteopathic group could be observed after seven days.

2 RCTs zu Schulterschmerzen

kurz-, mittel-, langfristige Verbesserung der Schmerzen in 1/2 RCTs

No improvement was found in the outcome ROM in either of the studies. The other outcomes (arm, shoulder and hand disability, change in activities, activity/functionality) showed heterogeneous results, with some improvements at specific test points.

heterogene Ergebnisse zu anderen Endpunkten

Low back pain

For low back pain (n=1 systematic review with ten included RCTs with high overall confidence in the study), the primary outcome of **pain** was reduced immediately after, on average, nine osteopathic sessions within a treatment period of ten weeks. Also, at the mid-term FU, pain was still improved.

The **functional status** also enhanced immediately after the treatment period, however, not at the mid-term FU.

1 Übersichtsarbeit zu Kreuzschmerzen: Verbesserung direkt nach Therapie (Schmerz, Funktionalität) und mittelfristig (nur Schmerz)

Knee pain

2 RCTs zu Knieschmerzen: kurzfristige Verbesserung der Schmerzen in 1 RCT

Regarding knee pain (n=2 with unclear RoB), one RCT assessed five sessions of osteopathic treatment[13], and the other RCT applied six sessions within three weeks. Both had a FU of one month. Pain was statistically significantly reduced in one RCT immediately after treatment and at short-term FU. Further, a clinically meaningful intra-group difference in the osteopathic group could be observed. The other study found no improvement in general health, including bodily pain, at the short-term FU.

tw. kurzfristige Verbesserungen bzw. heterogene Ergebnisse

Functionality and plantar pressure were positively affected at both test points in one study; the other outcomes showed no improvements or heterogeneous results.

Foot pain

2 RCTs zu Fußschmerzen: Reduktion der Schmerzen nach der Behandlung (2 RCTs) bzw. mittelfristig (1 RCT)

For the region of the foot (n=2 with unclear RoB), two RCTs applied eight and 12 treatment sessions within four weeks. One study had a mid-term FU, while the other only assessed outcomes immediately after the treatment. Pain outcomes (pain intensity, pressure pain thresholds, 'pain, disability and activity restriction') improved statistically significantly after the intervention and at the mid-term FUs. Also, a clinically meaningful reduction in pain was observed in one study.

Osteoporosis

1 RCT zu Osteoporose: keine Verbesserung der Schmerzen

In the elderly with osteoporosis (n=1 with high RoB), outcomes were only assessed immediately after six sessions of OMT within a treatment period of six weeks. The primary outcome of pain did not improve after the treatment. However, in the subscale 'pain' of the QoL assessment, pain was reduced.

tw. Verbesserung der LQ direkt nach Therapie

QoL improved after the six sessions as well as the subscales perception of health and path/mobility. Mental well-being, daily activities, housework, and leisure activities did not enhance.

Fibromyalgia

2 RCTs zu Fibromyalgie: unmittelbare Verbesserung der Schmerzen, jedoch heterogene Ergebnisse bei FUs

For fibromyalgia (n=2 with unclear to high RoB), one RCT applied 50 sessions in a period of 25 weeks and the other ten sessions within 20 weeks. Both had FUs until one year. Pain outcomes showed statistically significant between-group differences after the treatment and at mid-term FU in one study; also, a clinically meaningful improvement in the osteopathic group was observed, measured by the VAS and MPQ. In the other study, pain was only reduced immediately after treatment but not at the FUs.

tw. Verbesserungen in anderen Endpunkten, z. B. manche Subskalen zu LQ und Schlafqualität, Stimmung, Erschöpfung, etc.

Regarding QoL, most subscales (e.g. physical/social function, general health, vitality; except emotional role and mental health) improved immediately after the treatment but not at the FUs in one RCT. Regarding sleep quality, results were heterogeneous, with some improvements even at the mid- and/or long-term FUs (e.g., sleep duration, habitual sleep efficiency) but no improvements in other outcomes. In the other RCT, statistically significant group differences were observed for physical functioning, mood, fatigue, stiffness, clin-

[13] This RCT included a mixed population of patients with hip or knee pain; the results were not reported separately.

ical severity and clinical improvement (some of them not at the long-term FU) but not for postural stability and tiredness on walking (only immediately after treatment).

Summary of effects of the primary outcome pain

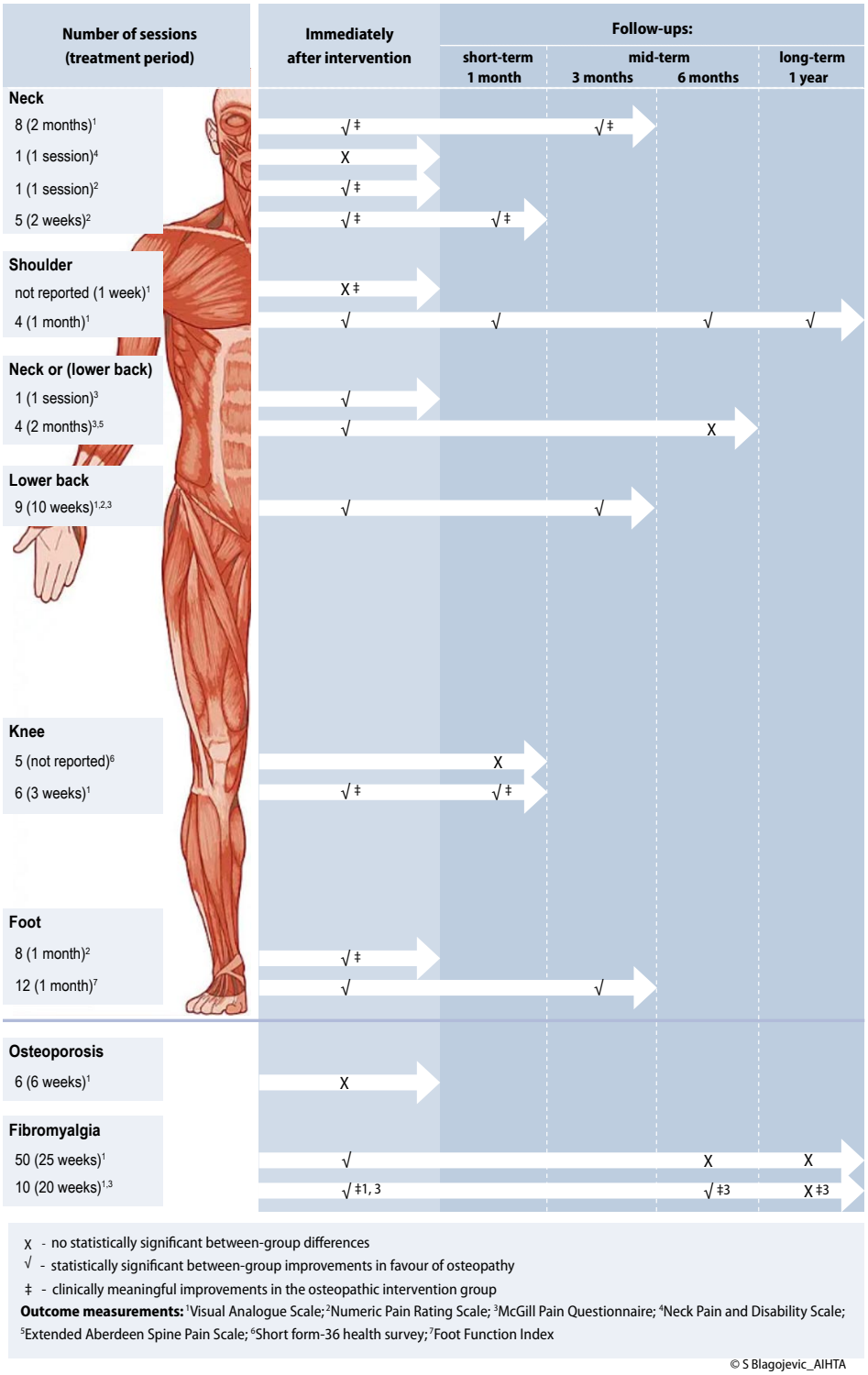

Figure 3-2: Summary of the effectiveness of osteopathic interventions on the primary outcome pain

3.3.2 Professionals involved

Osteopath*innen, (Physio)therapeut*innen/ Ärzt*innen (mit osteopathischer Ausbildung) etc.

Summarising the results regarding the different professions applying osteopathic techniques, operators with various occupations could be found. In four of sixteen studies, osteopaths performed the osteopathic intervention. In one study, physiotherapists and in three further studies, physiotherapists with advanced osteopathic qualifications applied osteopathic techniques. Osteopathic techniques were further applied by a therapist with osteopathic certification (n=1), a therapist (n=1), an expert craniosacral therapist (n=1), medical students of the Department of Osteopathic Manipulative Medicine (n=1), or general practitioners with osteopathic education (n=2). Two studies did not report who applied the intervention.

3.3.3 Type of osteopathic intervention

am häufigsten angewandt: Myofascial Release (5 RCTs), Cranio-Sacral-Therapie und OMT (jeweils 2 RCTs)

Various types of osteopathic interventions were applied in the included studies. Myofascial release was most often used (5 studies), followed by craniosacral therapy and OMT (2 studies, respectively). Furthermore, the operators used strain—counterstrain treatment, pressure release, fascial release, osteopathic spinal manipulation, and muscle energy technique (1 study, respectively). One study applied osteopathic interventions, and another used one or a combination of myofascial release, strain—counterstrain, muscle energy, soft tissue, high-velocity low-amplitude, or craniosacral manipulation.

Table 3-1: Summary of effectiveness outcomes, test points, number of sessions, treatment period, professionals involved, and type of osteopathic interventions

Outcomes	Time of testing, group difference (✓ s.s./X n.s.)					Number of sessions (treatment period)	Intervention applied by (profession)	Type of osteopathic intervention	[Ref]
	Immediately after intervention: 0-7 days after end of treatment	Short-term FU: 1-month FU	Mid-term FU		Long-term FU: 1-year FU				
			3-months FU	6-months FU					
Neck									
Pain:						8 (8 weeks)[14]	Physiotherapists with advanced craniosacral therapy qualification	Craniosacral therapy	[50]
Pain intensity	✓‡		✓‡						
Pain on movement	✓		✓						
Point of max. pain	✓		X						
Pain acceptance	X		X						
Pressure pain sensitivity:									
Musculus levator scapulae	X		X						
Musculus trapezius	✓		X						
Musculus semispinalis capitis	X		X						
Physical health:									
Functional disability	✓		✓						
Physical QoL	✓		✓						
Physical well-being	X		X						
Mental health:									
Mental QoL	X		X						
Anxiety	X		✓						
Depression	X		X						
Stress perception	X		X						
Body awareness:									
Body awareness	✓		X						
Body dissociation	X		X						
Global improvement	✓		✓						

[14] "Outcomes were assessed before and after treatment (week 8) and again 3 months later (week 20)."

Outcomes	Time of testing, group difference (✓ s.s./X n.s.)					Number of sessions (treatment period)	Intervention applied by (profession)	Type of osteopathic intervention	[Ref]
	Immediately after intervention: 0-7 days after end of treatment	Short-term FU: 1-month FU	Mid-term FU		Long-term FU: 1-year FU				
			3-months FU	6-months FU					
Pain intensity	X					1 (1 session)[15]	General practitioner with completed full osteopathic curriculum	Strain—counterstrain treatment	[51]
Mobility restriction	X								
Level of pain (subjective pain)	✓‡					1 (1 session)	NR	Pressure release	[15]
Myofascial trigger points of sternocleidomastoid muscle right/left (objective pain)	✓								
Cervical joint range (objective pain)	X								
QoL	X								
Pain intensity	✓‡	✓‡				5 (2 weeks)[16]	Therapist with experience and certificate in myofascial release therapy	Myofascial release	[52]
Pressure pain thresholds:									
Suboccipita left/right	✓	✓							
Thoracic left	X	X							
Thoracic right	✓	✓							
Cervical active ROM:									
Flexion	X	X							
Extension	X	X							
Side bending left/right	X	X							
Rotation right	X	✓							
Rotation left	✓	✓							
Neck or (lower back)									
Pain	✓					1 session (1 session)[17]	Osteopath	Fascial release	[53]

[15] „After receiving the allocated treatment patients underwent a second measurement."

[16] Patients were assessed „at the end of treatment and at 1-month follow-up."

[17] Patients were assessed 3 days after the session.

Outcomes	Time of testing, group difference (✓ s.s./X n.s.)					Number of sessions (treatment period)	Intervention applied by (profession)	Type of osteopathic intervention	[Ref]
	Immediately after intervention: 0-7 days after end of treatment	Short-term FU: 1-month FU	Mid-term FU		Long-term FU: 1-year FU				
			3-months FU	6-months FU					
Spinal pain and disability	✓			X		4 (2 months)[18]	General practitioner registered as osteopath	Osteopathic spinal manipulation	[54]
Pain	X			X					
Physical health	X			X					
Mental health	✓			✓					
QoL	X			X					
Shoulder									
Pain	X‡					NR (7 days)[19]	Physiotherapists	Myofascial release	[28]
ROM: Cervical flexion/ extension, Cervical side flexion (right/left) and Cervical rotation (right/left)	X								
Neck disability	X								
Pain	✓	✓		✓	✓	4 (4 weeks)[20]	Osteopath	Muscle energy technique	[27]
Shoulder pain and disability	✓	✓		✓	✓				
Arm, shoulder and hand disability	✓	X		✓	✓				
Change in activities	✓	✓		X	X				
Activity/functionality	✓	X		X	✓				
ROM (standing posture, thoracic flexion, thoracic extension, total thoracic ROM)	X								
Lower back									
Pain	✓		✓			9 (10 weeks)[21]	NR	Osteopathic interventions	[9]
Functional status	✓		X						

[18] Patients were assessed „before randomization, after 2 months when treatment in the intervention group was complete, and finally after 6 months. ”

[19] Patients were assessed „on seventh day following intervention.”

[20] „Measures (were) recorded at baseline, discharge, 4-week follow-up, 6 months, and 12 months.”

[21] Presented in means. 12 weeks follow-up.

Outcomes	Time of testing, group difference (✓ s.s./X n.s.)					Number of sessions (treatment period)	Intervention applied by (profession)	Type of osteopathic intervention	[Ref]
	Immediately after intervention: 0-7 days after end of treatment	Short-term FU: 1-month FU	Mid-term FU		Long-term FU: 1-year FU				
			3-months FU	6-months FU					
Knee									
Functional independence	X					5 (NR)[22]	Osteopathic medical students	One or a combination of: myofascial release, strain—counterstrain, muscle energy, soft tissue, high-velocity low-amplitude (not at the surgical site), or craniosacral manipulation	[13]
Daily analgesic medication use	X								
Length of stay	X								
Rehabilitation efficiency	✓								
General health (physical functioning, physical role limitations, bodily pain, general health, vitality, social functioning, emotional role limitations, mental health)		X[23]							
Pain	✓‡	✓‡				6 (3 weeks)[24]	Osteopath	OMT	[29]
Functionality	✓	✓							
Dynamic knee valgus	✓	X							
Plantar pressure in middle foot	✓	✓							
Posterior thigh flexibility	✓	X							
Hip ROM	X	X							
Foot									
Pain intensity (left/right foot)	✓‡					8 (4 weeks)[25]	Therapist	Myofascial release	[30]
Pain, disability and activity restriction	✓		✓			12 (4 weeks)[26]	Physiotherapists certified in myofascial release	Myofascial release	[31]
Pressure pain thresholds (Gastrocnemius, Soleus and Calcaneus)	✓		✓						

[22] Measures were taken from rehabilitation unit admission to discharge, at rehabilitation unit discharge, from rehabilitation unit admission to 4 weeks after discharge.

[23] "The research coordinator subsequently conducted SF-36 telephone interviews 4 weeks after discharge from the rehabilitation unit."

[24] Patients were assessed „before the interventions, after the 6 interventions, and at 30-day follow-up."

[25] Patients were assessed before and after therapy.

[26] Measures were taken at „week 1 (pretest score), week 4 (posttest score), and follow-up at week 12 after randomization."

Outcomes	Time of testing, group difference (✓ s.s./X n.s.)					Number of sessions (treatment period)	Intervention applied by (profession)	Type of osteopathic intervention	[Ref]
	Immediately after intervention: 0-7 days after end of treatment	Short-term FU: 1-month FU	Mid-term FU		Long-term FU: 1-year FU				
			3-months FU	6-months FU					
Osteoporosis									
Pain	X					6 (6 weeks)[27]	Osteopath	OMT	[33]
QoL	✓								
QoL-subscales:									
Pain	✓								
Perception of health	✓								
Path/Mobility	✓								
Mental well-being	X								
Daily activities	X								
Housework	X								
Leisure activities	X								
Fibromyalgia									
Pain	✓			X	X	50 (25 weeks)[28]	Expert craniosacral therapist	Craniosacral therapy	[46]
State anxiety	X			X	X				
Trait anxiety	✓			X	X				
Depression	X			X	X				
QoL:									
Physical function	✓			✓	X				
Physical role	✓			X	X				
Body pain	✓			X	X				
General health	✓			X	X				
Vitality	✓			✓	X				
Social function	✓			X	X				
Emotional role	X			X	X				
Mental health	X			X	X				

[27] Patients were assessed at the 1st and 6th session of treatment.

[28] Outcomes „were determined at baseline and at 10 minutes, 6 months and 1-year post-treatment."

Outcomes	Time of testing, group difference (✓ s.s./X n.s.)					Number of sessions (treatment period)	Intervention applied by (profession)	Type of osteopathic intervention	[Ref]
	Immediately after intervention: 0-7 days after end of treatment	Short-term FU: 1-month FU	Mid-term FU		Long-term FU: 1-year FU				
			3-months FU	6-months FU					
Sleep quality:									
Subjective sleep quality	✓			X	X				
Sleep latency	X			X	X				
Sleep duration	✓			✓	✓				
Habitual sleep efficiency	X			✓	✓				
Sleep disturbance	✓			✓	X				
Daily dysfunction	X			X	✓				
Pain (MPQ)	✓‡			✓‡	X‡	10 (20 weeks)[29]	Physiotherapist specialised in myofascial therapy	Myofascial release	[35]
Pain: sensory	✓			✓	✓				
Pain: affective	✓			✓	X				
Pain: sensory + affective	✓			✓	✓				
Pain (VAS)	✓‡			✓	X				
Physical functioning	✓			✓	X				
Mood	✓			✓	✓				
Fatigue	✓			✓	✓				
Tiredness on walking	✓			X	X				
Stiffness	✓			✓	X				
Clinical severity	✓			✓	X				
Clinical improvement	✓			✓	✓				
Postural stability	X			X	X				

Abbreviations: ✓, statistically significant improvement favouring the osteopathic intervention group. **X,** *no statistically significant difference.* **‡,** *clinically meaningful improvement in the osteopathic intervention group. FU, follow-up. max., maximum. MPQ, McGill Pain Questionnaire. NR, not reported. OMT, osteopathic manipulative treatment. QoL, quality of life. ROM, range of motion. s.s., statistically significant. n.s., not statistically significant. VAS, Visual Analogue Scale.*

[29] Patients were assessed after 20 weeks of myofascial therapy, at six months post intervention and at one year post intervention.

3.3.4 Safety

Adverse events

Ten of 16 included studies reported on adverse events of osteopathy. Thereof, adverse events occurred in three studies regarding neck and low back pain.

10/16 Studien berichten unerwünschte Ereignisse

For the region of the **neck**, three of four studies reported adverse events. Thereof, two studies reported that no (serious) adverse events occurred. However, minor adverse events during or subsequent to the treatment occurred in six patients and mild transient adverse effects in four patients. Patients reported pain, shivering, tiredness, strong emotional reactions, weeping, and dizziness.

Nacken: unerwünschte Ereignisse in 2/3 Studien

For the regions of the **neck or (lower) back,** one of two studies stated that no adverse events were occurring; the second study did not report adverse events. No adverse events occurred in treating **shoulder** pain by osteopathy; the other study did not state any events.

Nacken/Rücken/Schulter: keine unerwünschten Ereignisse

For the region of the **lower back**, the systematic review and meta-analysis concluded that increased pain occurred in ten subjects (1/10 study) and increased back muscle spasticity occurred on one occasion (1/10 study). There was no data collection (1/10 study), and the other studies did not report adverse events (7/10 studies).

Kreuz: unerwünschte Ereignisse

No adverse events were reported in both studies for the regions of the **knee**. No serious adverse events occurred regarding the region of the **foot**; the second study on foot did not report adverse events.

Knie: keine unerwünschten Ereignisse (berichtet)

No serious adverse events occurred for osteoporosis in the one included study. Also, for **fibromyalgia,** both studies stated that no adverse events occurred.

Osteoporose/Fibromyalgie: keine unerwünschten Ereignisse

Side effects

None of the 16 included studies reported side effects due to osteopathy.

4 Results of part 2: Overview of current training and quality requirements for osteopaths in Europe

Teil 2: Ausbildungs- und Qualitätsanforderungen

Worldwide, osteopaths have different training and quality requirements. Furthermore, different benchmarks for good osteopathic care exist. The following section will give a more detailed insight into Europe's training, education and legal regulation and its benefits. Furthermore, an overview of training, education and practice of osteopathy in selected countries will be provided.

4.1 Facts and types of the osteopathic profession

Osteopathie wird weltweit praktiziert

Osteopathy is practised widely around the world. Estimates suggest that there are 38 to 49 osteopaths per 100.000 people in France, 20 to 23 in Italy, 20 in Spain, between 11 and 20 in Australia, New Zealand, Switzerland, between five to ten in the UK, Norway and Sweden and fewer than one per 100.000 in Argentina, Brazil and Greece [3, 4, 42].

Two related types of osteopathic profession with different fields of activity can be distinguished:

osteopathische Ärzt*innen praktizieren hauptsächlich osteopathische Medizin

- Osteopathic physicians practise osteopathic medicine and are medically trained physicians. Most of them are trained in the USA and practise there under the designation 'DOs' (Doctors of Osteopathic Medicine). As the present report focuses on Europe, osteopathic physicians in den USA are not in the scope.

Osteopath*innen arbeiten hauptsächlich in Primärversorgung

- Osteopaths practise osteopathy and mainly work as first-contact practitioners in primary care. They provide osteopathic manual therapy care and may not prescribe medications. Osteopaths are trained in osteopathic care and must be able to diagnose and refer patients if therapeutic interventions outside of their competence are required [42].

Osteopathie wird weltweit in 46 Ländern praktiziert

A recently published article stated that osteopathy is practised in around 46 countries worldwide, with around 117,600 registered osteopathic physicians and around 79,300 osteopaths. Osteopaths practise in 35 countries, with legal regulation in 13 countries and recognition of the professions as health professions in further six countries at that time [3].

4.2 Regulation of the osteopathic profession and its benefits

12 europäische Länder mit gesetzlichen Regulierungen für Osteopath*innen

In 1993, the statutory recognition of osteopaths started in Europe with the Osteopaths' Act in the UK. European countries have followed the UK and recognised and developed osteopaths' regulations [4]. As of July 2022, osteopathy is regulated by law in the USA, New Zealand, Australia, and 12 European countries. The European countries are Denmark, Finland, France, the UK, Iceland, Lichtenstein, Luxembourg, Malta, Norway[30], Portugal, Switzerland and Cyprus [4, 67, 68]. Osteopaths need a minimum standard of education and training and must be formally registered to practise osteopathy legally [42]. However, the recognition and regulation of the practice of osteopathy vary widely from country to country [2]. In other countries, a regulation is not the case, and the osteopathy practice is neither formally recognised nor regulated [42].

gesetzlich reguliert bedeutet Berufsbezeichnung „Osteopath*in" ist gesetzlich geschützt

The term 'regulation' or 'regulated by law' is defined as *"that the title 'osteopath' is protected by law, and that osteopaths and/or osteopathic physicians can only use the titles if they meet certain statutory conditions in terms of competencies and registration and/or licensure. This would normally require statutory registration, as the health professional must comply with set standards of practice that protect the patients they treat; statutory regulation is set out in national or state/provincial law* [4, p. 5]." The European Federation & Forum for Osteopathy (EFFO), merging the former European Federation of Osteopaths (EFO) and the Forum for Osteopathic Regulation in Europe (FORE), published a report in 2021 [4] on the regulation of the osteopathic profession. The EFFO represents the osteopaths' lead professional associations and regulatory authorities from 22 European countries plus Canada and Israel and aims to establish regulation, standards, and recognition for European osteopaths. Hence, the recognition and awareness of the osteopathic profession's role can be advanced and high standards of osteopathic care and patient's safety can be ensured. The EFFO is a member of the Osteopathic International Alliance (OIA), a global osteopathic organisation of over 60 professional associations, universities, research groups, and regulators.

EFFO: Europäische Föderation & Forum für Osteopathie

EFFO empfiehlt gesetzliche Anerkennung und Regulierung von Osteopathie …

The EFFO recommends recognising and regulating osteopathy as an independent, primary healthcare profession and that the title 'osteopath' is protected by law. Osteopaths should only be able to use the title if certain statutory conditions in terms of competencies and registration and/or licensure are met. This requires statutory registration, which is set out in national or state/provincial law, and osteopaths must comply with set standards of practice that finally protect their patients. The benefits of high patient satisfaction, good patient outcomes, and safe practice can be seen in countries with properly trained and regulated osteopaths [4].

… und Einhaltung der Europäischen Norm für Osteopathie (EN16686)

The osteopathy profession has well-established, internationally recognised standards for practice and training. As mentioned in several European countries, the profession of osteopathy is legally licensed and regulated. In countries where this profession is not legally regulated, EFFO recommends compliance with the European Standard for Osteopathy (EN16686) [7] (see the following Chapter 4.3) [4].

[30] Title 'osteopath' regulated and protected as from 1st of July 2022. There is a transition period ending 1st of July 2023, until then, osteopaths can use the title as long as they present a formal application.

Regulierung führt zu Standardisierung und mehr Pts.-Sicherheit

The regulation of the osteopathic profession leads to appropriate, recognised, and standardised education, improving patient safety. Protecting the title 'osteopath' ensures that osteopaths have the competencies and skills to convey effective and safe osteopathic treatments [4].

National regulation should take into account international standards. The following section gives an overview of osteopathic standards.

4.3 Osteopathic standards

2 internationale Standards für Osteopathie

Two documents for international standards for osteopathy have been published:

- the WHO Benchmark for Training in Osteopathy, and
- the CEN standard.

These two standards are almost congruent, as the preexisting WHO benchmarks were taken into account in the development of the CEN standard [4].

4.3.1 The WHO Benchmark for Training in Osteopathy

beschreibt Berufsprinzipien und Ausbildungsprogrammarten …

The Benchmark for Training in Osteopathy was published in 2010 by the WHO. It describes the core philosophy and principles of the profession, the types of osteopathic training programmes, core competencies, and a benchmark training curriculum [4].

…für eine Standardisierung und sichere Praxis

The document sets out what the community of practising osteopaths considers to be appropriate models and levels of education and training in osteopathy, with consumer protection and patient safety as the core of professional practice. They are intended to:

- *"support countries to establish systems for the qualification, accreditation or licensing of practitioners of traditional medicine;*
- *assist practitioners in upgrading their knowledge and skills in collaboration with providers of conventional care;*
- *allow better communication between providers of conventional and traditional care as well as other health professionals, medical students and relevant researchers through appropriate training programmes;*
- *support integration of traditional medicine into the national health system"* [2, p. 10].

The benchmarks provide a reference point to which actual practice can be compared and evaluated. It provides training benchmarks for all trainees and what the community of practitioners considers to be contraindications for safe practice and for minimising the risk of accidents [2].

4.3.2 The European Standard on osteopathic healthcare provision (EN16686)

Maßstab für hochwertige Ausbildung, Sicherheit, klinische Praxis und Ethik für Osteopathie in Europa

2015 formell genehmigt und in 33 Länder auf nationaler Ebene veröffentlicht

The European Standard on osteopathy (EN16686) was developed in 2011 by the Project Committee on 'Services for Osteopaths' (CEN/TC 414) of the European CEN [7]. The CEN Standard sets a benchmark for high-quality education, safety, clinical practice, and ethics for osteopathy in Europe and serves as a key reference for the legislative work related to regulation [4]. For the first time, pan-European standards of osteopathy have been formally agreed expected for delivering high-quality osteopathic care, education, ethics, and safety in Europe. The Standard brought together European healthcare professionals and was initiated and led by the Forum for Osteopathic Regulation in Europe and the European Federation of Osteopaths. The Project Committee's secretariat was provided by CEN's members in Austria (Austrian Standards). In 2015, the Standard was formally approved and published nationally in 33 European countries. The Standard does not supersede national legislation in European countries with regulations on osteopathy, e.g. Finland, France, Iceland, Malta, Portugal, Switzerland and the UK [7].

gemeinsame Kernkompetenzen bei Diagnose, Management und Behandlung

Regarding quality clinical care, osteopaths share core competencies (e.g. basic, clinical and osteopathic sciences and clinical skills) that guide them in diagnosing, managing and treating patients and, therefore, form the foundation for the osteopathic approach to healthcare. Within the European Standard, an understanding of osteopathic models of disease and health, critical awareness of relevant research and practice and principles of relevant healthcare approaches should be provided for osteopaths [7].

ethische und berufliche Verhaltensstandards

Osteopaths shall follow high standards of ethical and professional behaviour. They shall comply with any legal requirements or regulations within their country and, therefore:

- *"act in the patient interest,*
- *work in partnership with the patient,*
- *maintain public trust and confidence in the osteopathic profession,*
- *maintain, respect and protect patient information, and*
- *work in partnership with healthcare providers"* [7, p. 2].

Ausbildungs- und Trainingsstandards

Thus, high education and training standards are essential to delivering quality care in a high standard of training and education. The European Standard distinguishes between two types of training (Type I or Type II, for more information, see the following Chapter 4.4), both of which are intended to deliver the same learning outcomes. According to the European Standard, osteopaths shall also continue professional development (CPD, Continuing Professional Development), which includes maintaining and developing their skills and knowledge of osteopathic treatment and science [7].

mehr Vertrauen in Kompetenzen von Osteopath*innen

Due to the European Standard with greater consistency in osteopathic qualifencies if they move to another country. Furthermore, the osteopathic profession's interaction with European institutions and stakeholders is enhanced [7].

As mentioned above, a uniform standard of training and education for osteopaths is considered important. The following chapter gives an overview of education and training and their standards.

4.4 Osteopathic education and training

Maßstäbe für Ausbildung

Regulating and preventing practice by unqualified osteopaths require proper education, training, examination and licensing system. Benchmarks for training have to consider

- the training content,
- the training method,
- to whom training is provided and by whom,
- roles and responsibilities of future osteopaths, as well as
- required education levels to undertake training [2].

2 Arten von Ausbildung:

According to experts, time is required to gain adequate knowledge of osteopathy. Depending on prior training and clinical experience of training a distinction between two types of training can be made:

Typ I: wenig/keine Ausbildung im Gesundheitsbereich

- Type I: for future osteopaths with no or little prior healthcare training but with a high school education or equivalent (typically four-year, full-time programmes; 4,200-4,800 hours, including at least 1,000 hours of supervised clinical practice and training including completing a thesis or project), and

Typ II: Personen mit Ausbildung in Gesundheitsberuf

- Type II: for future osteopaths with prior training as healthcare professionals where the course length and content may be modified depending on the prior training, knowledge and experience (2,000 hours over a minimum of four years, including at least 1,000 hours of supervised clinical practice and training) [2, 7].

Kompetenzen in Ausbildungsprogrammen und Maßstab für Ausbildungscurriculum

Learning outcomes shall be the same for both types. Some essential competencies in practice in all training programmes are, e.g. expertise in the diagnostic and OMT of neuromusculoskeletal disorders, knowledge of indications for and contraindications to osteopathic treatment, understanding of the body's biomechanics, and ability to appraise medical/scientific literature critically. The benchmark training curriculum for osteopathy is divided into six parts:

- basic science (e.g. anatomy, physiology, biomechanics),
- clinical science (e.g. models of health and disease, pathophysiology),
- osteopathic science (e.g. osteopathic models and techniques, joint physiology and kinetics),
- practical skills (e.g. physical/clinical examination, orthopaedic diagnosis, understanding of relevant research),
- osteopathic skills (e.g. different osteopathic techniques), and
- practical supervised clinical experience (in appropriate osteopathic clinical environment providing high-quality clinical support and teaching) [2].

klinische Praxis und Ausbildung unter Aufsicht

During training, several hours must be spent through supervised clinical practice and training. Osteopathic skills and physical examination must be delivered through direct contact. In contrast, other academic curriculum content (e.g. basic knowledge and understanding of standard medical treatments) can be delivered in various training formats [7].

Curriculum legt Fokus auf Pts.

The curriculum teaches its elements with a focus on the patient (rather than the disease), emphasising the important therapeutic partnership between patient and therapist and seeing the patient as someone who wants to promote optimal health [7].

Qualifikationsnachweis sollte das Bildungsniveau sein

According to the EFFO, osteopath education programmes should meet national requirements for recognised qualifications, when applicable. Proof of qualification should state the level of education, preferably in the format of university degrees based on a defined level of the European Credit Transfer and Accumulation System (ECTS) or equivalent. Proof of qualification should be supported by a transcript of records or similar, describing the content and amount of training, preferably stating the number of ECTS [4].

Bildungsanbieter sollten regelmäßig extern überprüft werden

Education providers should regularly undergo an external audit based on requirements described by CEN and/or national requirements for recognised qualifications. Education providers not yet accredited by a nationally recognised auditor should actively pursue accreditation by a relevant national governing body as a higher teaching institution. This applies to providers delivering both Type I and Type II education programmes [4].

The following section gives an overview of the various training and regulation of osteopathy in different European countries.

4.5 Country facts

10 Länder: Überblick zu Regulierung, Ausbildung und Ausübung der Osteopathie

A total of ten European countries were included in the analysis (for country selection criteria, see Chapter 2.3.2 and Table A-28). These countries are Austria (AT), Germany (DE), Switzerland (CH), Norway (NO), Denmark (DK), France (FR), Italy (IT), Finland (FI), Portugal (PT) and the United Kingdom (UK). The number of practising osteopaths in the included countries varies from five (DK) to 38 (FR) osteopaths per 100.000 people. In the following, an overview of osteopathy's regulation, education, and practice is given for these ten countries. All information can be found in the extraction tables in the appendix (see Chapter "*Factsheets on regulation, education and practice of osteopathy in the selected countries*", Table A-29 to Table A-38), with given information in italics completed by experts from the respective countries.

4.5.1 Regulation

nationale Verbände

Each of the ten countries has at least one national association for osteopathy. Some countries (AT, DE, FR, IT, PT) even have several associations for osteopaths. Membership in an association requires the fulfilment of different criteria (e.g. certain level of education or legal recognition), depending on the association and the country.

Berufsbezeichnung "Osteopath*in" in 6 Ländern geschützt

In six countries (CH, DK, FI, FR, PT, UK), the title 'osteopath' is fully regulated and protected by law. In these countries, only persons who meet the corresponding requirements (e.g. degree of training) and are recognised by the respective authorities are allowed to work as osteopaths. In Norway, the title 'osteopath' has been regulated and protected since 1st July 2022. However, there is a transitional period until July 2023, when the title 'osteopath' can be used by osteopaths as long as they present a formal application. From 1st July 2023, only registered osteopaths will be allowed to use the title. The title 'osteopath' is not yet protected in Austria, Germany and Italy.

gesetzliche Regulierung in 7 Ländern

Legal regulations exist in seven countries (CH, DK, FI, FR, NO, PT, UK), with various official documents on regulations available (see Appendix Table A-29 to Table A-38). The UK was the first country to recognize osteopaths in Europe (since 1993) legally. Italy has a law in place, but there are no implementing decrees yet[31]. In Austria, there is no legal regulation; therefore, osteopathy is practised by various professional groups with different training standards[32] General practice is given by doctors and dentists. Austrian osteopaths with a non-medical basic profession practise osteopathy based on their professional law (primarily the Medical Technical Service Act (MTD Act)). Germany also has no legal regulations, and osteopaths work under the 'Heilpraktiker Law' or as medical doctors.

3 Länder mit Regulierung basierend auf CEN/WHO Standards

In the countries where legislation exists or is in progress, the legislation of three countries (DK, NO, PT) is based on CEN/WHO benchmarks. In four countries, the legislation had already been implemented before CEN publication (CH, FI, FR, UK), and in Italy, CEN has been presented to the Ministry during discussions about recognition.

Anerkennung, Registrierung und nationale Register für Osteopath*innen

In most countries (CH, DK, FR, FI, PT, UK), recognition and registration as an osteopath are granted by or on behalf of governmental (health) authorities. The recognition by a national authority is also planned for Norway and Italy after the legislation is fully implemented. In addition, all countries have a public or national register of all practising osteopaths. These registers are operated either by national associations for osteopathy (AT, DE, FIN, FR, IT, NO) or national authorities (CH, DEN, PT, UK). In Norway and Italy, registration in a registry operated by national authorities will be applicable after full regulation.

4.5.2 Education

Mindestausbildung in 5 Ländern: Bachelor-Niveau

In five countries (DK, FI, NO, PT, UK), at least a Bachelor's degree[33] or equal requirements[34] are needed to practise as an osteopath. In Switzerland, a Master's degree[35] is required; in France, an osteopath needs a degree or diploma from an approved school[36]. No minimum requirements are currently necessary for practising in Austria, Germany and Italy. However, in Italy, a Bachelor's degree will also be necessary to practise after legislation.

versch. Ausbildungsmöglichkeiten

From country to country, there are different offers of training and study programmes for Osteopathy, which may vary in their curricula. The offers range from one to more than 40 different institutions providing training in osteopathy. Type I and Type II education (see Chapter 4.4) is currently offered in

[31] There are three decrees which need to be done before the law will be active. 1) definition of professional profile (done), 2) definition of the university curriculum (work in progress), 3) definition of the criteria of equivalence and equipollence (not started yet)

[32] In Austria, osteopathy is mainly practised by doctors and physiotherapists with extensive osteopathic training.

[33] e.g. 240 ECTS University of Applied Sciences diploma, Type I education (FI)

[34] e.g. Type II education, 4 years part-time (FI)

[35] 5 years full-time study

[36] The training does not have university equivalence; the level of training required to practise osteopathy in France has been defined since 2014 (4,860 for high school graduates, 1,894 hours for physiotherapists, 700 hours for physicians)

four countries (FI, FR, IT, UK). In three countries, only Type I education (CH, NO, PT) is offered; in three countries (AT, DE, DK), only Type II education is offered.

4.5.3 Practice

Osteopath*innen arbeiten hauptsächlich in privaten Praxen

In each of the ten countries, patients can self-refer. In all countries except France, osteopathy is located in primary healthcare. In six countries (AT, CH, DE, DK, FI, PT), osteopaths mainly work in private practice. In France, osteopaths practice in private clinics or private maternity hospitals. Further, some physiotherapists and also osteopaths in France may practice osteopathy within the National Health Services but not under the title of osteopath. Also, in Norway, osteopaths work in private practice and national health services; the same should apply in Italy after regulation. In the UK, osteopathy is, besides private practice, offered in secondary and hospital settings.

Behandlungen von Privatversicherungen übernommen

Osteopathic treatments are, partially or fully, covered by private insurance in all countries. Interestingly, in Denmark, under certain circumstances (e.g. if treatment by an osteopath is necessary due to a recognised occupational accident), treatment is also covered by work-related insurance. Furthermore, in Germany and Austria, in some cases, statutory and regional health insurance may cover or give a subsidy for osteopathic treatment. However, no exact or insufficient information was found on when the therapy costs are covered and for which indications. In most countries, reimbursement of treatment costs depends on the contract with the (private) insurance company (AT, CH, DK, NO, PT, UK).

8 Länder haben Beschränkungen für die Ausübung von Osteopathie

In eight countries, no restrictions exist on the practice of osteopathy. In France, there are some restrictions to which the osteopath must adhere (e.g. gynaeco-obstetrical manipulations and pelvic touching[37]). Also, in Italy, the osteopath is not allowed to use internal and invasive techniques with the professional profile that has just been approved.

in Großbritannien: Verpflichtung zu kontinuierlicher, beruflicher Weiterbildung

Most countries have no requirements for continuing professional development (CPD). The only country where CPD is mandatory is the UK. The regulator specifies CPD requirements and requires 90 hours of study over three years to address osteopathic practice standards. However, in some other countries, it is necessary to have a certain number of CPD hours to remain a national association member.

[37] Pelvic touching can be applied for e.g. pregnant people or urinary incontinence.

4.6 Summary of the current training and quality requirements for osteopaths in Europe

in 12 europäischen Ländern ist Osteopathie reguliert

Part 2 of the current report gives insight into osteopathy's training, education, practice, and legal regulation. In 12 European countries, osteopathy is already regulated by law. The EFFO represents the osteopaths' lead professional associations and regulatory authorities. It aims to establish regulations, standards, and recognition for osteopaths. The EFFO recommends legal recognition and regulation of osteopathy and compliance with the European Standard for Osteopathy (EN16686) because regulations lead to standardisation and more patient safety.

2 internationale Standards für Osteopathie

There exist two international standards for osteopathy. First, the WHO Benchmark for Training in Osteopathy describes professional principles and types of training programmes for standardisation and safe practice. Second, the European Standard on osteopathic healthcare provision (EN16686) provides a benchmark for high-quality education, safety, clinical practice and ethics for osteopathy in Europe. It was formally approved in 2015 and published in 33 countries at a national level. The EN16686 provides common core competencies in the diagnosis, management and treatment of patients as well as ethical and professional standards. The aim of the European Standard is to increase trust in the competencies of osteopaths.

10 Länder analysiert

In the current report, ten European countries were analysed: AT, CH, DE, DK, FI, FR, IT, NO, PT, and the UK, concerning osteopathy's regulation, education, and practice. The number of practising osteopaths in the included countries varies from 5 (DK) to 38 (FR) per 100.000 people. See Figure 4-1 (visual approach based on [1]) for an overview and the main points of interest for the selected countries.

Regulierung in 7 Ländern; Berufsbezeichung in 6 Ländern geschützt

Each of the included countries has at least one national association for osteopathy. A legal regulation exists in seven countries, whereof in three countries, the regulation is based on CEN/WHO standards. The title 'osteopath' is fully protected in six of the ten countries. The recognition and registration are done by or on behalf of state (health) authorities and national registers.

Ausbildung: Typ I und II

Two types of education can be distinguished. Type I education is provided for persons with little or no previous training in the health sector, and Type II is for persons with prior training in a health profession. The educational curriculum regulates essential competencies in training programmes and focuses on the care for the whole patient rather than specific diseases.

Ausbildungen verschieden

Different training and study options for osteopathy exist in the included countries, which may vary in the curricula. As mentioned above, education can be distinguished between Type I and Type II training. However, there is a minimum education in five countries, i.e. Bachelor's degree.

private Praxis und Versicherungen

Osteopaths mainly work in private practices, and osteopathic therapies are mainly covered by private insurance. Eight of the ten included countries have restrictions on the practice of osteopathy (e.g. pelvic touch). Only in the UK a continuation of professional development is mandatory.

Österreich: keine Regulierung und Berufsbezeichnung nicht geschützt

In Austria, osteopathy is not yet regulated, and the title 'osteopath' is unprotected and is used by various professional groups with different training standards. Approximately 2,000 osteopaths (22 per 100.000 people) are practising, and two national associations of osteopathy exist. The OEGO maintains a

registry of members with a minimum qualification; however, there is no legal regulation regarding education level requirements. The type of education offered is type II education, and currently, various training and further education courses are offered in the field of osteopathy in Austria. Patients can self-refer, and in the case of prevention, a physician's referral is required for curative interventions. No defined standards for primary healthcare are applicable in Austria; however, newly created primary healthcare centres may offer osteopathy at their discretion. Osteopaths practise in private practice, and some private health insurances only cover osteopathic treatments if osteopathy is listed (in rare cases by regional health insurance support with subsidies). The practice without restriction is allowed for physicians and dentists. Osteopaths with a non-medical basic profession are permitted to practise osteopathy based on their professional law (mostly the Medical-Technical Services Act (MTD Act)) after being referred by a doctor. There are no continuing professional development requirements for osteopaths.

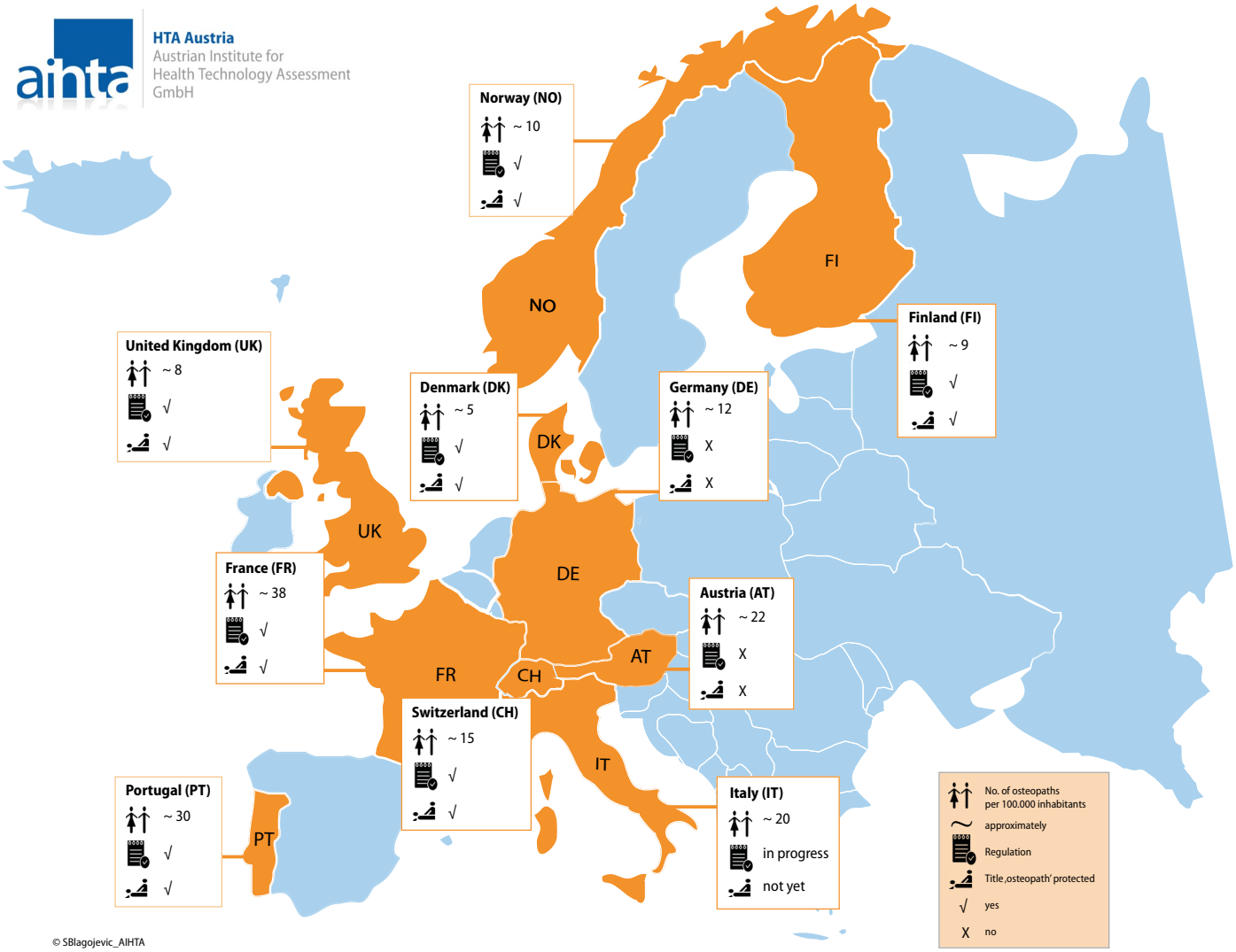

Figure 4-1: Overview and main points of interest for the selected countries

5 Discussion

Osteopathy is a growing profession. However, the effectiveness and safety of osteopathy in, e.g. treating musculoskeletal pain are unclear [3]. It has no consistent education, practice, or training standards [7]. Large heterogeneity in regulating and recognising osteopathic practice exists across different countries [1].

Osteopathie als wachsende Berufsgruppe mit heterogenen Standards

Therefore, this systematic review aimed

- to summarise the evidence on the effectiveness and safety of osteopathy in treating musculoskeletal pain (part 1), and
- to describe current training and quality requirements for European osteopaths (part 2).

Teil 1: Wirksamkeit/Sicherheit

Teil 2: Ausbildungs-/ Qualitätsanforderungen

For the first part, we included studies evaluating osteopathy for treating pain in the following eight regions and diseases: neck, neck or (lower) back, shoulder, lower back, knee, foot, osteoporosis, and fibromyalgia. The second part assessed regulation, training and practice in the following ten countries: AT, CH, DE, DK, FI, FR, IT, NO, PT and the UK.

8 Körperregionen/ Erkrankungen und 10 Länder eingeschlossen

5.1 Part 1: Effectiveness, safety and involved professions of osteopathic interventions

We included 15 RCTs and one systematic review and meta-analysis in our data analysis and synthesis, assessing eight different regions and diseases. The operators applied various osteopathic techniques:

15 RCTs und 1 systematische Übersichtsarbeit zu 8 Körperregionen/ Erkrankungen eingeschlossen

versch. osteopathische Techniken angewandt

- **Neck:** pressure release (n=1), myofascial release (n=1), craniosacral therapy (n=1), strain—counterstrain treatment (n=1)
- **Neck or (lower) back:** fascial release (n=1), osteopathic spinal manipulation (n=1)
- **Shoulder:** myofascial release (n=1), muscle energy technique (n=1)
- **Lower back**[38]**:** osteopathic interventions (i.e. OMT (n=6), myofascial release (n=2), craniosacral treatment (n=1) and osteopathic visceral manipulation (n=1))
- **Knee:** OMT (n=1), one or a combination of the following techniques: myofascial release, strain—counterstrain, muscle energy, soft tissue, high-velocity low-amplitude, or craniosacral manipulation (n=1)
- **Foot:** myofascial release (n=2)
- **Osteoporosis:** OMT (n=1)
- **Fibromyalgia:** craniosacral therapy (n=1), myofascial release (n=1)

[38] Here the osteopathic techniques of the included RCTs of the systematic review and meta-analysis are presented.

versch. Kontrollinterventionen

These osteopathic techniques were compared to the following comparison groups[39] in the RCTs:

- Sham treatment (7 studies)
- Waiting list or no intervention (2 studies)
- Placebo (3 studies)
- Exercise programme (1 study)
- Standard physical therapy (1 study)
- Usual care (1 study)
- Kinesiotaping (1 study)
- Active release technique (1 study)
- Muscle energy technique + soft tissue massage (1 study)
- Myofascial release and exercise programme (1 study)

Qualität und Vertrauen in eingeschlossene Studien mäßig zufriedenstellend

As already described above, 20 other thematically relevant RCTs were not included in the analyses due to the RoB. The quality of evidence in the included studies is moderately satisfactory. No trial was found with a low RoB. The RoB of the 15 included RCTs was unclear (n=8) to high (n=7). The RoB was *unclear* for the regions of knee and foot. For the region of 'neck or (lower) back' and osteoporosis, the RoB was *high*. The RoB for the regions of the neck, shoulder, and fibromyalgia was *unclear to high*. The systematic review and meta-analysis concerning the indication of chronic non-specific low back pain [9] was rated with high overall confidence; none of the RCTs showed a low RoB.

In the following, the effectiveness and safety of osteopathy as well as professions applying osteopathic interventions, are summarised.

Effectiveness

Osteopathie ist eine sichere Behandlungsform

This systematic review presents evidence on the effectiveness and safety of osteopathic treatment for musculoskeletal pain in eight body regions and diseases. The results of this review strengthen the evidence that osteopathic treatment represents a safe therapeutic choice for the analysed body regions and diseases.

Nacken/Kreuz: (kurz-/)mittelfristige Schmerzverbesserung

Osteopathy can be considered in patients suffering from *neck* and *low back* pain as (short- and) mid-term effects, and some clinically meaningful reductions in pain were observed. However, long-term effects are missing.

Fuß: mittelfristige Verbesserung
Schulter: kurz-/mittel-/ langfristige Verbesserung

It seems that *foot* pain can possibly be reduced in the mid-term by osteopathic treatment. Also, a clinically meaningful improvement was found. For *shoulder* pain, short-, mid- and long-term inter-group effects could be observed in one study but not in the other trial. However, pre-post improvements and clinically meaningful intra-group improvements in the osteopathic treatment group were found in the other study.

[39] Some RCTs included more than one comparison group (i.e. 3- or 4-arm-studies). The 10 included RCTs in the systematic review and meta-analysis compared osteopathic interventions to the following: no active treatment (sham therapy or no intervention; n=5), active treatment (standard exercise, classic massage; n=5) [9].

Only immediate statistically and some clinically meaningful effects on pain could be found for patients with *fibromyalgia*. However, discrepancies could be observed in the mid- and long-term FUs. The results for all other body regions and diseases (i.e. neck or (lower) back, knee, osteoporosis) are inconclusive, no effects were found, or the evidence is insufficient to make a statement. No statistically or clinically significant deteriorations occurred due to osteopathic interventions.

Fibromyalgie: Verbesserungen nur unmittelbar nach Behandlung; anderen Körperregionen/ Erkrankungen: keine abschließende Aussage möglich

A more detailed table summarising effectiveness outcomes, test points, number of sessions, treatment period, professionals involved, and type of osteopathic interventions can be found in Table 3-1.

Comparison of the primary outcome with the excluded studies

Ergebnisvergleich der ein- mit ausgeschlossenen Studien

In addition to the 16 studies (15 RCTs, 1 systematic review and meta-analysis) included in the evidence synthesis, further 20 thematically relevant RCTs were identified in the systematic literature search but were not included in the analyses (further details see Chapter 2.2). The aim was to cover all eight body regions and diseases with the best available evidence. However, not to miss any essential results from the 20 excluded RCTs (see Table A-2), the primary outcome of pain was extracted and compared to the main results of the included studies. Excerpt extraction tables of the excluded studies (n=20) can be found in the Appendix (Table A-22 to Table A-27). This comparison did not reveal any fundamental discrepancies, as described in the following.

Nacken (Übereinstimmung der ein- und ausgeschlossenen Studien): Verbesserung der Schmerzen in 9/11 ausgeschlossenen RCTs

For the region of the **neck** (n=11), in the excluded studies, fascial treatment, OMT (combined with exercise), myofascial release (combined with exercise), cervical high-velocity low-amplitude manipulation, autogenic/reciprocal inhibition muscle energy techniques, and osteopathic medicine were applied. Comparing our results with the excluded studies yielded similar results: The between-group difference in neck pain outcomes (e.g. average/current pain, and neck pain and disability) improved statistically significantly in nine [69-77] of eleven excluded studies [69-79] due to osteopathic treatments.

Schulter (Übereinstimmung): Verbesserung der Schmerzen in 3/4 ausgeschlossenen RCTs

For the region of the **shoulder**, in the excluded studies, myofascial release, osteopathic treatment, and spencer muscle energy technique were applied. The included studies showed a statistically significant between-group difference in (shoulder) pain favouring the osteopathic group when applying four osteopathic sessions within four weeks but not in another study after a treatment period of seven days. In three [25, 80-82] of the four excluded studies [25, 80-82], statistically significantly improved pain outcomes between the groups could be observed. This means that if all in- and excluded RCTs are taken into account, there seems to be efficacy in terms of pain reduction in shoulder pain.

Fuß (keine Übereinstimmung): Verbesserung (1 RCT) vs. keine Verbesserung (1 RCT)

For the region of the **foot**, in the excluded studies, OMT and myofascial trigger point manual therapy combined with self-stretching were applied. In our results, statistically significant between-group differences in pain could be observed. However, mismatches with the excluded studies could be found as pain outcomes improved in one study [83] but not in the other one [84]. However, this might be because, in the study with no inter-group improvements, only one single session of OMT was compared to the standard of care measured after only one week [84]. In the other study with improvements, pain was reduced after 16 osteopathic sessions [83]. This mismatch might suggest that one single session is insufficient for reducing pain in patients with foot pain.

Fibromyalgie (Übereinstimmung): Effekte nur unmittelbar nach der Behandlung

For **fibromyalgia**, in the excluded studies, craniosacral therapy, massage-myofascial release therapy, and osteopathic medicine were applied. In our report, pain was consistently reduced immediately after the osteopathic treatment. However, discrepancies could be observed at the mid- and long-term FUs. In the excluded studies [34, 36, 45], similar results were found: Pain mostly improved immediately after the treatment, and discrepancies could be observed at the mid- and long-term FUs.

Safety: adverse events

unerwünschte Nebenwirkungen in 3/10 Studien; Nacken: z. B. Zittern, Schmerzen, Müdigkeit, Schwindel, Weinen

Osteopathy can be seen as a safe treatment for the analysed body regions and diseases. Ten of 16 included studies reported on adverse events of osteopathy. Thereof, adverse events occurred in three studies regarding neck and low back pain. Two studies concerning **neck** pain reported minor adverse events during or subsequent to the treatment in six patients (i.e. increased neck pain, pain in the jaw area, shivering, tiredness, strong emotional reactions, weeping) and mild transient adverse effects in four patients (i.e. pain and dizziness).

Kreuz: Schmerzen, Verspannungen

For the region of the **lower back**, adverse events were rare. The systematic review and meta-analysis concluded that increased pain occurred during the first week of myofascial release treatment (1/10 studies) and also increased back muscle spasticity (1/10 studies).

Professions applying osteopathic interventions

Osteopath*innen, Physiotherapeut*innen/ Allgemeinmediziner*innen mit osteopathischer Ausbildung etc.

Operators applying osteopathic techniques in various occupations could be found. Osteopaths performed the osteopathic intervention in four of 16 studies; followed by physiotherapists with advanced osteopathic qualifications (3/16 studies) and general practitioners with osteopathic education (2/16 studies). Furthermore, physiotherapists, therapists (with osteopathic certification), expert craniosacral therapists, and osteopathic medical students were mentioned applying osteopathic interventions in the included studies. From a critical point of view, the descriptions of the involved professionals did not follow any standardisation, e.g. it is unclear whether the osteopaths and other operators had any additional qualifications, which may not have been stated.

5.1.1 Discussion of the findings of part 1

Medizinische Universität Graz: systematische Übersichtsarbeit über Reviews – Vergleich mit unseren Ergebnissen:

A systematic overview of reviews was conducted by the Medical University of Graz [67], commissioned by the Austrian Association of Osteopathy (OEGO, Österreichische Gesellschaft für Osteopathie) in 2022. It aimed to assess the effectiveness and safety of osteopathic treatments in people of any age with diseases/complaints from the fields of orthopaedics, paediatrics, gynaecology, internal medicine, oncology, neurology, dentistry and maxillofacial surgery, and urology. Of the 27 included systematic reviews, 15 assessed musculoskeletal diseases, especially non-specific low back pain. The following diseases were studied in both reports and compared in the following:

chronische Schmerzpts.: gleiche Hauptergebnisse

- Osteopathic treatments show significant improvements in patients with **chronic non-oncological pain** of different causes regarding pain, functionality, and QoL compared to the control interventions [67]. In our report, five [9, 29, 35, 46, 50] of the 16 included studies only assessed *chronic pain* patients of different causes. Focusing on these studies, our results go in line with the findings by the Medical University of Graz

regarding the outcomes of pain (5/5 studies), functionality (4/4 studies), and QoL (2/2 studies). However, in more detail, no improvement could be observed in *mental* QoL [50], functional status at the *FU* assessment at 12 weeks [9], physical function assessed after *one year* [35, 46], and a mismatch could be found regarding pain assessed after *six months* and *one year* [35, 46].

- Osteopathic treatments significantly improve pain in patients with chronic non-specific **low back** pain compared to control interventions [67], which aligns with our results.

Kreuz: gleiche Ergebnisse

- Osteopathic treatments significantly improve pain, but not functionality, in patients with chronic or acute non-specific **neck** pain compared to control interventions [67]. This goes in line with our results.

Nacken: gleiche Ergebnisse

- Osteopathic treatments show *no* significant effect on pain and QoL in patients with **fibromyalgia** compared to control interventions. Two systematic reviews were considered (with 5-7 RCTs included in the reviews), with a FU between one and 14 months and overall low reliability of the evidence [67]. Our findings, however, show effects on pain immediately after osteopathic treatment but mismatches in mid- and long-term FUs [35, 46]. QoL was enhanced in six of eight subscales at the six-month FU; however, no improvements could be found at the one-year FU [46]. This discrepancy between the findings of the Medical University of Graz and ours might be because different studies were analysed.

Fibromyalgie: ungleiche Ergebnisse da versch. Studien analysiert

Tendenz zu Kurzzeiteffekten

- Overall, all included systematic reviews did not show a significantly higher rate of adverse events with osteopathic treatments compared to control interventions. Serious adverse outcomes very rarely occurred in all included systematic reviews [67]. This goes in line with our results.

Sicherheit: gleiche Ergebnisse

Many patients seek care for musculoskeletal conditions. Neck and lower back pain accounted for the highest proportion of patient complaints across all countries, representing the two most common regions in musculoskeletal pain disorders [42]. In our systematic literature search, we focused on populations with musculoskeletal pain (e.g. back pain, shoulder impingement syndrome, and rheumatic conditions) and identified most studies on neck and low back pain. There are less studies available on other regions, such as shoulder or foot pain, which should be considered for further research.

muskuloskelettale Beschwerden häufig

viele Studien zu Nacken-/Kreuzschmerz

The WHO stated in a report that both back and neck pain are the leading cause of global years lived with disability, accounting for 5.6% of all years lived with disability in 2019 (see Figure 5-1, adapted from [85]).

WHO: Rücken- und Nackenschmerz weltweit führende Ursache für mit Beeinträchtigung gelebte Jahre

For the region of the **neck**, two systematic reviews [6, 24] were included in the systematic overview of the Medical University of Graz. The first systematic review and meta-analysis investigating OMT suggested clinically relevant effects of OMT for reducing pain in patients with *chronic* non-specific neck pain. However, larger, high-quality RCTs with robust comparison groups are recommended as the only three included studies present a lack of long-term measurements, small sample sizes, and different comparison groups. No serious adverse events were reported. Transient minor events such as tiredness on the treatment day and short-term worsening of symptoms in other 'familiar' regions were noted [6]. The second systematic review and meta-analysis assessed spinal manipulative therapy for *acute* neck pain. The authors concluded that spinal manipulative therapy alone or combined with other modalities positively affected those patients. Although, restricted quality and quantity, high heterogeneity, and pragmatic design limit the findings. No se-

Nacken: 2 systematische Übersichtsarbeiten stimmen mit unseren Ergebnissen überein hinsichtlich Effektivität und Sicherheit

vere or serious adverse events were reported. However, increased neck pain, headache, dizziness/vertigo, nausea, paraesthesia, upper limb pain, neck stiffness, fatigue, mild lower/upper back pain, and unpleasant spinal posture changes were reported [24].

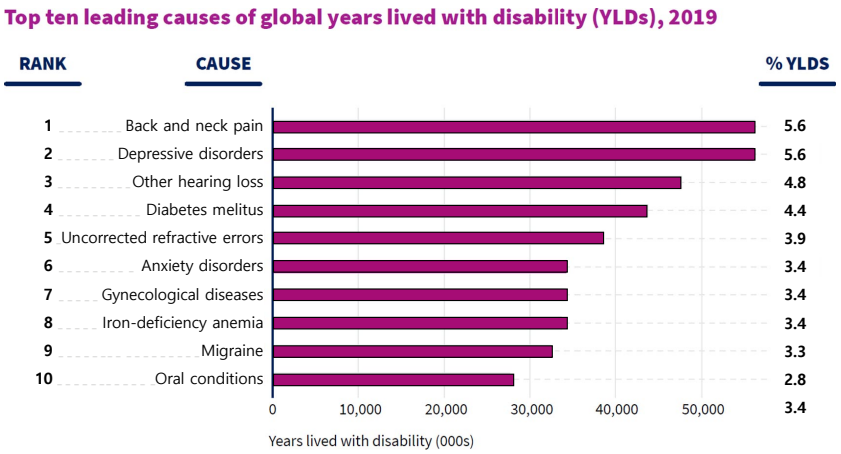

Figure 5-1: Top ten leading causes of global years lived with disability (YLDs), 2019

Kreuz: Bericht von GÖG stimmt mit unseren Ergebnissen überein

For the region of the **lower back**, we included a 2021 published systematic review and meta-analysis in our report, including ten trials [9]. The Gesundheit Österreich GmbH (GÖG) published a report in 2018. OMT showed significant improvements in pain patients with chronic non-specific low back pain [12]. These results align with the findings of the current report.

Kreuz: zusätzliche systematische Suche nach Primärstudien

The systematic literature search in the included systematic review [9], published in 2021, was conducted in April 2020. Compared to our systematic search for primary research with a search period until May 2022, there remains a gap of two years for the region of the lower back. Therefore, we searched for RCTs to cover this gap. We found three relevant RCTs [86-88]. Myofascial release [86, 87] and OMT [88] were compared to no treatment [86], mulligan sustained natural apophyseal glides[40] [87], and Kaltenborn-evjenth[41] orthopaedic manual therapy [88]. A rough picture shows that in two of the three studies, pain was improved in the inter-group comparison in favour of the osteopathic group [86, 88]. In one study, the comparison between the groups showed no statistically significant differences regarding the outcome pain; however, there was a statistically significant pre-post improvement in both groups [87].

[40] „The Mulligan concept is based on the theory that minor positional faults of articulating joints' surfaces following injury or strain result in a painful and restricted, range of motion (ROM). Mulligan Sustained Natural Apophyseal Glides (SNAGs) technique adds a passive accessory glide, parallel to the joint plane using a vertebral spinous process or transverse process, during which the patient performs the previously painful or restricted active movement" [87].

[41] "Central to the Kaltenborn-Evjenth approach is the emphasis on restoration of the gliding component of a normal joint roll-gliding movement. Also central is the concept of a treatment plane defined as the plane across the concave joint surface" [88].

körperliche *und* psychosoziale Faktoren relevant in Schmerzbehandlung

As our results could show, next to physical factors, psychosocial factors (e.g. mental health, depression, anxiety, body awareness, social functioning, and QoL) are also relevant in treating patients with pain issues (see also the biopsychosocial structure-function model in Chapter 1.2.3). A systematic review assessed the effects of osteopathic treatment on *psychosocial* factors in people with persistent pain, including 16 RCTs. The authors found improvements in anxiety and health status, a reduction in fear avoidance, and an increase in QoL [5]. These results partly align with the findings of the current report.

Heterogenität in RCTs

pts.-berichtete Endpunkte

breites Spektrum an Werten zu klinisch relevanten Verbesserungen

versch. Messinstrumente

A large heterogeneity of the included RCTs, such as professions involved, sample size, blinding, comparison, number of sessions, treatment period, duration of sessions, frequency of treatment and FUs, might have influenced the results. Many outcomes were assessed with patient-reported measures, e.g. VAS. However, these measures are accepted as standard and valid as pain is entirely a subjective experience. Using patient-reported outcome measurements increases patient involvement and can improve pain management of patients [89]. Furthermore, many different outcome measurements were used for assessing the primary and secondary outcomes. However, for evaluating pain, mostly the VAS and NPS were used. In seven of the 15 included RCTs, clinically meaningful improvements for these outcome measures were observed. However, in the literature, the range of the minimal clinically important difference values was broad. For instance, for the VAS, the range of clinically important pain reduction was between 1.4 to 5.2 cm.

Kurz-, Mittel- und Langzeiteffekte

It is also interesting to determine whether an osteopathic treatment has short-, mid- and/or long-term effects and how many osteopathic treatment sessions are needed. In the included 16 studies, osteopathic treatment was applied between one session [9, 15, 51, 53] and 50 [46] sessions in a treatment period between one session and 25 weeks. Every included study measured the outcomes immediately after the intervention (0-7 days after end of treatment). Short-term effects (1 month FU) were assessed in four studies, mid-term effects (3-6 months FU) in seven studies, and long-term effects (1 year FU) in three studies. Statistically significant effects can be found in all categories of length of FUs (see Table 3-1). Also, some improvements were detected in two of three studies after only one session of osteopathy. What else needs to be considered is that we do not know what the patients do between the end of the osteopathic therapy and the FU assessments (e.g. exercise, manual therapy, medication or massage). This bias needs to be assessed by, e.g. log books documenting which intervention(s) patients did.

Verblindung in wenigen Studien (möglich)

In the included RCTs, serious limitations of the studies were given due to the lack of patient and assessor/therapist blinding. However, the nature of the intervention of osteopathy does hardly allow for blinding those who deliver osteopathy or those who receive it. One option for blinding osteopaths and therapists seems to demand cross-over studies. Five [13, 31, 46, 50, 51] of the included 15 RCTs reported a double-blind study design (e.g. simulated treatment with disconnected ultrasound, 2-month lead-up period[42] between study commencement and enrolment of the first participant).

schwere Verallgemeinerbarkeit und Übertragbarkeit …

The majority of the included studies report results from research conducted in Europe (i.e. Spain, Italy, Germany, the UK, and Poland). However, five of the 15 included RCTs were conducted outside of Europe (i.e. Australia, Brazil, India, USA, and Qatar). Therefore, it is likely to impact the generalisability

[42] This period prevented physicians from knowing whether a participant is receiving treatment immediately after enrollment or after the waiting period

… da in versch. Ländern durchgeführt und …

and applicability of the findings to other jurisdictions. For instance, in the USA, general osteopathic practice is substantially different to the rest of the world as osteopathic practitioners are trained as physicians before specialising in OMT. In contrast to the USA, European and Australasian osteopathic training focuses on OMT and does not result in licensure to practise medicine as a physician [18].

… versch. osteopathische Techniken angewandt sowie heterogene Häufigkeit und Dauer

Although all included studies dealt with osteopathic techniques, however, the interventions applied were heterogeneous. On the one hand, this generally concerns the type of technique used (see Chapter 5.1) but also the frequency and duration of the intervention. In the included RCTs, osteopathic interventions were mostly applied as a sole technique (n=12), except in three studies (i.e. OMT[43], one technique or a combination). Therefore, one main limitation is that various types of osteopathic techniques were applied, and discrepancies and variations were observed even inside the same typology of intervention.

manchmal ungenaue Beschreibung der Techniken

Furthermore, the descriptions of the interventions in the studies were sometimes vague. Therefore, the interpretation of the results might be affected by the inclusion of studies investigating different osteopathic approaches. In osteopathic treatment, the diagnosis and treatment process is entirely based on the palpatory findings of the operator. However, this aspect should not represent a methodological limitation as the person-centred model and the whole-body vision is typical of osteopathic treatment. At this point, it is essential to remember that all different osteopathic techniques are based on one common therapeutic aim: promoting the optimal function of tissues to restore the body's functions. Nonetheless, such differences in terms of technicalities and dosage and length of treatment represent an obstacle to precisely estimating osteopathy's therapeutic role [9].

Variabilität auch in der *gleichen* Technik der manuellen Behandlung

Discrepancies and variations of techniques were observed even *inside the same typology* of intervention. Though, it is essential to consider that a certain degree of variability in manual interventions is predictable. This fact is even more notable in osteopathic treatment with its holistic approach because diagnosis and treatment processes are entirely based on palpatory findings (and not, e.g. on symptoms or instrumental examinations) [9].

osteopathische manipulative Behandlung: effektiv und sicher bei muskuloskelettalen Schmerzen

Two of the included RCTs applied OMT. A recently published overview of systematic reviews and meta-analysis summarised the available clinical evidence on the efficacy and safety of this commonly used osteopathic technique for different conditions, mostly low back pain. OMT was more effective than the comparators in reducing pain and improving functional status for musculoskeletal disorders. No adverse events were reported in most of the included systematic reviews [90].

Myofascial Release: Divergenz unserer Ergebnisse im Vergleich zu Meta-Analyse zu Kreuzschmerzbehandlung

Myofascial release was another commonly (n=8) used technique for different conditions. In the included systematic review and meta-analysis for low back pain [9], two of the included 10 RCTs applied myofascial release. Another systematic review and meta-analysis included eight RCTs and investigated the effects of the myofascial release technique on patients with low back pain. It shows a significant efficacy of myofascial release on pain intensity compared to the control intervention when all RCTs are considered. However, the sensitivity analysis to clarify the increased heterogeneity shows no significant effect after omitting two RCTs. Furthermore, it induced a significant

[43] Various manipulative techniques that can be combined with other advice or treatments, such as physical activity or diet.

decrease in back disability [91]. This discrepancy may be because there is an overlap of only two RCTs in these two systematic reviews discussed.

High-velocity low-amplitude: Review zeigt positive Effekte

The high-velocity low-amplitude technique was applied in only one study regarding knee pain. A literature review confirms our results. It found that high-velocity low-amplitude techniques can influence pain modulations in patients with musculoskeletal disorders [92].

kraniale Osteopathie: Zuverlässigkeit der Wirksamkeit berücksichtigen

In the published literature, it is discussed whether *cranial* osteopathy is effective. The reliability of the osteopathic treatments' effectiveness must be taken into account. A systematic review assessed the reliability of clinical efficacy of cranial osteopathy. The results demonstrated, consistently with those of previous reviews, that methodologically strong evidence on the reliability of the efficacy of therapeutic strategies and techniques in cranial osteopathy is almost non-existent [1]. However, effects due to craniosacral therapy were found in three of the included studies assessing short-term (1 study), mid-term (2 studies), and long-term (1 study) effects.

keine wesentlichen Ergebnisunterschiede unter Berücksichtigung der Kontrollgruppe

It must be mentioned that the comparative interventions in the included studies were very different (i.e. ultrasound electrotherapy, kinesiotaping, physical therapy, active release, muscle energy technique, (soft tissue) massage, exercise, light-touch sham treatment, sham ultrasound/short-wave, placebo, no intervention/waiting list, and usual care for the respective disease). In the qualitative synthesis of the current systematic review, we could not notice any substantial difference in the results when considering the type of control group, which goes in line with a systematic review and meta-analysis regarding low back pain [9].

Osteopathie als *ein* Baustein des Behandlungsplanes

Finally, it must be mentioned that disability can be influenced by different factors, such as depression, anxiety, or fear of movement, which should be considered in pain management. Osteopathic treatment should therefore represent a single relevant component inside a comprehensive treatment plan [9].

5.2 Part 2: Current training and quality requirements for osteopaths in Europe

europäische Regulierungen in 7/10 Ländern

Berufsbezeichung in 6 Ländern geschützt

Concerning the regulatory status and quality requirements, ten countries (AT, CH, DE, DK, FI, FR, NO, IT, PT and the UK) were analysed. Each of them has at least one national association for osteopathy. A legal regulation exists in seven countries, and the title 'osteopath' is fully protected in six of the ten countries. However, different training and study options for osteopathy exist in the included countries, varying in their curricula. A minimum of education is prescribed in five countries. Osteopaths particularly work in private practices, and osteopathic therapies are mainly covered by private insurance. The EFFO, the osteopaths' lead professional associations and regulatory authorities, aims to establish regulation, standards, and recognition for osteopaths. Two international standards exist for osteopathy: the WHO Benchmark for Training in Osteopathy and the European Standard on osteopathic healthcare provision (EN16686). The information collected in this report as well as the Benchmark documents should be used to inform and guide the regulatory process in Austria.

5.2.1 Discussion of the findings of part 2

Qualifikationen und Regulierungen von Land zu Land unterschiedlich

Different training and quality requirements exist for osteopaths in the ten analysed European countries. This result goes in line with a country survey (i.e. Switzerland, Italy, Spain, Belgium-Luxemburg, Australia, the Belgium-Netherlands-Luxemburg region (Benelux), Germany, Canada, and the UK). This survey revealed little difference between osteopaths and their practices. However, qualifications and regulations differ between countries. The legal status of osteopathy's regulation and recognition may also impact service delivery, education standards, and/or private health insurance reimbursement for the cost of care. Countries with statutory recognition and regulation of osteopathy as a healthcare profession may have more mainstream and stricter academic standards conforming more to evidence-based care, form, and teaching. This approach focuses more on musculoskeletal health than osteopathy in the cranial field and visceral techniques [42].

Österreich: Regulierung wichtig für Pts.-Sicherheit

In Austria, osteopathy is not yet regulated, and the title 'osteopath' is unprotected. However, the regulation of the osteopathic profession is essential and leads to appropriate, recognised, and standardised education, improving patient safety. Therefore, protecting the title 'osteopath' ensures that osteopaths have the competencies and skills to convey effective and safe osteopathic treatments.

Charakteristika österreichischer Osteopath*innen

The Foundation COME (Centre for Osteopathic Medicine) Collaboration of Italy conducted a cross-sectional survey regarding the rates of osteopathic practitioners in Austria. This profession profile allows a clear comparison with other European countries. Almost all respondents had preliminary healthcare training, mainly in physiotherapy (72%). Most were self-employed (88%) and worked as sole practitioners (54%). The most frequently used treatment techniques were visceral, cranial, and articulatory/mobilisation techniques. As estimated by the respondents, most patients consulted an osteopath for musculoskeletal complaints mainly localised in the cervical and lumbar region, which aligns with our observations. Interestingly, although most respondents experience a strong osteopathic identity, only 17% advertise themselves exclusively as osteopaths [93].

deutschsprachiger Raum: laufende Studie zu Merkmalen, Chancen und Herausforderungen von Osteopath*innen

In the German-speaking territory, the acknowledgement of the occupational profile and training structures strongly differ, and the importance of the profession of osteopathy within the healthcare system is controversial. An ongoing comprehensive mixed methods study examines osteopaths' characteristics, possibilities, opportunities and challenges in Austria, Germany, and Switzerland. This study's results will give insights into how osteopaths define themselves compared to professionals from other occupational profiles, how they describe aspects of their work and how they might contribute to improving and conserving the quality of osteopathic treatment. Identifying central issues might help clarify and define this profession [94].

Großbritannien: biopsychosozialer Ansatz von Osteopath*innen

A cross-sectional questionnaire-based survey conducted in the UK investigated the attitudes and beliefs of UK-registered osteopaths towards chronic pain and the management of chronic pain sufferers. However, those osteopaths do not have a more biopsychosocial approach to treating and managing chronic pain patients than other healthcare providers. Nevertheless, the ability to engage with psychosocial factors of the patients' pain experiences is supported. The authors suggest that training is needed to increase osteopaths' attitudes towards managing chronic pain sufferers and their expertise in knowledge of chronic pain [22].

Frankreich: Studie zu Beziehungskomponente in Ausbildungsprogrammen

A French cross-sectional survey investigated how initial osteopathic training values relational competency, patient education, and the competency-based approach. In France, the first country with an osteopathic regulation, international osteopathic recommendations and registration guidelines are promoted. Despite patient education practices and relational competencies, challenges are present in clinical settings due to a lack of training. The latest national osteopathic standards for practice and education defined relational competency, including patient education. The study aimed to determine learning, teaching, and assessment methods related to relational competency in initial osteopathic training programmes and to identify the role of patient education in this relational competency. The authors found that relational competencies, including patient education, appeared in various courses, enhanced by clinical learning. This competency-based approach is also important for Austrian institutes as an alignment among intended learning outcomes, teaching, and assessment is crucial [95].

Italien: Osteopath*in als neuer Gesundheitsberuf

In the case of Italy, where the regulation is in progress and, therefore, the title of 'osteopath' is not yet protected, the adaptation of the comprehensive healthcare reform, including the recognition of osteopaths as new health professions, was discussed in the parliament and senate for almost five years. After the entry into force of the new law, it must be adopted within three months at the state-regional conference, and the newly created health profession must be discussed. This is also important for Austria as healthcare issues always affect the region. Within six months of the law coming into force, core competencies, areas of activity, training in osteopathy and the recognition of previous training and transitional periods must be defined [96].

Australien: klinische Managementmerkmale von Osteopath*innen

An Australian analysis of a nationally representative sample presented a secondary data analysis of the Australian osteopathy practice-based research network. It aimed to examine the clinical management characteristics of osteopaths. Most (98%) osteopaths treat neck pain. Osteopaths perform, on average, 37 patient treatments per week. There are differences in the clinical management strategies of experienced and novice osteopaths, including utilising a multidisciplinary approach to patient management. Training and quality requirements vary in countries; clinical management strategies may also differ [23]. As differences between experienced and novice osteopaths exist, practice in education and training is essential, which is also noted in the WHO Benchmark for Training in Osteopathy and the CEN standard. This aspect must also be considered in the Austrian osteopathic education system.

unterschiedliche Techniken in versch. Ländern …

As already described above (see Chapter 5.1.1), various types of osteopathic techniques were applied in the included studies for part 1. Having an insight into other countries, a large range and diversity of techniques used by osteopaths exist, not restricted to manual techniques alone. In the Benelux region, Spain and Germany, there is a preference for more gentle techniques (e.g. osteopathy in the cranial field, visceral and functional techniques) compared with the UK and Australia, where the preference appears to be more towards structural techniques (e.g. soft tissue manipulation, spinal manipulation, high-velocity thrust). Also, exercise, physical activity, lifestyle and dietary advice are frequently used by osteopaths confirming that osteopathy is a complex, multi-component therapy [42].

… ev. nicht vergleichbar

There is variation in the emphasis and use of osteopathic techniques and the style of practice. Therefore, it is unknown whether the treatment approaches used in different countries are comparable to the typical treatment approaches used by osteopaths in, e.g. the UK and Australia and osteopathic physicians in the USA. OMT interventions may emphasise different manual treatment approaches, such as direct, indirect, cranial or visceral techniques [6].

5.3 Limitations

Ergebnisabgleich der ein- und ausgeschlossenen Studien

Due to the high amount of relevant studies in this systematic review, only the best available evidence was included for the detailed analysis to cover all regions and diseases. However, the results of the primary outcome pain of the excluded studies were also extracted, which makes a comparison possible.

eingeschlossene Primär- vs. Sekundärliteratur

Low back pain was covered by a systematic review and meta-analysis [9], and all other indications by primary research. However, the systematic review included two of ten RCTs with <50 subjects in the meta-analyses. Also, almost exclusively, RCTs with high RoB were included in the meta-analyses. Furthermore, the systematic review and meta-analysis only included English-language RCTs. Therefore, any German-language RCTs on low back pain were not considered for inclusion. Thus, different inclusion criteria were applied for low back pain and other indications. This might have influenced the results of the report.

versch. Techniken untersucht, Vergleichbarkeit in Ländern?

In the current review, there was no focus on one particular osteopathic technique, but studies with various techniques were included. Therefore, we cannot say that one specific technique is better than another. Also, we did not investigate to what extent osteopathic techniques are comparable with each other and whether the techniques correspond to what is applied in Austria.

keine systematische Suche, sondern Handsuche und Expert*innen-Konsultation für Teil 2

Furthermore, we searched for training and quality requirements for osteopaths using a structured and extensive hand search. We did not perform a systematic literature search in databases because regulations of the osteopathic profession in Europe (e.g. evaluation reports, curricula, educational/study programmes) are often published on websites and in reports of different organisations. Another limitation is that some countries only provide the regulation documents in their national language. As we could only include documents in English or German, we had to exclude regulation documents unavailable in one of these languages. However, we included a broad range of European countries and contacted experts to further identify and complete the country's information. Not all, though, eight of ten contacted experts responded and have valorised our results.

Nevertheless, though those limitations are given, the results provide a valid impression of the effectiveness and safety of osteopathy for musculoskeletal pain in several regions and diseases and give a comprehensive overview of training and quality requirements in Europe.

6 Conclusion

Osteopathie ist eine sichere Behandlungsform

This systematic review presents evidence on the effectiveness and safety of osteopathic treatment for musculoskeletal pain in eight body regions and diseases. The results of this review suggest that osteopathic treatment represents a safe therapeutic choice for the analysed body regions and diseases, as only very few patients reported minor adverse events.

Nacken/Kreuz: Schmerzverbesserung; Schulter/Fuß: mögliche Verbesserung

According to the current evidence, osteopathy can improve *neck* and *low back* pain in the short- and mid-term. Further published systematic reviews and meta-analyses underline this finding. It seems that *shoulder* and *foot* pain can possibly be reduced by osteopathic treatment.

andere Körperregionen/ Erkrankungen: keine abschließenden Aussagen möglich

The results for all other body regions and diseases (i.e. neck or (lower) back, knee, osteoporosis, fibromyalgia) are inconclusive, the evidence is insufficient to make a statement, or no or only immediate effects were found. No statistically or clinically significant deteriorations occurred due to osteopathic interventions.

qualitativ hochwertige Studien mit Langzeitbeobachtung nötig

However, it must be taken into account that there is more evidence published for neck and low back pain than for other regions and diseases. More high-quality research with mid- and long-term FUs focusing on technical approaches, the dosage of treatments, and safety are necessary to produce higher-quality evidence that helps influence clinical practice and healthcare policies.

Regulierung vor Refundierung wichtig

Regulations of the osteopathic profession are crucial to increase trust in osteopathy and ensure the safety of patients. However, before reimbursing osteopathic treatments, regulation is needed, and the title of osteopaths needs to be protected. It is essential to orientate on international standards and adapt those for Austria. Based on the set standards, training and quality requirements must be adapted to meet the international standards for osteopathy.

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Appendix

Quality appraisal

Quality appraisal of the randomised controlled trials using the 'Cochrane Collaboration Tool 1'

*Table A-1: Quality appraisal of the **included** randomised controlled trials using the 'Cochrane Collaboration Tool 1' – study level*

Indication	Trial	Adequate generation of randomisation sequence	Adequate allocation concealment	Blinding		Incomplete outcome data addressed	Selective outcome reporting unlikely	No other aspects which increase the risk of bias	Risk of bias – study level
				Patient	Treating physician/therapist[44]/outcome assessor				
Neck or (lower) back	Williams 2003 [50]	Unclear[45]	Unclear[46]	No[47]	Unclear[48]	Unclear[49]	Unclear[50]	Yes[51]	High[52]
Neck or (lower) back	Tozzi 2011 [49]	Yes	Unclear[46]	No[53]	Yes[54]	Yes	Unclear[48]	Yes[51]	High[52]
Fibromyalgia	Castro-Sanchez 2011a [36]	No[55]	Unclear[56]	No[57]	Yes[58]	Yes[59]	Unclear[48]	Yes[51]	High[60]

[44] The nature of the intervention does not always allow to blind those who deliver osteopathy. Since it is not always possible to blind a treating physician/therapist to osteopathy, we assessed the blinding of the trials with 'yes', i.e. low risk of bias if we judged that the lack of blinding was not affecting the results.

[45] "The unit of randomization was the patient." Random number tables wer used and „kept secure from all participants. Using information from the referral form, she stratified the sample by symptom location, the referring GPs' perception of symptom severity and whether the pain was a first episode or a recurrence."

[46] Insufficient information about the allocation concealment: no description of the used method.

[47] "The intervention group was referred to the osteopathic clinic based in Llanfairfechan health centre."

[48] Insufficient information to permit judgement of 'Yes' or 'No'.

[49] Insufficient reporting of reasons for missing data.

[50] Insufficient information (no study protocol available) to permit judgement of low risk of bias.

[51] No other aspects that can increase the risk of bias have been found.

[52] Due to the lack of blinding of the patients, a high risk of bias can be assumed.

[53] Only "the Sham-Control group blindly received a sham treatment."

[54] "Two medical doctors … were asked to compare the results independently. They were blind to the groups (Experimental and Control) from which the images were obtained." Treating physicians were blinded, but not in all treatment measurements.

[55] "Patients were randomly assigned by means of a balanced stratified assignment to an experimental (n=47) or placebo (n=47) group." However, random components in the sequence generation process are not adequate.

[56] "The sequences assigned to patients were placed in envelopes containing the allocation to each study group." However, method of concealment is not described in sufficient detail to allow a definite judgement. It remains unclear whether envelopes were sequentially numbered, opaque and sealed.

[57] "The patients themselves were not blinded to their status."

[58] "Outcomes were determined by another researcher, who was blinded to the study group of patients. However, the physiotherapist (specialist in myofascial therapy) who administered both intervention protocols" was not blinded.

[59] Reasons for missing outcome data unlikely to be related to true outcome.

[60] Due to inadequate generation of randomisation sequence and the lack of blinding of the patients, a high risk of bias can be assumed.

Indication	Trial	Adequate generation of randomisation sequence	Adequate allocation concealment	Blinding		Incomplete outcome data addressed	Selective outcome reporting unlikely	No other aspects which increase the risk of bias	Risk of bias – study level
				Patient	Treating physician/therapist[44]/outcome assessor				
Fibromyalgia	Matarán-Penarrocha 2011 [44]	Unclear[61]	Unclear[46]	Yes[62]	Yes[63]	Yes	Unclear[48]	Yes[51]	Unclear
Foot	Ajimsha 2014 [32]	Unclear[48]	Unclear[46]	Yes[64]	Yes[65]	Yes	Unclear[48]	Yes[51]	Unclear
Foot	Bac 2022 [31]	Yes[66]	Unclear[46]	Unclear[48]	Yes[67]	Yes	Yes[68]	Yes[51]	Unclear
Knee	Zago 2021 [30]	Yes[69]	Yes[70]	Unclear[48]	Yes[71]	Yes	Yes[68]	Yes[51]	Unclear
Knee	Licciardone 2004 [14]	Unclear[48]	Unclear[72]	Yes[62]	Yes[73]	Yes	Unclear[48]	Yes[51]	Unclear
Shoulder/Arm	Hunter 2022 [25]	Yes[74]	Yes[75]	No[76]	Yes[77]	Yes	Unclear[78]	Yes[51]	High[52]
Shoulder/Arm	Mishra 2018 [26]	Yes[79]	Unclear[46]	Unclear[48]	Unclear[48]	Yes	Unclear[80]	Yes[51]	Unclear

61 Patients „were randomly assigned by means of a balanced stratified assignment to an intervention (n=52) or placebo (n=52) group."
However, insufficient information about the sequence generation process to permit judgement of 'Yes' or 'No'.

62 This is a double-blinded study.

63 This is a double-blinded study. However, no information is gives if the treating physician/therapist and/or outcome assessor were blinded.

64 This is a double-blinded study. However, no information is gives if the patients were blinded.

65 „Both groups were treated by clinicians blinded to the group and the outcome of the study." "Two evaluators blinded to the group to which the participants belonged analyzed scores."

66 "Qualification was based on the simple randomization (coin toss) performed by the main author."

67 "Until the final preparation of the database, the main author was the only person who knew which group each researched person was assigned to.
The therapy was performed by other therapists, and the examinations were performed by another member of the therapeutic team."

68 Study protocol available.

69 "Randomization was performed on the first day (www.random.org)."

70 "The numbers were placed in a sealed and opaque envelope and drawn by the participants."

71 "Data analysis was performed by a fourth member of the research group to maintain data blinding" "Blinding of the researchers was also performed, and each intervention was made by 2 independent researchers."

72 "Precoded cards in sealed envelopes were used to randomly allocate patients to groups" However, method of concealment is not described in sufficient detail to allow a definite judgement. It remains unclear whether envelopes were sequentially numbered and opaque.

73 "All study personnel who were responsible for developing OMT plans or measuring primary outcomes were blinded to group assignments. The only personnel aware of these assignments were the undergraduate fellows who performed OMT and sham treatments; however, they did not measure any of the study outcomes."

74 "Each participant was assigned to 1 of the 3 groups by simple randomization in a 1:1:1 ratio using a computerized random number generator."

75 „Allocation concealment was achieved by using an external individual, independent to participant recruitment and the treating practitioner, placing the generated random numbers into sequentially numbered sealed opaque envelopes."

76 This is a single-blinded trial.

77 "The treating practitioner was not blinded; however, when providing manual therapy a practitioner cannot be blinded to the technique they apply" But ist is also stated: "Measurements were conducted by a registered osteopath with 7 years clinical experience, blinded to group allocation."

78 Study protocol available. However, primary/secondary outcomes and measurements are not predefined in the protocol.

79 Patients "were divided into two groups, Group A and Group B, 30 each, through the computer randomisation."

80 Study protocol available, however, this was retrospectively registered.

Indication	Trial	Adequate generation of randomisation sequence	Adequate allocation concealment	Blinding		Incomplete outcome data addressed	Selective outcome reporting unlikely	No other aspects which increase the risk of bias	Risk of bias – study level
				Patient	Treating physician/ therapist[44]/outcome assessor				
Neck	Capó-Juan 2017 [16]	Yes[81]	Yes[82]	Yes[83]	No[83]	Yes[84]	Unclear[85]	Yes[51]	High[86]
Neck	Haller 2016 [46]	Yes[87]	Unclear[88]	Yes[89]	Yes[90]	Yes[91]	Yes[92]	Yes[51]	Unclear[93]
Neck	Klein 2013 [47]	Yes[94]	Yes[95]	Yes[96]	Yes[96]	Yes[97]	Unclear[98]	Yes[51]	Unclear[99]
Neck	Rodrıguez-Huguet 2020 [48]	Yes[100]	Unclear[101]	No[133]	Yes[102]	Yes[97]	Yes[103]	Yes[51]	High[104]
Osteoporosis	Papa 2012 [34]	Yes[105]	Unclear[178]	No[106]	Yes[107]	Yes[108]	Unclear[98]	Yes[51]	High[52]

Interpretation: see page 107 (at the end of Table A-2)

81 "The patients were assigned to different groups (A, B, or C) according to an allocation number generated from a random table."
82 "Only the Principal Physiotherapist knew the assignment group of each patient."
83 Single blinded randomised controlled trail – "In single blind trials the recipient party (patient) is blinded."
84 No missing data, all participants evaluated.
85 No study protocol available.
86 Due to the lack of blinding of the outcome acessors, a high risk of bias can be assumed.
87 "A nonstratified allocation sequence with randomly varying block lengths using the random number generator RANUNI from the SAS/STAT software" was used.
88 Opaque envelops sorted in the ascending order of randomisation were used. However, method of concealment is not described in sufficient detail to allow a definite judgement. It remains unclear whether envelopes were sequentially sealed.
89 "Patients were blinded to the group allocation and to the fact that 1 group would receive sham treatment as it was recommended for manual therapy trials; instead they were told that 2 different CST techniques would be tested."
90 "Investigators assessing outcomes remained blind to patients' group allocation during the whole study period."
91 No missing data.
92 Outcome measurement according to the study protocol.
93 One domain (patient blinding) was answered with "Unclear", which is why an unclear risk of bias can be assumed.
94 The "Research Randomizer … with variable block sizes of 8, 10 and 12 (permuted block design)" was used.
95 Sequentially numbered, opaque, sealed envelopes were used.
96 "With patients, the study assistant and outcome assessor (AB) blinded."
97 No missing outcome data.
98 NI about a study protocol.
99 Due to the lack of a study protocol, the risk for bias cannot be classified.
100 "Allocation was created by … using a random allocation software program."
101 Allocation „was concealed in sequentially numbered envelopes." However, method of concealment is not described in sufficient detail to allow a definite judgement. It remains unclear whether envelopes were opaque and sealed.
102 "Data collection was conducted by a physician who was blinded as to which participants received experimental or comparison intervention."
103 Outcomes were reported as intended in the protocol.
104 Due to the lack of blinding of the participants, a high risk of bias can be assumed.
105 "Patients were randomized through a computer-generated sequence."
106 Single-blinded trail and blinded was an investigator.
107 "An investigator blinded to group assignment."
108 "Twenty-four of them did not complete the study for reasons not dependent on the current study, complications of underlying conditions for 4 and 6 for difficulty in reaching the venue of the study."

*Table A-2: Quality appraisal of the **excluded** randomised controlled trials using the 'Cochrane Collaboration Tool 1' – study level*

Indication	Trial	Adequate generation of randomisation sequence	Adequate allocation concealment	Blinding		Incomplete outcome data addressed	Selective outcome reporting unlikely	No other aspects which increase the risk of bias	Risk of bias – study level
				Patient	Treating physician/ therapist[109]/outcome assessor				
Fibromyalgia	Castro-Sanchez 2011b [43]	No[110]	Unclear[111]	No[112]	Yes[113]	Yes	Unclear[114]	Yes[115]	High[116]
Fibromyalgia	Castro-Sanchez 2011c [35]	No[117]	Unclear[118]	Unclear[114]	Unclear[114]	Yes	Unclear[114]	Yes[115]	High[119]
Fibromyalgia	Coste 2021 [37]	Yes	Unclear[120]	No[121]	No[122]	No[123]	No[124]	Yes[115]	High[125]
Foot	Eisenhart 2003 [77]	Unclear[114]	Unclear[120]	Unclear[114]	Unclear[114]	Yes	Unclear[114]	Yes[115]	Unclear
Foot	Renan-Ordine 2011 [78]	Yes[126]	Unclear[120]	Unclear[114]	Yes[127]	Unclear[128]	Unclear[114]	Yes[115]	Unclear

[109] The nature of the intervention does not always allow to blind those who deliver osteopathy. Since it is not always possible to blind a treating physician/therapist to osteopathy, we assessed the blinding of the trials with 'yes', i.e. low risk of bias if we judged that the lack of blinding was not affecting the results.

[110] "The final study group of 92 patients (aged 16-65 years) were assigned by a balanced stratified random assignment method to an intervention group for craniosacral therapy (n=46 females) or a placebo group for sham treatment with disconnected magnetotherapy equipment (n=46 females)." However, random components in the sequence generation process are not adequate.

[111] "The sequences assigned to patients were placed in envelopes containing the allocation to each study group." However, method of concealment is not described in sufficient detail to allow a definite judgement. It remains unclear whether envelopes were sequentially numbered, opaque and sealed.

[112] "Patients were not blinded to the therapy allocation although the patients were not aware that one was a sham treatment."

[113] "Craniosacral and magnetotherapy therapists were not blinded to the therapy allocation." However, „pain intensity and heart rate variability were evaluated by a blinded assessor, who did not know whether patients belonged to the intervention or placebo group."

[114] Insufficient information to permit judgement of 'Yes' or 'No'.

[115] No other aspects that can increase the risk of bias have been found.

[116] Due to inadequate generation of randomisation sequence and the lack of blinding of the patients, a high risk of bias can be assumed.

[117] The authors did not state any sequence generation. However, it is to be assumed that the sequence generation occurred as in their previous studies from 2011.

[118] Patients "were randomly assigned to an experimental (n=32) or placebo (n=32) group by using sealed envelopes." However, method of concealment is not described in sufficient detail to allow a definite judgement. It remains unclear whether envelopes were sequentially numbered and opaque.

[119] Due to inadequate generation of randomisation sequence, a high risk of bias can be assumed.

[120] Insufficient information about the allocation concealment: no description of the used method.

[121] „Patients were blind to treatment assignment." However, „the differential dropout rate before the end of the first treatment session, resulting in missing-not-at-random data, suggests that blinding was not successful for some of the included subjects."

[122] "The therapists were necessarily unblinded to study group assignment given their role in delivering the assigned treatment, but they were not aware of block size and variation." However, „A blind interim assessment of treatment credibility and expectancies of improvement was conducted on the first 30 patients (2 × 15) included in the trial."

[123] Imbalance in numbers or reasons for missing data across groups.

[124] In the study protocol the Brief Pain Inventory (BPI) was defined as a secondary outcome measurement. However, results on pain measured by the BPI were not presented in the published article.

[125] Due to the lack of blinding of the patients and therapists, imbalance in numbers or reasons for missing data across groups, and selective outcome reporting, a high risk of bias can be assumed.

[126] "Participants were randomly assigned to 2 groups using a table of random numbers created by on-line software (www.randomization.com)."

[127] "Pressure pain thresholds (PPT) levels and SF-36 scoring were assessed by an assessor blinded to group assignment."

[128] Insufficient reporting of attriction/exclusions to permit judgement of ‚Yes' or ‚No' (number of analysed patients not stated).

Indication	Trial	Adequate generation of randomisation sequence	Adequate allocation concealment	Blinding		Incomplete outcome data addressed	Selective outcome reporting unlikely	No other aspects which increase the risk of bias	Risk of bias – study level
				Patient	Treating physician/therapist[109]/outcome assessor				
Shoulder/Arm	Ajimsha 2012 [63]	Unclear[114]	Unclear[120]	No[129]	Yes[130]	Yes	Unclear[114]	Yes[115]	High[131]
Shoulder/Arm	Geldschläger 2004 [65]	No[132]	Unclear[120]	No[133]	No[134]	Unclear[135]	Unclear[114]	Yes[115]	High[136]
Shoulder/Arm	Iqbal 2020 [64]	Yes[137]	Unclear[120]	Yes[129]	No[129]	Yes	Unclear[138]	Yes[115]	High[139]
Shoulder/Arm	Schwerla 2020 [23]	Yes[140]	No[141]	No[142]	No[143]	Yes	Unclear[144]	Yes[115]	High[145]
Neck	Brück 2021 [79]	Yes[146]	Unclear[147]	No[148]	Yes[149]	Yes[150]	Unclear[144]	Unclear[151]	High[131]
Neck	Cholewicki 2021 [80]	Yes[152]	Yes[153]	No[133]	Yes[154]	Yes[155]	No[156]	Yes[115]	High[131]

129 This is a single-blinded trial.
130 "Two evaluators blinded to the group to which the participants belonged analyzed scores." However, the „practitioners could not be blinded."
131 Due to the lack of blinding of the patients, a high risk of bias can be assumed.
132 Sequence generated by rules based on date of admission.
133 Patients were not blinded.
134 Therapists were not blinded.
135 No reasons for missing outcome data stated.
136 Due to inadequate generation of randomisation sequence, the lack of blinding of the patients and therapists, a high risk of bias can be assumed.
137 "The subjects were randomly allocated into two equal groups using the sealed envelope method."
138 "The current RCT was not registered with the relevant registry due to the unavailability of trial registry in the country and the institution at the time."
139 Due to lack of blinding of the therapists and outcme assessors, a high risk of bias can be assumed.
140 "A computer-generated randomization list with variable block lengths of 4-8 was held."
141 "Participants' allocation to the respective groups was revealed only after date of birth and initials had been conveyed by telephone, and documented in the original randomization list."
142 No patient blinding.
143 No evaluator blinding.
144 Study protocol available, however, this was retrospectively registered.
145 Due to inadequate allocation concealment, the lack of blinding of the patients and therapists, a high risk of bias can be assumed.
146 "Patients were randomly allocated by drawing lots."
147 "20 sealed envelopes were in one box. For each subject, one envelope was drawn by a blinded assessor." However, method of concealment is not described in sufficient detail to allow a definite judgement. It remains unclear whether envelopes were sequentially numbered and opaque.
148 "The participants could not be blinded."
149 "All data were collected by the practice staff who were not involved in the intervention and were not informed about group allocation", "therapists could not be blinded to the intervention."
150 No missing data.
151 The study protocol mentions 4 measurement points, but only 2 are mentioned in the study.
152 "Randomization module in REDCap was used to assign participants to group allocation."
153 "The allocation table was generated by a computer … no way to predict any participant's allocation before enrolment."
154 "The PI, statistician, and treating team physicians were all blinded to group assignment (i.e. OMT or waiting period)."
155 Information about missing data is given.
156 Change in medication was intended to be evaluated in the protocol but no information (NI) about that was given in the study.

Indication	Trial	Adequate generation of randomisation sequence	Adequate allocation concealment	Blinding		Incomplete outcome data addressed	Selective outcome reporting unlikely	No other aspects which increase the risk of bias	Risk of bias – study level
				Patient	Treating physician/therapist[109]/outcome assessor				
Neck	El-Gendy 2019 [81]	Yes[157]	Yes[158]	No[159]	No[160]	Yes[161]	Unclear[162]	Yes[115]	High[163]
Neck	Groisman 2020 [82]	Yes[164]	Yes[165]	No[166]	Yes[167]	Yes[168]	No[169]	Yes[115]	High[170]
Neck	Leaver 2010 [83]	No[171]	Yes[172]	No[173]	Yes[174]	Yes[175]	Yes[176]	Yes[115]	High[131]
Neck	Martínez-Segura 2006 [84]	Yes[177]	Unclear[178]	No[179]	Yes[180]	Yes[181]	Unclear[182]	Yes[115]	High[131]
Neck	McReynolds 2005 [85]	Yes[183]	Yes[184]	No[185]	Unclear[186]	Yes[181]	Unclear[182]	Yes[115]	High[131]

157 "Patients were randomly assigned into 3 equal groups … with the use of a computer-based randomization program."
158 "Patients were blinded about which group they were allocated by an independent researcher."
159 Authors did not state that patients were blinded.
160 Authors did not state that assessors or treating physicians/therapists were blinded.
161 No missing data, no dropouts.
162 No study protocol available.
163 Due to the unclear information regarding the blinding and the lack of a study protocol, the risk of bias is high.
164 "An online software … was used to generate a randomization list, and 90 participants were allocated into two treatments groups."
165 "Generated numbers were placed in 90 sealed opaque envelopes…only opened after the participant had completed all the baseline assessments."
166 "All the participants were told about the existence of the EG and OMT/EG groups."
167 "The evaluators who carried out the assessments were blinded in relation to the group that each participant belonged"; "The therapists who performed the treatments could not be blinded."
168 "Test considers the missing data allowing for intent-to-treat analysis. Effects on time, group and time-by-group interaction were considered."
169 Other outcome measurements used as intended in the protocol.
170 Due to the lack of blinding of the patients and deviations from the protocol, a high risk of bias can be assumed.
171 "Randomization occurred at the point in the course of treatment at which the treating practitioner chose to introduce manipulation."
172 Numbered sealed opaque envelopes were used.
173 "It was not possible to blind the participants or practitioners to treatment allocation because of the nature of the interventions."
174 "Data collection and analysis were conducted by researchers who were blind to treatment allocation"; "It was not possible to blind … practitioners to treatment allocation."
175 Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups.
176 Outcome data reported according to the study protocol.
177 "Were divided randomly into 2 groups using a table of random numbers."
178 NI about adequate allocation concealment.
179 The authors stated that they„ cannot say that subjects were truly blinded because patients could know that they had been allocated to receive high velocity-low amplitude thrust (joint cavitation) or control mobilization procedure (nontissue tension)."
180 "Outcomes were assessed by an examiner blinded to the treatment allocation of the subject."
181 No missing outcome data.
182 NI about a study protocol.
183 "Enrolling physicians randomly assigned patients to receive either OMT or IM ketorolac using a predetermined random number table."
184 "The treatment arm was not disclosed to patients until after informed consent was obtained."
185 "Attempts were not made to blind patients or physicians as to which treatment was being given at the time of treatment."
186 NI if outcome assessors were blinded.

Indication	Trial	Adequate generation of randomisation sequence	Adequate allocation concealment	Blinding		Incomplete outcome data addressed	Selective outcome reporting unlikely	No other aspects which increase the risk of bias	Risk of bias – study level
				Patient	Treating physician/therapist[109]/outcome assessor				
Neck	Osama 2021 [86]	Yes[187]	Unclear[188]	No[133]	Yes[189]	Yes[175]	No[190]	Yes[115]	High[191]
Neck	Rezkallah 2018 [87]	Yes[192]	Unclear[193]	Yes[194]	No[194]	Yes[175]	Unclear[182]	Yes[115]	High[195]
Neck	Rodríguez-Fuentes 2016 [88]	Unclear[196]	Unclear[178]	Yes[175]	No[194]	Yes[181]	Unclear[182]	Yes[115]	High[195]
Neck	Rotter 2020 [89]	Yes[197]	Yes[198]	No[199]	No[200]	Yes[201]	Yes[202]	Yes[115]	High[203]

Interpretation:

Low risk of bias: Plausible bias unlikely to seriously alter the results. Low risk of bias for all key domains.

Unclear risk of bias: Plausible bias that raises some doubt about the results. Unclear risk of bias for one or more key domains.

High risk of bias: Plausible bias that seriously weakens confidence in the results. High risk of bias for one or more key domains.

187 "Randomly allocated via block randomization to the three treatment groups."

188 Sealed envelopes were used. However, method of concealment is not described in sufficient detail to allow a definite judgement. It remains unclear whether envelopes were sequentially numbered and opaque. However, it is not stated that they were numbered and opaque.

189 "It was a single blind study with the assessor being blind."

190 Cervical Range of Motion (CROM) and Neck Disability Index (NDI) not evaluated as written in the study protocol.

191 Due to the lack of blinding of the patients the deviations from the study protocol, a high risk of bias can be assumed.

192 "Randomization was implemented simply by means of a computer-generated randomized table using the SPSS programme."

193 "Individual and sequentially numbered index cards were secured in opaque envelopes." However, method of concealment is not described in sufficient detail to allow a definite judgement. It remains unclear whether envelopes were sealed.

194 Single blinded randomised controlled trail – "In single blind trials the recipient party (patient) is blinded."

195 Due to the lack of blinding of the outcome assessors, a high risk of bias can be assumed.

196 "Patients … were randomly distributed into two groups according to two therapeutic intervention programs" – NI about randomisation process.

197 "Patients were randomized to one of the two treatment groups (1:1 ratio) by a computer-generated block randomization process in the study center with variable block length."

198 "The allocation was performed in the study center by a study nurse and was concealed." The allocation was performed in the study center by a study nurse and was concealed.

199 "The blinding of patients or the therapist with regard to group allocation was not feasible."

200 "Blinding of outcome assessors (patients) was not feasible…"; "…the blinding of patients or the therapist with regard to group allocation was not feasible."

201 Reasons for missing outcome data unlikely to be related to true outcome.

202 Outcomes reported according to study protocol.

203 Due to the lack of blinding of the patients and outcome assessors, a high risk of bias can be assumed.

Quality appraisal of the systematic review and meta-analysis concerning chronic non-specific low back pain using AMSTAR 2

Table A-3: Quality appraisal of the systematic review and meta-analysis concerning chronic non-specific low back pain using AMSTAR 2

Dal Farra et al., 2021 [9]	Reviewers (LG, VH)
1. Did the research questions and inclusion criteria for the review include the components of PICO?	Yes
2. Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review, and did the report justify any significant deviations from the protocol?	Yes
3. Did the review authors explain their selection of the study designs for inclusion in the review?	Yes
4. Did the review authors use a comprehensive literature search strategy?	Yes
5. Did the review authors perform study selection in duplicate?	Yes
6. Did the review authors perform data extraction in duplicate?	Yes
7. Did the review authors provide a list of excluded studies and justify the exclusions?	Partial Yes[204]
8. Did the review authors describe the included studies in adequate detail?	Yes
9. Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies included in the review?	Yes
10. Did the review authors report on the sources of funding for the studies included in the review?	No[205]
11. If meta-analysis was performed, did the review authors use appropriate methods for statistical combination of results?	Yes
12. If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	Yes
13. Did the review authors account for RoB in individual studies when interpreting/discussing the results of the review?	Yes
14. Did the review authors provide a satisfactory explanation for and discussion of any heterogeneity observed in the results of the review?	Yes
15. If they performed quantitative synthesis, did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	Yes
16. Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	Yes
Overall Confidence	**High**

Reasoning
No or one non-critical weakness: the systematic review provides an accurate and comprehensive summary of the results of the available studies that address the question of interest.

[204] Authors provided the number of excluded studies and exclusion reasons, but not a list of references of excluded studies.

[205] The authors did not provide information regarding the sources of funding for the studies included in the review.

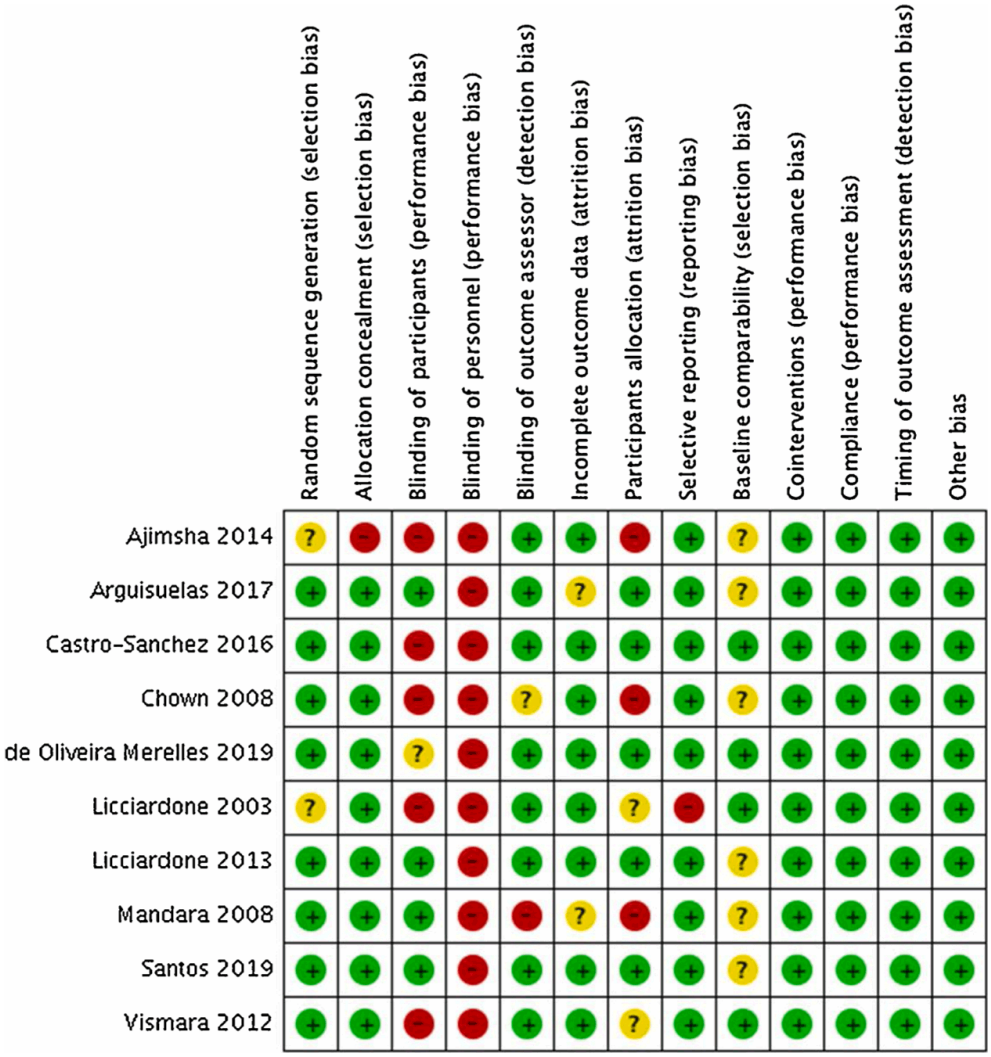


Figure A-1: Risk of bias summary of the systematic review and meta-analysis covering the body region of the lower back [9]

Extraction tables for part 1

Overview of study characteristics of included studies

Table A-4: Overview of study characteristics and description of interventions of included studies: neck part 1

Author, year [reference]	Haller 2016 [46]	Klein 2013 [47]
Indication	Neck pain	Neck pain
Acute vs chronic	Chronic	Acute
Country (corresponding author)	Germany	Germany
Study design	Double-blind RCT	Double-blind RCT
Number of randomised patients (age mean (SD))	54 (81.5% female; 44.6 ±10.0)	61 (45 female; IG: 47.9 (10.1); CG: 41.9 (10.4))
Dropout rate	Lost to assessment at week 8: 3 Lost to assessment at week 20: 9	0
Intervention/technique	Craniosacral therapy	Strain—counterstrain treatment
Intervention applied by (profession)	Licensed physiotherapists with advanced craniosacral therapy qualification, and on average 6 years of clinical practice	General practitioner with additional qualifications in sports medicine, manual therapies and completed full osteopathic curriculum (postgraduate) with 8 years of experience in using osteopathic treatments
Comparison	Light-touch sham treatment	Sham treatment[206]
Total number of sessions	8	1
Treatment period	8 weeks	1 session
Duration of each session	45 min	NR
Frequency of treatment	1x/week	NR
Follow-up assessment	3 months after treatment	None

Abbreviations: CG, control group. IG, intervention group. min, minutes. NR, not reported. RCT, randomised controlled trial. SD, standard deviation.

Table A-5: Overview of study characteristics of included studies: neck part 2

Author, year [reference]	Capó-Juan 2017 [16]	Rodríguez-Huguet 2020 [48]
Indication	Cervical myofascial pain	Neck pain
Acute vs chronic	NR	Subacute-chronic
Country (corresponding author)	Spain	Spain
Study design	3-arm, experimental, single-blind RCT	Single-blind RCT
Number of randomised patients (age range)	75 (60 female; 20-55)	54 (26 female; inclusion criteria: 20-60)
Dropout rate	0	0
Intervention/technique	Pressure release	Myofascial release
Intervention applied by (profession)	NR	Therapist with 9 years of experience in myofascial release therapy technique and certificate
Comparison	Kinesiotaping; placebo[207]	Standard physical therapy[208]
Total number of sessions	1	5
Treatment period	1 session	2 weeks
Duration of each session	NR	45 min
Frequency of treatment	1x	2.5x/week
Follow-up assessment	None	1 month

Abbreviations: Min, minutes. NR, not reported.

[206] „The finger of the therapist was placed at the height of C4 paravertebraly on the right hand side of the dorsal part and the head was rotated by 30° to the left to basic position without any flexion, extension or lateral flexion. This position was also held for 90 s. Afterwards, a slow reposition to basic position was carried out.“

[207] algometric bilateral pressure

[208] massage, ultrasound therapy, and transcutaneous electric nerve stimulation

Table A-6: Overview of study characteristics and description of interventions of included studies: neck or (lower) back

Author, year [reference]	Tozzi 2011 [49]	Williams 2003 [50]
Indication	Neck or low back pain	Neck or back pain
Acute vs chronic	Acute/Chronic	(Sub)acute
Country (corresponding author)	Italy	UK
Study design	RCT	Pragmatic RCT
Number of randomised patients (age range)	120 (IG: 18 female; 21-58; CG: 18 female; 18-56)	201 (female: NR; 16-65[209])
Dropout rate	NR	18[210]
Intervention/technique	Fascial release	Osteopathic spinal manipulation
Intervention applied by (profession)	Osteopath (5 years experience)	General practitioner registered as osteopath
Comparison	Sham treatment	Usual care
Total number of sessions	1	3-4
Treatment period	1 session	2 months
Duration of each session	4-8 min	NR
Frequency of treatment	NR	0.5-1x/week
Follow-up assessment	None	6 months

Abbreviations: CG, control group. IG, intervention group. NR, not reported. RCT, randomised controlled trial. UK, United Kingdom.

Table A-7: Overview of study characteristics and description of interventions of included studies: shoulder

Author, year [reference]	Mishra 2018 [26]	Hunter 2022 [25]
Indication	Upper trapezius spasm	Shoulder impingement syndrome
Acute vs chronic	NR	NR
Country (corresponding author)	India	Australia
Study design	RCT	3-arm single-blind RCT
Number of randomised patients (age range or mean ± SD)	60 (31 female; 20-55)	75 (25 per group) (IG: 10 female; 62.0 ± 9.6; placebo group: 9 female; 61.4 ± 11.3; muscle energy technique + soft tissue massage group: 9 female; 56.9 ± 9.2)
Dropout rate	0	18 (until last FU)
Intervention/technique	Myofascial release	Muscle energy technique
Intervention applied by (profession)	Physiotherapists	Osteopath (14 years clinical experience)
Comparison	Active release technique	Muscle energy technique + soft tissue massage; placebo
Total number of sessions	NR	4
Treatment period	7 days	4 weeks (test point week 3)[211]
Duration of each session	NR	15 min
Frequency of treatment	NR	1x/week
Follow-up assessment	None	4 weeks after discharge (test point week 7), 6 months (test point week 29), 1 year (test point week 55)

Abbreviations: FU, follow-up. min, minutes. NR, not reported. RCT, randomised controlled trial.

[209] target population

[210] IG: 70 patients (76%) returned 2 month questionnaire. 63 patients (70%) returned 6 month questionnaire. Data from medical records: 86 patients (95%). CG: 72 patients (66%) returned 2 month questionnaire. 72 patients (66%) returned 6 month questionnaire. Data from medical records: 101 patients (93%).

[211] First test point at week 3 (= discharge) → discrepancy in article was found as the treatment period was 4 weeks

Table A-8: Overview of study characteristics and description of interventions of included studies: lower back

Author, year [reference]	Dal Farra, 2021 [9]
Indication	Low back pain
Acute vs chronic	Chronic
Country (corresponding author)	Italy
Study design	Systematic review and meta-analysis
Included study design	RCTs
Number of included studies	10
Number of included patients (age mean (SD))	1,160 (female: NR; mean age 43.3 +/- 7.7)
Dropout rate	Range: 0–77%
Intervention/technique	Osteopathic interventions, i.e. OMT (n=6), myofascial release (n=2), craniosacral treatment (n=1) and osteopathic visceral manipulation (n=1)
Intervention applied by (profession)	NR
Comparison	No active treatment (sham therapy or no intervention; n=5), active treatment (standard exercise, classic massage; n=5)
Total number of sessions	Range 1-24, mean 8.7 +/- 5.8
Treatment period	Ranged 2-24 weeks, mean 9.9 +/- 7.04
Duration of each session	15-60 min, mode: 45 min
Frequency of treatment	2x/week to1x/month
Follow-up assessment	4-24 weeks (in 6/10 studies)

Abbreviations: Min, minute. NR, not reported. OMT, osteopathic manipulative treatment.

Table A-9: Overview of study characteristics and description of interventions of included studies: knee

Author, year [reference]	Zago 2021 [30]	Licciardone 2004 [14]
Indication	Patellofemoral pain syndrome	Knee or hip osteoarthritis, or hip fracture
Acute vs chronic	Chronic	Acute (postoperative)
Country (corresponding author)	Brazil	USA
Study design	3-arm RCT	Double-blind RCT
Number of randomised patients (age range)	82 (48 female; 18-35)	60 (42 female; 69.2 (10.3))
Dropout rate	Withdrawal from eligible patients: 5	Loss to 4-week postdischarge FU: 8
Intervention/technique	OMT	One or a combination of: myofascial release, strain—counterstrain, muscle energy, soft tissue, high-velocity low-amplitude (not at the surgical site), or craniosacral manipulation
Intervention applied by (profession)	Osteopath (8 years of experience)	Medical students (undergraduate fellows still in the training process; Department of Osteopathic Manipulative Medicine)
Comparison	Exercise programme; waiting list	Sham treatment (range-of-motion activities, light touch)
Total number of sessions	6	5.4
Treatment period	3 weeks	NR
Duration of each session	40 min	10-30 min
Frequency of treatment	2x/week	2.4x/week
Follow-up assessment	30 days	4 weeks after discharge (only SF-36)

Abbreviations: Min, minutes. NR, not reported. OMT, osteopathic manipulative treatment. RCT, randomised controlled trial. USA, United States of America.

Table A-10: Overview of study characteristics and description of interventions of included studies: foot

Author, year [reference]	Bac 2022 [31]	Ajimsha 2014 [32]
Indication	Flat foot with foot pain	Unilateral plantar heel pain
Acute vs chronic	NR	NR
Country (corresponding author)	Poland	Qatar
Study design	4-arm RCT	Double-blind RCT
Number of randomised patients (age range or mean ± SD)	70 (47 female after dropout; 20–49)	66 (49 female; IG: 42.4 ± 4.6; CG: 40.8 ± 7.1)
Dropout rate	10	1
Intervention/technique	Myofascial release	Myofascial release
Intervention applied by (profession)	Therapist	Physiotherapists certified in myofascial release (trained for min. 100 h, median experience of 12 months)
Comparison	Exercise programme; myofascial release and exercise programme[212]; no intervention	Sham ultrasound therapy
Total number of sessions	8	12
Treatment period	4 weeks	4 weeks
Duration of each session	40 min	30 min
Frequency of treatment	2x/week	3x/week
Follow-up assessment	None	12 weeks after randomisation

Abbreviations: CG, control group. h, hours. IG, intervention group. min., minimum. min, minutes. NR, not reported. RCT, randomised controlled trial. SD, standard deviation.

Table A-11: Overview of study characteristics and description of interventions of included studies: osteoporosis

Author, year [reference]	Papa 2012 [34]
Indication	Osteoporosis
Acute vs chronic	NR
Country (corresponding author)	Italy
Study design	Single-blind RCT
Number of randomised patients (age mean (SD))	72 (51 female; IG: 77.2 (5.3); CG: 76.8 (8.2))
Dropout rate	0
Intervention/technique	OMT
Intervention applied by (profession)	Osteopath
Comparison	Sham manipulative treatment
Total number of sessions	6
Treatment period	6 weeks
Duration of each session	30 min
Frequency of treatment	1x/week
Follow-up assessment	None

Abbreviations: OMT, osteopathic manipulative treatment. RCT, randomised controlled trial.

[212] The control group 'myofascial release and exercise programme' was not compared in this report because it includes an osteopathic technique.

Table A-12: Overview of study characteristics and description of interventions of included studies: fibromyalgia

Author, year [reference]	Matarán-Penarrocha 2011 [44]	Castro-Sanchez 2011 [36]
Indication	Fibromyalgia	Fibromyalgia
Acute vs chronic	Chronic	Chronic
Country (corresponding author)	Spain	Spain
Study design	Double-blind longitudinal clinical RCT	Single-blind RCT
Number of randomised patients (age range; mean (SD))	Randomised: 104 Analysed: 84 (81 females; range 34–63; mean 49.08 ± 14.17)	94 (female: NR; range 45-65; mean 54.4)
Dropout rate	20	8
Intervention/technique	Craniosacral therapy	Myofascial release
Intervention applied by (profession)	Expert craniosacral therapist	Physiotherapist (specialist in myofascial therapy)
Comparison	Placebo (simulated treatment with disconnected ultrasound)	Sham short-wave and ultrasound electrotherapy
Total number of sessions	50	10
Treatment period	25 weeks	20 weeks
Duration of each session	1 h	1 h
Frequency of treatment	2x/week	2x/week
Follow-up assessment	6 months, 1-year post-treatment	6 months, 1-year post-treatment

Abbreviations: H, hour. NR, not reported. RCT, randomised controlled trial.

Summary of effectiveness and description of interventions of included studies

Table A-13: Summary of effectiveness of included studies: neck part 1

Author, year [reference]		**Haller 2016 [46]**	**Klein 2013 [47]**
Indication		Neck pain	Neck pain
Acute vs chronic		Chronic	Acute
Intervention/technique		Craniosacral therapy	Strain—counterstrain treatment
Comparison		Light-touch sham treatment	Sham treatment
Number of randomised patients (age mean (SD))		54 (81.5% female; 44.6 ±10.0)	61 (45 female; IG: 47.9 (10.1); CG: 41.9 (10.4))
Outcomes (measurements)		Pain intensity (VAS), pain on movement (POM), point of max. pain (PPT), musculus levator scapulae (PPT), musculus trapezius (PPT), musculus semispinalis capitis (PPT), functional disability (NDI), physical QoL (SF-12), physical well-being (FEW), mental QoL (SF-12), anxiety (HADS), depression (HADS), stress perception (PSQ), pain acceptance (ERDA), body awareness (SBC), body dissociation (SBC), global improvement (PGI-I)	Mobility restriction (CROM), pain intensity (NPDS)
Effectiveness outcomes	**Absolute effects (95% CI or mean (SD); p-value of overall effect)**	***Between-group difference*** (95% CI; p-value): **Pain:** *Pain intensity:* ***week 8:*** -21.0 (-32.6 to -9.4); **p=0.001**; ***week 20:*** -16.8 (-27.5 to -6.1); **p=0.003** *Pain on movement:* ***week 8:*** -18.6 (-29.2 to -8.0); **p=0.001**; ***week 20:*** -11.4 (-20.9 to -1.9); **p=0.020** *Point of max. pain:* ***week 8:*** 50.3 (2.8 to 97.7); **p=0.038**; ***week 20:*** 23.9 (-9.9 to 57.3); n.s. **Pressure pain sensitivity:** *Musculus levator scapulae:* ***week 8:*** 34.2 (-2.9 to 71.3); n.s.; ***week 20:*** 10.4 (-25.1 to 45.8); n.s. *Musculus trapezius:* ***week 8:*** 31.8 (1.2 to 62.4); **p=0.042**; ***week 20:*** 4.4 (-28.9 to 37.7); n.s. *Musculus semispinalis capitis:* ***week 8:*** 5.8 (-19.2 to 30.8); n.s.; ***week 20:*** 15.1 (-12.4 to 42.5); n.s. **Physical health:** *Functional disability:* ***week 8:*** -8.2 (-14.4 to -2.1); **p=0.010**; ***week 20:*** -6.5 (-11.1 to -2.0); **p=0.006** *Physical QoL:* ***week 8:*** 5.8 (1.3 to 10.4); **p=0.013**; ***week 20:*** 5.9 (2.8 to 9.1); **p=0.000** *Physical well-being:* ***week 8:*** 0.2 (-0.2 to 0.5); n.s.; ***week 20:*** 0.2 (-0.1 to 0.7); n.s. **Mental health:** *Mental QoL:* ***week 8:*** 3.5 (-1.6 to 8.5); n.s.; ***week 20:*** 2.7 (-3.2 to 8.6); n.s. *Anxiety:* ***week 8:*** -1.0 (-2.8 to 0.9); n.s.; ***week 20:*** -2.1 (-3.8 to -0.3); **p=0.020** *Depression:* ***week 8:*** -0.7 (-2.2 to 0.8); n.s.; ***week 20:*** -1.9 (-3.9 to 0.2); n.s. *Stress perception:* ***week 8:*** -0.4 (-8.2 to 7.4); n.s.; ***week 20:*** -6.4 (-15.5 to 2.8); n.s. *Pain acceptance:* **week 8:** 0.1 (-0.2 to 0.4); n.s.; **week 20:** 0.2 (-0.1 to 0.4); n.s. **Body awareness:** *Body awareness:* ***week 8:*** 0.3 (0.1 to 0.5); **p=0.001**; ***week 20:*** 0.1 (-0.1 to 0.4); n.s. *Body dissociation:* ***week 8:*** 0.9 (-0.1 to 0.4); n.s.; ***week 20:*** 0 (-0.3 to 0.3); n.s. **Global improvement:** *Global improvement:* ***week 8:*** -1.0 (-1.5 to -0.5); **p=0.000**; ***week 20:*** -0.7 (-1.3 to -0.1); **p=0.029** ***Intra-group pre-post difference of the IG*** (mean (SD)): **Pain intensity:** Baseline: 64.1 (12.8); ***week 8:*** 31.7 (20.7); ***week 20:*** 31.6 (19.0)	***Within-group differences*** (mean (SD); p-value): **Pain intensity:** *baseline – after intervention 1:* IG: 0.7 (0.7); **p<0.001** CG: 0.3 (0.9); n.s. **Mobility restriction:** *baseline – after intervention 1:* IG: 2.0 (6.9); n.s. CG: 0.5 (5.7); n.s. ***Comparison between groups after intervention 1*** (mean (SD); p-value): **Pain intensity:** n.s. **Mobility restriction:** n.s.

Author, year [reference]		Haller 2016 [46]	Klein 2013 [47]
	Relative effects (95% CI; p-value of overall effect)	NR	NR
Safety outcomes	**Adverse events: Relative effects (95% CI)**	Serious adverse events: none Minor adverse events during or subsequent to the treatment: n=6 (increased neck pain, pain in the jaw area, shivering, tiredness, strong emotional reactions, weeping)	Mild transient adverse effects (n=4; pain apart from one verum patient reporting dizziness)
	Side effects	NR	NR
Conclusion		Craniosacral therapy was effective and safe in reducing neck pain intensity and may improve functional disability and the QoL up to 3 months after intervention.	Strain—counterstrain as a single intervention did not have immediate effects on mobility and pain over sham treatment.

Abbreviations: CG, control group. CI, confidence interval. CROM, Cervical Range of Motion. ERDA, Emotional/Rational Disease Acceptance Questionnaire. FEW, Questionnaire for Assessing Subjective Physical Well-being. HADS, Hospital Anxiety and Depression Scale. IG, intervention group. n.s., not significant. NDI, Neck Disability Index scale. NPDS, Neck Pain and Disability Scale. NR, not reported. PGI-I, Patients' Global Impression of Improvement. POM, Pain on Movement Questionnaire. PPT, pressure pain thresholds. PSQ, Perceived Stress Questionnaire. QoL, quality of life. SBC, Scale of Body Connection. SD, standard deviation. SF-12, 12-item Short Form Health Survey. VAS, Visual Analogue Scale.

Table A-14: Summary of effectiveness and description of interventions of included studies: neck part 2

Author, year [reference]		Capó-Juan 2017 [16]	Rodríguez-Huguet 2020 [48]
Indication		Cervical myofascial pain	Neck pain
Acute vs chronic		NR	Subacute-chronic
Intervention/technique		Pressure release	Myofascial release
Comparison		Kinesiotaping; placebo[213]	Standard physical therapy[214]
Number of randomised patients (age range)		75 (20-55)	54 (26 female; inclusion criteria: 20-60)
Outcomes (measurements)		Level of pain (subjective pain) (NPS), myofascial trigger points of sternocleidomastoid muscle (objective pain) (algometry), cervical joint range (objective pain) (goniometry), QoL (SF-12)	Pain intensity (NPRS), cervical active ROM (flexion, extension, side bending, rotation) (goniometer), pressure pain thresholds[215] (pressure algometer)
Effectiveness outcomes	**Absolute effects (mean (SD); p-value of overall effect or mean difference; 95% CI; p-value; effect size)**	***Pre-post differences*** (mean (SD); p-value): **Level of pain (subjective pain):** IG: pre: 5.36 (0.37), post: 4.24 (0.38); **p<0.001;** Placebo: pre: 5.04 (0.48), post: 4.40 (0.41); p>0.05; Kinesiotaping: pre: 5.32 (0.42), post: 2.92 (0.52); **p<0.001;** **Myofascial trigger points of sternocleidomastoid muscle (objective pain):** *Sternocleidomastoid right:* IG: pre: 1.76 (0.24), post: 3.12 (0.28); **p<0.001**; Placebo: pre: 1.80 (0.27), post: 1.68 (0.33); p>0.05; Kinesiotaping: pre: 1.88 (0.26), post: 4.72 (0.32); **p<0.001**;	***Between-group differences*** (mean difference; 95% CI; p-value; effect size): ***2 weeks:*** **Pain intensity:** -1.04; -1.71 to -0.36; **p<0.01**; medium **Cervical active ROM:** *Flexion:* -0.85; -5.28 to 3.57; n.s.; negligible *Extension:* -1.15; -5.74 to 3.45; n.s.; negligible *Side bending left:* 0.52; -3.09 to 4.13; n.s.; negligible *Side bending right:* -0.52; -4.36 to 3.33; n.s.; negligible

[213] algometric bilateral pressure

[214] massage, ultrasound therapy, and transcutaneous electric nerve stimulation

[215] i.e. „minimal amount of pressure necessary to evoke pain or discomfort at the trigger point"

Author, year [reference]		Capó-Juan 2017 [16]	Rodríguez-Huguet 2020 [48]
Effectiveness outcomes *(continuation)*	**Absolute effects (mean (SD); p-value of overall effect or mean difference; 95% CI; p-value; effect size)** *(continuation)*	*Sternocleidomastoid left:* IG: pre: 2.08 (0.23), post: 3.52 (0.33); **p<0.001**; Placebo: pre: 1.80 (0.28), post: 1.28 (0.28); p>0.05; Kinesiotaping: pre: 2.12 (0.27), post: 4.28 (0.31); **p<0.001**; **Cervical joint range (objective pain):** *Flexion:* IG: pre: 40.00 (1.77), post: 44.00 (1.29); **p<0.001**; Placebo: 38.60 (1.81), post: 38.60 (1.17); p>0.05 Kinesiotaping: pre: 34.20 (1.59), post: 44.00 (1.82); **p<0.001**; *Extension:* IG: pre: 43.60 (1.51):, post: 45.80 (1.46); **p<0.05**; Placebo: pre: 40.60 (1.66), post: 40.00 (1.63); p>0.05; Kinesiotaping: pre: 35.80 (1.31), post: 46.20 (1.05); **p<0.001**; *Right rotation:* IG: pre: 55.00 (1.91), post: 56.60 (1.84); p>0.05; Placebo: pre: 55.00 (1.47), post: 54.40 (1.64); p>0.05; Kinesiotaping: pre: 46.00 (1.89), post: 61.20 (1.20); **p<0.001**; *Left rotation:* IG: pre: 54.20 (1.79), post: 56.80 (1.95); p>0.05; Placebo: pre: 55.20 (1.51), post: 54.80 (1.71); p>0.05; Kinesiotaping: pre: 47.80 (1.98), post: 63.20 (1.11); **p<0.001**; **QoL:** IG: pre: 24.36 (1.93), post: 19.32 (1.62); **p<0.05**; Placebo: pre: 24.40 (2), post: 22.20 (1.74); **p<0.05**; Kinesiotaping: pre: 25 (2.18), post: 14.68 (2.36); **p<0.001** ***Between-group differences at 3. appointment (p-value):*** **Level of pain (subjective pain):** Pressure release vs placebo: n.s. Pressure release vs kinesiotaping: **p<0.05** **Myofascial trigger points of sternocleidomastoid muscle (objective pain):** *Sternocleidomastoid right:* Pressure release vs placebo: **p<0.05** Pressure release vs kinesiotaping: n.s. *Sternocleidomastoid left:* Pressure release vs placebo: **p<0.001** Pressure release vs kinesiotaping: n.s. **Cervical joint range (objective pain):** Pressure release vs placebo: n.s. Pressure release vs kinesiotaping: n.s. **QoL:** Pressure release vs placebo: n.s. Pressure release vs kinesiotaping: n.s.	*Rotation left:* 3.81; 0.13 to 7.50; **p<0.05**; medium *Rotation right:* 3.37; -0.27 to 7.01; n.s.; small **Pressure pain thresholds:** *Suboccipita left:* 0.21; 0.03 to 0.40; **p<0.05**; medium *Suboccipita right:* 0.32; 0.12 to 0.51; **p<0.01**; large *Thoracic left:* 0.14; -0.09 to 0.37; n.s.; small *Thoracic right:* 0.31; 0.06 to 0.56; **p<0.05**; medium ***1 month:*** **Pain intensity:** -1.56; -2.30 to -0.81; **p<0.001**; large **Cervical active ROM:** *Flexion:* 2.26; -2.96 to 7.48; n.s.; negligible *Extension:* 0.96; -5.36 to 7.28; n.s.; negligible *Side bending left:* 4.52; -0.67 to 9.70; n.s.; small *Side bending right:* 2.52; -1.85 to 6.88; n.s.; small *Rotation left:* 7.37; 2.92 to 11.82; **p<0.01**; medium *Rotation right:* 5.15; 0.68 to 9.61; **p<0.05**; medium **Pressure pain thresholds:** *Suboccipita left:* 0.34; 0.08 to 0.61; **p<0.05**; medium *Suboccipita right:* 0.29; 0.04 to 0.54; **p<0.05**; medium *Thoracic left:* 0.29; -0.02 to 0.59; n.s.; small *Thoracic right:* 0.35; 0.03 to 0.66; **p<0.05**; medium ***Change score of the IG*** (mean (SD)): **Pain intensity:** 2 weeks: -4.82 (0.88); 1-month: -6.00 (1.07)
	Relative effects (95% CI; p-value of overall effect)	NR	NR

Author, year [reference]		Capó-Juan 2017 [16]	Rodríguez-Huguet 2020 [48]
Safety outcomes	Adverse events: Relative effects (95% CI)	NR	None
	Side effects	NR	NR
Conclusion		Kinesiotaping and pressure release are two therapeutic techniques which help to reduce pain, show increased levels in Goniometry (cervical movements) and contribute to improve QoL. It seems that kinesiotaping could be more effective than pressure release.	Myofascial release therapy could be better than a standard physical therapy program for improving pain and suboccipital pressure pain thresholds in patients with neck pain. However, the difference between both treatments is less than the minimum detectable change of the numerical pain rating scale.

Abbreviations: IG, intervention group. NPRS, Numerical pain rating scale. NPS, Numerical Pain Scale. ROM, range of motion. QoL, quality of life. SF-12, 12-Item Short Form Survey.

Table A-15: Summary of effectiveness of included studies: neck or (lower) back

Author, year [reference]		Tozzi 2011 [49]	Williams 2003 [50]
Indication		Neck or low back pain	Neck or back pain
Acute vs chronic		Acute/Chronic	(Sub)acute
Intervention/technique		Fascial release	Osteopathic spinal manipulation
Comparison		Sham treatment	Usual care
Number of randomised patients (age range)		120 (IG: 18 female; 21-58; CG: 18 female; 18-56)	201 (female: NR; 16-65[216])
Outcomes (measurements)		Pain (SF-MPQ)[217]	Spinal pain and disability (EASPS), pain (SMPQ), physical and mental health (SF-12), QoL (EQ-5D)
Effectiveness outcomes	Absolute effects (mean (SD); 95% CI; p-value of overall effect)	***Between-group difference*** (mean (SD); p-value): **Pain:** IG: pre: 24.7 (8.6); post: 15.5 (9.8); CG: pre: 24.9 (9.2); post: 25.1 (8.9); **p<0.0001**	***Improvement in mean scores (mean change) at 2 months:*** (mean (SD); 95% CI; p-value): **Spinal pain and disability:** IG: 13.9 (12.8); CG: 8.6 (14.2); 0.7 to 9.8; **p=0.02** **Pain:** IG: 4.6 (8.0); CG: 2.1 (7.0); -0.1 to 5.0; n.s. **Physical health:** IG: 5.4 (8.9); CG: 4.1 (8.6); -1.7 to 4.3; n.s. **Mental health:** IG: 7.9 (11.2); CG: 1.2 (12.0); 2.7 to 10.7; **p=0.001** **QoL:** IG: 0.11 (0.28); CG: 0.06 (0.29); -0.04 to 0.15; n.s. ***Improvement in mean scores (mean change) at 6 months:*** (mean (SD); 95% CI; p-value): **Spinal pain and disability:** IG: 14.9 (16.1); CG: 10.4 (18.0); -1.5 to 10.4; n.s. **Pain:** IG: 6.6 (8.8); CG: 3.7 (8.1); -0.05 to 5.8; n.s. (p=0.05) **Physical health:** IG: 7.4 (10.3); CG: 5.5 (9.4); -1.6 to 5.4; n.s. **Mental health:** IG: 6.8 (13.6); CG: 1.4 (11.3); 1.0 to 9.9; **p=0.02** **QoL:** IG: 0.10 (0.30); CG: 0.10 (0.28); -0.1 to 0.1; n.s.
	Relative effects (95% CI; p-value of overall effect)	NR	NR

[216] target population

[217] All ultrasound measures are not considered as they were not the focus of this report.

Author, year [reference]		Tozzi 2011 [49]	Williams 2003 [50]
Safety outcomes	Adverse events: Relative effects (95% CI)	NR	None
	Side effects	NR	NR
Conclusion		Manual fascial techniques are effective manual techniques to improve pain perception over a short-term duration in people with non-specific neck or low back pain.	In a primary care osteopathy clinic, spinal pain and disability, and mental health could be improved.

Abbreviations: CG, control group. EASPS, Extended Aberdeen Spine Pain Scale. EQ-5D, EuroQol. IG, intervention group. n.s., not significant. QoL, quality of life. SF-12, 12-item Short Form Health Survey. SF-MPQ, Short-Form McGill Pain Assessment Questionnaire. SMPQ, Short-form McGill Pain Questionnaire.

Table A-16: Summary of effectiveness of included studies: shoulder

Author, year [reference]		Mishra 2018 [26]	Hunter 2022 [25]
Indication		Upper trapezius spasm	Shoulder impingement syndrome
Acute vs chronic		NR	NR
Intervention/technique		Myofascial release	Muscle energy technique
Comparison		Active release technique	Muscle energy technique + soft tissue massage; placebo
Number of randomised patients (age range or mean ± SD)		60 (31 female; 20-55)	75 (IG: 10 female; 62.0 ± 9.6; placebo group: 9 female; 61.4 ± 11.3; muscle energy technique + soft tissue massage group: 9 female; 56.9 ± 9.2)
Outcomes (measurements)		Cervical ROM (neck ROM), neck disability (NDI), pain (VAS)	Arm, shoulder and hand disability (DASH), shoulder pain and disability (SPADI), pain (VAS), change in activities (GROC), activity/functionality (PSFS), ROM (inclinometer; only after treatment)
Effectiveness outcomes	Absolute effects (mean (SD) or mean difference; 95% CI; p-value of overall effect)	***Difference between groups*** (mean (SD); p-value ***in favour of CG***): **Pain:** IG: -2.48 (0.86), CG: -4.79 (1.13); **p<0.001** **ROM:** *Cervical flexion:* IG: 5.63 (2.22), CG: 11.86 (4.05); **p<0.001** *Cervical extension:* IG: 6.10 (4.02), CG: 11.70 (4.05); **p<0.001** *Cervical side flexion (right):* IG: 5.73 (2.65), CG: 8.70 (3.78); **p<0.001** *Cervical side flexion (left):* IG: 6.13 (4.00), CG: 11.93 (4.77); **p<0.001** *Cervical rotation (right):* IG: 5.50 (2.82), CG: 9.20 (6.68); **p<0.01** *Cervical rotation (left):* IG: 5.46 (4.32), CG: 9.86 (5.71); **p<0.001** **Neck disability:** IG: -8.66 (4.67), CG: -13.33 (3.69); **p<0.001** ***Intra-group analysis (mean (SD)):*** Statistically significant pre-post differences in both groups (**p<0.001** in all measurements) **Pain intensity:** IG: pre: 6.10 (1.17); post: 3.61 (1.26) Mean of the difference of the IG: -2.48 (0.8585)	***Mean difference between groups*** (mean difference; 95% CI; p-value): **Pain:** *IG vs placebo group (CG):* ***Week 3:*** -15.5 (-24.5 to -6.5); **p=0.001**; ***Week 7:*** -10.8 (-20.4 to -1.3); **p=0.03;** ***Week 29:*** -14.1 (-26.0 to -2.2); **p=0.02; *Week 55:*** -17.3 (-30.9 to -3.8); **p=0.01** *IG vs MET+STM:* ***Week 3:*** -7.7 (-16.8 to 1.5); n.s.; ***Week 7:*** -6.6 (-16.2 to 3.0); n.s. ***Week 29:*** -7.0 (-19.4 to 5.3); n.s.; ***Week 55:*** -14.8 (-28.6 to -1.1); **p=0.04** **Shoulder pain and disability:** *IG vs placebo group (CG):* ***Week 3:*** -14.7 (-23.0 to -6.3); **p=0.001**; ***Week 7:*** -11.8 (-21.8 to -1.9); **p=0.020** ***Week 29:*** -14.9 (-26.3 to -3.5); **p=0.010**; ***Week 55:*** -19.0 (-32.4, -5.7); **p=0.005** *IG vs MET+STM:* ***Week 3:*** -1.1 (-9.8 to 7.5); n.s.; ***Week 7:*** -5.8 (-16.0 to 4.3); n.s. ***Week 29:*** -2.5 (-14.4 to 9.4); n.s.; ***Week 55:*** -7.6 (-21.2, 6.1); n.s.

Author, year [reference]		Mishra 2018 [26]	Hunter 2022 [25]
Effectiveness outcomes *(continuation)*	**Absolute effects (mean (SD) or mean difference; 95% CI; p-value of overall effect)** *(continuation)*		**Arm, shoulder and hand disability:** *IG vs placebo group (CG):* ***Week 3:*** -8.4 (-14.0 to -2.8); **p=0.003**; ***Week 7:*** -6.2 (-14.0 to 1.6); n.s. ***Week 29:*** -11.1 (-18.6 to -3.7); **p=0.004**; ***Week 55:*** -13.4 (-23.9 to -2.9); **p=0.013** *IG vs MET+STM:* ***Week 3:*** -0.26 (-6.0 to 5.5); n.s.; ***Week 7:*** -3.4 (-11.2 to 4.5); n.s. ***Week 29:*** -2.1 (-9.9 to 5.7); n.s.; ***Week 55:*** -4.1 (-14.8 to 6.7); n.s. **Change in activities:** *IG vs placebo group (CG):* ***Week 3:*** 1.5 (0.9 to 2.2); **p<0.001**; ***Week 7:*** 1.0 (0.1 to 1.9); **p=0.03** ***Week 29:*** 1.0 (-0.1 to 2.1); n.s.; ***Week 55:*** 1.4 (-0.1 to 2.8); n.s. *IG vs MET+STM:* ***Week 3:*** 0.3 (-0.4 to 1.0); n.s.; ***Week 7:*** 0.3 (-0.6 to 1.2); n.s. ***Week 29:*** -0.2 (-1.3 to 0.9); n.s.; ***Week 55:*** 0.5 (-1.0 to 2.0); n.s. **Activity/functionality:** *IG vs placebo group (CG):* ***Week 3:*** 1.3 (0.1 to 2.5); **p=0.03**; ***Week 7:*** 0.8 (-0.4 to 2.1); n.s. ***Week 29:*** 0.6 (-0.7 to 1.9); n.s.; ***Week 55:*** 1.8 (0.5 to 3.2); **p=0.008** *IG vs MET+STM:* ***Week 3:*** 0.3 (-0.9 to 1.5); n.s.; ***Week 7:*** 0.7 (-0.5 to 2.0); n.s. ***Week 29:*** -0.4 (-1.8 to 1.0); n.s.; ***Week 55:*** 0.2 (-1.2 to 1.5); n.s. **ROM:** *IG vs placebo group (CG) – week 3:* Standing posture: 1.6 (-1.8 to 5.0); n.s.; Thoracic flexion: -0.2 (-2.6 to 2.1); n.s. Thoracic extension: -1.3 (-5.2 to 2.6); n.s.; Total thoracic ROM: 1.2 (-2.8 to 5.2); n.s. *IG vs MET+STM – week 3:* Standing posture: 0.2 (-3.2 to 3.5); n.s.; Thoracic flexion: 0.5 (-1.9 to 2.8); n.s. Thoracic extension: -1.5 (-5.4 to 2.5); n.s.; Total thoracic ROM: 1.9 (-2.0 to 5.9); n.s.
	Relative effects (95% CI; p-value of overall effect)	NR	NR
Safety outcomes	**Adverse events: Relative effects (95% CI)**	NR	None
	Side effects	NR	NR
Conclusion		Both techniques are effective in alleviating pain, ROM, and neck disability. However, active release therapy gave better results as compared to myofascial release.	Muscle energy technique of the thoracic spine with or without soft tissue massage improved the pain and disability in individuals with shoulder impingement syndrome and may be recommended as a treatment approach.

Abbreviations: CG, control group. CI, confidence interval. DASH, Disabilities of the Arm Shoulder and Hand questionnaire. GROC, Global Rating of Change. IG, intervention group. MET+STM, muscle energy technique + soft tissue massage. n.s., not significant. NDI, Neck Disability Index scale. NR, not reported. PSFS, Patient-Specific Functional Scale. ROM, range of motion. SD, standard deviation. SPADI, Shoulder Pain and Disability Index. VAS, Visual Analogue Scale.

Table A-17: Summary of effectiveness of included studies: lower back

Author, year [reference]		Dal Farra, 2021 [9]
Indication		Low back pain
Acute vs chronic		Chronic
Intervention/technique		Osteopathic interventions
Comparison		No active treatment (sham therapy or no intervention), active treatment (standard exercise, classic massage)
Number of included patients (age mean (SD))		1,160 (female: NR; mean age 43.3 +/- 7.7)
Outcomes (measurements)		Pain (VAS, NRS, MGPQ) Functional status (ODI, RMDQ, QBPDS)
Effectiveness outcomes	Absolute effects (95% CI; p-value of overall effect)	NR
	Relative effects (95% CI; p-value of overall effect)	**Pain:** ES =-0.59 [-0.81, -0.36]; **P<0.00001**; heterogeneity: moderate-to-substantial and significant (I^2=59%; P=0.005); 10 studies (12 articles) (n=1,049 patients) **FU (12 weeks):** ES = -0.73 [-1.09, -0.37]; **P<0.0001**; heterogeneity: heterogenous and not significant (I^2=0%; P=0.93); 2 studies (n=128 patients) **Functional status:** ES=-0.42 [-0.68, -0.15]; **P=0.002**; heterogeneity: substantial and significant (I^2=72%; P<0.0001); 10 studies (12 articles) (n=1,055 patients) **FU (12 weeks):** ES= -0.32 [-0.74, 0.09]; P=0.13; heterogeneity: substantial and significant (I^2=77%; P=0.002); 4 studies (5 articles) (n=676 patients)
Safety outcomes	Adverse events: Relative effects (95% CI)	Increased pain in 10 subjects during the first week of myofascial release treatment (1/10 study); Increased back muscle spasticity in one occasion (1/10 study); No data collection (1/10 study); NR (7/10 studies)
	Side effects	NR
Conclusion		Osteopathy is effective in pain levels and functional status improvements in chronic low back pain patients. Myofascial release reported better level of evidence for pain reduction if compared to other interventions.

Abbreviations: ES, effect size. FU, follow-up. MGPQ, McGill Pain Questionnaire. NR, not reported. NRS, Numerical Rating Scale. ODI, Oswestry Disability Index. QBPDS, Quebec Pain Disability Scale. RMDQ, Roland and Morris Disability Questionnaire. VAS, Visual Analogue Scale.

Table A-18: Summary of effectiveness of included studies: knee

Author, year [reference]		Zago 2021 [30]	Licciardone 2004 [14]
Indication		Patellofemoral pain syndrome	Knee or hip osteoarthritis, or hip fracture
Acute vs chronic		Chronic	Acute
Intervention/technique		OMT	One or a combination of: myofascial release, strain—counterstrain, muscle energy, soft tissue, high-velocity low-amplitude (not at the surgical site), or craniosacral manipulation
Comparison		Exercise programme & waiting list	Sham treatment (range-of-motion activities, light touch)
Number of randomised patients (age range)		82 (48 female; 18–35)	60 (42 female; 69.2 (10.3))
Outcomes (measurements)		Pain (VAS), functionality (LKSS), dynamic knee valgus (SDT), plantar pressure in middle foot (SB), posterior thigh flexibility (SRT), hip ROM (fleximetry)	Functional independence (FIM), daily analgesic medication use (mg/d), length of stay (days), rehabilitation efficiency (FIM total score change per rehabilitation unit day), general health (SF-36)
Effectiveness outcomes	**Absolute effects (mean (SD); 95% CI; p-value of overall effect)**	***Change from admission to discharge*** (mean (SD); p-value): **Functional independence:** OMT: 26.5 (7.0); CG: 26.2 (6.5); n.s. **Daily analgesic medication use:** *Acetaminophen:* OMT: -741 (1471); CG: -371 (1715); n.s. *Hydrocodone:* OMT: -9.9 (16.9); CG: -8.0 (13.3); n.s. ***At rehabilitation unit discharge*** (mean (SD); p-value): **Length of stay:** OMT: 15.4 (6.6); CG: 12.3 (7.4); n.s. **Rehabilitation efficiency:** OMT: 2.0 (0.7); CG: 2.6 (1.1); **p=0.01** ***Change from admission to 4 weeks after discharge*** (mean (SD); p-value): **General health:** *Physical functioning:* OMT: -10.0 (31.3); CG: -15.0 (27.2); n.s. *Physical role limitations:* OMT: -16.3 (42.4); CG: -7.0 (37.9); n.s. *Bodily pain:* OMT: 22.9 (36.7); CG: 13.3 (38.0); n.s. *General health:* OMT: 4.9 (19.9); CG: 3.3 (17.9); n.s. *Vitality:* OMT: 9.2 (23.2); CG: 9.0 (33.7); n.s. *Social functioning:* OMT: 16.4 (41.5); CG: 1.0 (32.5); n.s. *Emotional role limitations:* OMT: 24.4 (58.5); CG: 22.7 (45.9); n.s. *Mental health:* OMT: 10.6 (23.4); CG: 4.8 (12.7); n.s.	***Difference between groups after 3 weeks*** (mean (SD); (95% confidence interval)); p-value): **Pain:** OMT group: −6.56 (2.03); (−7.64 to −5.48); EP group: −4.43 (1.26); (−5.11 to −3.76); CG: −0.18 (0.91); (−0.67 to 0.29); OMT vs EP: NR; OMT vs CG: **p<0.05** **Functionality:** OMT group: 31.86 (18.41); (21.23 to 42.49); EP group: 19.75 (13.45); (12.58 to 26.92); CG: −0.37 (2.27); (−1.58 to 0.83); OMT vs EP: **s.s.**; OMT vs CG: NR **Dynamic knee valgus:** OMT group: 7.81 (5.30); (4.98 to 10.64); EP group: 1.50 (9.47); (−3.54 to 6.54); CG: 1.81 (10.54); (−3.80 to 7.42); OMT vs EP: **s.s.**; OMT vs CG: **s.s.** **Plantar pressure in middle foot:** OMT group: −0.42 (0.16); (−0.51 to −0.33); EP group: −0.18 (0.28); (−0.33 to −0.02); CG: −0.02 (0.30); (−0.18 to 0.13); OMT vs EP: **s.s.**; OMT vs CG: **s.s.** **Posterior thigh flexibility:** OMT group: 5.62 (4.20); (3.37 to 7.86); EP group: 6.13 (4.01); (3.99 to 8.27); CG: −1.08 (1.54); (−1.90 to −0.25); OMT vs EP: NR; OMT vs CG: **s.s.** **Hip ROM:** OMT group: −0.93 (12.71); (−7.71 to 5.83); EP group: 6.50 (9.73); (1.31 to 11.68); CG: −0.68 (3.32); (−2.45 to 1.08); OMT vs EP: n.s.; OMT vs CG: n.s. ***Difference between groups at 30-day FU*** (mean (SD) (95% confidence interval)): **Pain:** OMT group: −6.56 (2.03); (−7.65 to −5.48); EP group: −4.43 (1.26); (−5.11 to −3.76); CG: 0.50 (1.03); (−1.05 to 0.05); **s.s.** **Functionality:** OMT group: 30.21 (19.72); (18.83 to 41.60); EP group: 18 (13.02); (11.06 to 24.94); CG: 1.06 (3.31); (−0.70 to 2.82); **s.s.**

Author, year [reference]		Zago 2021 [30]	Licciardone 2004 [14]
	Absolute effects (mean (SD); 95% CI; p-value of overall effect) *(continuation)*		**Dynamic knee valgus:** OMT group: 10 (6.14); (6.72, 13.27); EP group: 1.50 (9.47); (−3.54 to 6.54); CG: −0.75 (10.18); (−6.17 to 4.67); n.s. **Plantar pressure in middle foot:** OMT group: −0.40 (0.21); (−0.52 to −0.29); EP group: −0.18 (0.28); (−0.33 to −0.02); CG: −0.02 (0.10); (−0.08 to 0.03); **s.s.** **Posterior thigh flexibility:** OMT group: 5.58 (3.74); (3.58 to 7.57); EP group: 5.58 (4.04); (3.43 to 7.74); CG: −0.77 (1.54); (−1.59 to 0.04); n.s. **Hip ROM:** OMT group: 5.31 (5.32); (−5.56 to 16.19); EP group: 6.56 (5.43); (−4.54 to 17.67); CG: −0.59 (5.25); (−11.32 to 10.13); n.s. ***Intra-group pre-post difference of the IG*** (mean (SD)): **Pain:** pre: 6.62 (2.02); post: 0.62 (0.25); FU: 0.06 (0.25)
	Relative effects (95% CI; p-value of overall effect)	NR	NR
Safety outcomes	**Adverse events: Relative effects (95% CI)**	NR	NR
	Side effects	NR	NR
Conclusion		Both OMT and EP are effective in reducing knee pain in runners with PFPS, but there were no differences between the 2 interventions. However, OMT had greater effects on PPMF, DKV, and ROM of hip extension.	OMT does not appear to be efficacious in acute rehabilitation patients who recently underwent surgery for knee or hip osteoarthritis or a hip fracture. The only significant difference between groups was decreased rehabilitation efficiency with OMT.

Abbreviations: CG, control group. EP, exercise programme. FIM, Functional Independence Measure. FU, follow-up. LKSS, Lysholm Knee Scoring Scale. n.s., not significant. NR, not reported. OMT, osteopathic manipulative treatment. ROM, range of motion. SB, static baropodometry. SDT, step-down test. SF-36, Medical Outcomes Study Short Form-36. SRT, sit and reach test. s.s., statistically significant. VAS, Visual Analogue Scale.

Table A-19: Summary of effectiveness of included studies: foot

Author, year [reference]		Bac 2022 [31]	Ajimsha 2014 [32]
Indication		Flat foot with foot pain	Unilateral plantar heel pain
Acute vs chronic		NR	NR
Intervention/technique		Myofascial release	Myofascial release
Comparison		Exercise programme; myofascial release and exercise programme[212]; no intervention	Sham ultrasound therapy
Number of randomised patients (age range or mean ± SD)		70 (47 female after dropout; 20–49)	66 (49 female; IG: 42.4 ± 4.6; CG: 40.8 ± 7.1)
Outcomes (measurements)		Pain intensity (NRS scale), foot load distribution and selected static/dynamic foot indicators (FreeMed ground reaction force platform)	Pain, disability and activity restriction (FFI), pressure pain thresholds (mechanical pressure algometer)
Effectiveness outcomes	**Absolute effects (mean (SD) or mean ± SD (95% CI of the mean); p-value of overall effect)**	***Differences before and after***[218] (mean (SD); p-value of between measurements comparison): **Pain intensity:** *Left foot:* IG: −3.26 (2.54); **p=0.002**; E: −1.93 (2.12); **p=0.012**; CG: −0.80 (1.69); n.s. Between-group comparison (p-value): IG vs E: n.s.; IG vs CG: **p=0.018** *Right foot:* IG: −2.66 (1.63); **p=0.001**; E: −1.66 (1.79); **p=0.012**; CG: −0.80 (1.61); n.s. Between-group comparison (p-value): IG vs E: n.s.; IG vs CG: **p=0.015**	***Differences after 4 weeks*** (mean ± SD (95% CI of the mean); p-value): **Pain, disability and activity restriction:** IG: pre: 63.01 ± 4.44 (59.43–64.79), post: 17.39 ± 4.02 (16.08–21.26); **72.4% reduction**; CG: pre: 61.38 ± 5.22 (58.58–64.15), post: 56.85 ± 6.91 (53.02–58.88); 7.4% reduction; group comparison: **p<0.001** **Pressure pain thresholds** (group-by-time interactions for changes)**:** *Gastrocnemius:* IG: pre: 1.8 ± 0.44 (1.7–2.1), post: 2.9 ± 0.82 (2.8–3.1); CG: pre: 2.0 ± 0.22 (1.8–2.1), post: 2.2 ± 0.51 (2.0–2.4); **p<0.001** *Soleus:* IG: pre: 2.0 ± 0.48 (1.9–2.2), post: 3.1 ± 0.91 (2.8–3.2); CG: pre: 2.2 ± 0.52 (2.0–2.4), post: 2.2 ± 0.31 (2.1–2.3); **p<0.001** *Calcaneus:* IG: pre: 2.1 ± 0.38 (1.9–2.2), post: 3.4 ± 0.95 (3.1–3.6); CG: pre: 2.3 ± 0.77 (2.2–2.7), post: 2.5 ± 0.67 (2.3–2.6); **p<0.001** ***Differences after 12 weeks*** (mean ± SD (95% CI of the mean): **Pain, disability and activity restriction:** IG: post: 24.81 ± 3.98 (22.73–26.89); **60.6% reduction**; CG: post: 60.15 ± 8.11 (56.05–63.26); 2.0% reduction; group comparison: **p<0.001** **Pressure pain thresholds:** *Gastrocnemius:* IG: post: 2.6 ± 0.54 (2.4–2.7); CG: post: 2.1 ± 0.32 (2.0–2.2); **p<0.001** *Soleus:* IG: post: 2.7 ± 0.65 (2.6–2.9); CG: post: 2.1 ± 0.72 (2.0–2.3); **p<0.001** *Calcaneus:* IG: post: 3.1 ± 0.78 (2.9–3.2); CG: post: 2.4 ± 0.48 (2.2–2.7); **p<0.001**
	Relative effects (95% CI; p-value of overall effect)	NR	NR
Safety outcomes	**Adverse events: Relative effects (95% CI)**	NR	Serious adverse events: none
	Side effects	NR	NR
Conclusion		A limited influence of both exercises and myofascial release techniques on pain and selected static and dynamic indicators of a flat foot could be observed.	Myofascial release was more effective than sham ultrasound therapy regarding pain, disability and activity restriction, and pressure pain.

Abbreviations: CG, control group. CI, confidence interval. E, exercise group. FFI, Foot Function Index. IG, intervention group. NR, not reported. NRS, Numerical Rating Scale. SD, standard deviation.

[218] Foot load distribution was not extracted as it was not the objective of this report.

Table A-20: Summary of effectiveness of included studies: osteoporosis

Author, year [reference]		**Papa 2012 [34]**
Indication		Osteoporosis
Acute vs chronic		NR
Intervention/technique		OMT
Comparison		Sham manipulative treatment
Number of randomised patients (age mean (SD))		72 (51 female; IG: 77.2 (5.3); CG: 76.8 (8.2))
Outcomes (measurements)		Pain (VAS), QoL (QUALEFFO-41)
Effectiveness outcomes	**Absolute effects (mean ± SD; p-value of overall effect)**	***Between-group difference*** (mean ± SD; p-value): **Pain:** IG: pre: 4.4 ± 2.6, post: 4.1 ± 1.9; CG: pre: 4.8 ± 2.5, post: 4.6 ± 2.7; n.s. **QoL:** IG: pre: 107 ± 25, post: 91 ± 29; CG: pre: 112 ± 27, post: 110 ± 31; **p=0.001** *Subscales:* Pain: **p=0.003**; Perception of health: **p=0.005**; Path/Mobility: **p=0.049**; Mental well-being: n.s.; Daily activities: n.s.; Housework: n.s.; Leisure activities: n.s.
	Relative effects (95% CI; p-value of overall effect)	NR
Safety outcomes	**Adverse events: Relative effects (95% CI)**	None
	Side effects	NR
Conclusion		In a group of elderly subjects affected by osteoporosis, OMT was able to increase self-reported QoL, while the effect on body pain perception is unclear.

Abbreviations: OMT, osteopathic manipulative treatment. QoL, quality of life.
QUALEFFO-41, Quality of Life Questionnaire of the European Foundation for Osteoporosis.
VAS, Visual Analogue Scale.

Table A-21: Summary of effectiveness of included studies: fibromyalgia

Author, year [reference]		Matarán-Penarrocha 2011 [44]	Castro-Sanchez 2011 [36]
Indication		Fibromyalgia	Fibromyalgia
Acute vs chronic		Chronic	Chronic
Intervention/technique		Craniosacral therapy	Myofascial release
Comparison		Placebo (simulated treatment with disconnected ultrasound)	Sham short-wave and ultrasound electrotherapy
Number of randomised patients (age range; mean (SD))		Randomised: 104 Analysed: 84 (81 female; range 34–63; mean 49.08 ± 14.17)	94 (female: NR; range 45-65; mean 54.4)
Outcomes (measurements)		Pain (VAS), QoL (SF-36), sleep quality (PSQI), depression (BDI), anxiety (STAI)	Physical functioning (FIQ), mood (NDFG), pain (MPQ), fatigue (FIQ), tiredness on walking (FIQ), stiffness (FIQ), pain: sensory (MPQ), pain: affective (MPQ), pain: sensory + affective (MPQ), pain (VAS), clinical severity (CGIs), clinical improvement (CGIi), postural stability (stabilometer platform)[219]
Effectiveness outcomes	**Absolute effects (mean (SD); p-value of overall effect)**	***25 weeks after intervention*** (mean (SD); p-value): **Pain:** IG: **p<0.05**; CG: NR; between-group difference: **p<0.05** **QoL:** *Physical function:* IG: pre: 49.43 (6.90), post: 45.90 (5.87); **p<0.05**; CG: pre: 51.90 (9.92), post: 50.53 (9.12); n.s.; between-group difference: **p<0.01** *Physical role:* IG: pre: 25.17 (6.88), post: 22.10 (6.84); **p<0.05**; CG: pre: 25.86 (7.35), post: 25.80 (6.98); n.s.; between-group difference: **p<0.05** *Body pain:* IG: pre: 75.76 (7.20), post: 73.12 (6.08); **p<0.05**; CG: pre: 78.43 (12.75), post: 78.00 (13.07); n.s.; between-group difference: **p<0.05** *General health:* IG: pre: 67.02 (4.25), post: 64.40 (4.65); **p<0.05**; CG: pre: 68.28 (6.84), post: 68.35 (6.39); n.s.; between-group difference: **p<0.05** *Vitality:* IG: pre: 60.05 (5.23), post: 62.73 (5.27); **p<0.05**; CG: pre: 58.90 (6.27), post: 59.48 (7.73); n.s.; between-group difference: **p<0.05** *Social function*: IG: pre: 63.23 (7.12), post: 58.75 (6.74); **p<0.05**; CG: pre: 63.93 (12.41), post: 63.50 (11.57); n.s.; between-group difference: **p<0.05** *Emotional role:* between-group difference: n.s. *Mental health:* between-group difference: n.s. **State anxiety:** IG: **p<0.05**; CG: n.s.; between-group difference: n.s. **Trait anxiety:** IG: **p<0.05**; CG: n.s.; between-group difference: **p<0.05** **Depression:** between-group difference: n.s. **Sleep quality:** IG: **p<0.05;** CG: NR; between-group difference *(only sleep duration/disturbance, subjective quality)*: **p<0.05**	***Differences between groups*** (mean (SD); p-value): **Pain (MPQ):** ***Pre:*** IG: 9.2 (0.6), CG: 8.9 (1.1); ***20 weeks:*** IG: 7.3 (1.4), CG: 8.2 (1.1); **p=0.036** ***6 months:*** IG: 8.5 (0.7), CG: 8.0 (1.3); **p=0.042**; ***1 year:*** IG: 8.8 (0.5), CG: 8.7 (0.7); n.s. **Pain: sensory:** ***Pre:*** IG: 19.3 (9.2), CG: 19.9 (10.6); ***20 weeks:*** IG: 16.5 (8.6), CG: 20.3 (6.5); **p=0.021** ***6 months:*** IG: 17.3 (7.8), CG: 20.7 (7.1); **p=0.042**; ***1 year:*** IG: 18.2 (8.3), CG: 21.2 (7.9); **p=0.038** **Pain: affective:** ***Pre:*** IG: 5.6 (3.4), CG: 4.9 (4.2); ***20 weeks:*** IG: 4.2 (3.4), CG: 5.3 (4.1); **p=0.029** ***6 months:*** IG: 4.5 (2.9), CG: 5.2 (3.8); **p=0.042**; ***1 year:*** IG: 4.8 (3.6), CG: 5.1 (2.9); n.s. **Pain: sensory + affective:** ***Pre:*** IG: 24.9 (12.6), CG: 25.3 (10.7); ***20 weeks:*** IG: 20.6 (6.3), CG: 25.9 (5.3); **p=0.019** ***6 months:*** IG: 21.9 (7.2), CG: 26.2 (6.8); **p=0.022**; ***1 year:*** IG: 23.2 (7.6), CG: 26.7 (6.9); **p=0.036** **Pain (VAS):** ***Pre:*** IG: 9.13 (0.8), CG: 8.90 (1.3); ***20 weeks:*** IG: 7.98 (1.03), CG: 8.87 (1.01); **p=0.038** ***6 months:*** IG: 8.25 (1.13), CG: 8.94 (1.34); **p=0.043**; ***1 year:*** IG: 8.74 (1.08), CG: 8.92 (0.96); n.s. **Physical functioning:** ***Pre:*** IG: 64.95 (18.2), CG: 63.94 (16.4); ***20 weeks:*** IG: 56.10 (17.3), CG: 65.85 (18.5); **p=0.038** ***6 months:*** IG: 58.60 (16.3), CG: 64.08 (18.1); **p=0.048**; ***1 year:*** IG: 62.80 (20.1), CG: 65.01 (19.8); n.s. **Mood:** ***Pre:*** IG: 1.84 (1.56), CG: 2.04 (2.10); ***20 weeks:*** IG: 3.24 (1.46), CG: 1.96 (1.67); **p=0.028** ***6 months:*** IG: 2.88 (1.56), CG: 2.01 (1.44); **p=0.036**; ***1 year:*** IG: 2.55 (1.76), CG: 1.99 (1.62); **p=0.047**

[219] The analyses of tender points were not considered as they were not the focus of this report.

Author, year [reference]		Matarán-Penarrocha 2011 [44]	Castro-Sanchez 2011 [36]
	Absolute effects (mean (SD); p-value of overall effect) *(continuation)*	***6 months post-intervention*** (mean (SD); p-value): **State anxiety, depression, pain:** IG: n.s.; CG: n.s.; between-group difference: n.s. **QoL:** *Physical function:* IG: post: 46.05 (4.61) **p<0.05**; CG: post: 49.05 (8.03); n.s.; between-group difference: **p<0.05** *Vitality:* IG: post: 60.80 (5.11); n.s.; CG: post: 58.72 (7.78); n.s.; between-group difference: **p<0.05** *All other items:* IG: n.s.; CG: n.s.; between-group difference: n.s. **Sleep quality:** between-group difference *(only sleep duration/disturbance, habitual sleep efficiency)*: **p<0.05** ***1 year post-intervention*** (mean (SD); p-value): **Sleep quality** *(only sleep duration, habitual sleep efficiency, daily dysfunction)*: IG: **p<0.05**; CG: NR; between-group difference: **p<0.05** **Anxiety, depression, pain, QoL:** IG: n.s.; CG: n.s.; between-group difference: n.s.	**Fatigue:** ***Pre:*** IG: 8.1 (1.5), CG: 8.6 (1.3); ***20 weeks:*** IG: 7.2 (2.2), CG: 8.7 (1.9); **p=0.026** ***6 months:*** IG: 7.4 (1.9), CG: 8.5 (1.7); **p=0.037**; ***1 year:*** IG: 7.8 (2.3), CG: 8.8 (1.6); **p=0.038** **Tiredness on walking:** ***Pre:*** IG: 8.5 (2.3), CG: 7.9 (2.6); ***20 weeks:*** IG: 7.1 (2.1), CG: 7.9 (2.3); **p=0.044** ***6 months:*** IG: 7.5 (1.9), CG: 7.6 (1.8); n.s.; ***1 year:*** IG: 7.8 (2.2), CG: 7.7 (1.9); n.s. **Stiffness:** ***Pre:*** IG: 7.8 (1.9), CG: 6.9 (2.7)[220]; ***20 weeks:*** IG: 6.6 (2.8), CG: 7.5 (1.9); **p=0.042** ***6 months:*** IG: 6.9 (2.5), CG: 7.8 (2.4); **p=0.043**; ***1 year:*** IG: 7.3 (2.5), CG: 7.8 (2.1); n.s. **Clinical severity:** ***Pre:*** IG: 6.25 (0.73), CG: 5.92 (0.84); ***20 weeks:*** IG: 5.08 (1.03), CG: 6.02 (0.96); **p=0.044** ***6 months:*** IG: 5.28 (0.97), CG: 5.98 (0.84); **p=0.048**; ***1 year:*** IG: 5.49 (0.74), CG: 6.17 (0.91); n.s. **Clinical improvement:** ***Pre: IG:*** −5.38 (0.79), CG: −5.47 (0.46); ***20 weeks:*** IG: 5.28 (0.97), CG: 6.13 (1.03); **p=0.043** ***6 months:*** IG: 5.62 (0.88), CG: 6.30 (0.97); **0.046**; ***1 year:*** IG: 5.83 (1.24), CG: 6.49 (0.89); **p=0.049** **Postural stability:** ***Pre:*** IG: NR, CG: NR; ***20 weeks:*** IG: 5.10 (1.89), CG: 5.49 (0.94); n.s. ***6 months:*** IG: 5.42 (1.97), CG: 5.52 (1.06); n.s.; ***1 year:*** IG: 5.39 (1.24), CG: 5.50 (1.37); n.s.
	Relative effects (95% CI; p-value of overall effect)	NR	NR
Safety outcomes	**Adverse events: Relative effects (95% CI)**	None	None
	Side effects	NR	NR
Conclusion		Approaching fibromyalgia through craniosacral therapy improves anxiety and QoL levels. Craniosacral therapy reduces the perception of pain and fatigue and improves their night rest, increasing physical function.	Myofascial release techniques can be a complementary therapy for pain symptoms, physical function and clinical severity but do not improve postural stability in patients with fibromyalgia syndrome.

Abbreviations: BDI, Beck depression inventory. CG, control group. CGIi, Clinical Global Impression Improvement Scale. CGIs, Clinical Global Impression Severity Scale. FIQ, 10-item Fibromyalgia Impact Questionnaire. IG, intervention group. MPQ, McGill Pain Questionnaire. n.s., not significant. NDFG, number of days feeling good. NR, not reported. PSQI, Pittsburgh Sleep Quality Index. QoL, quality of life. SF-36, short form-36 health survey. STAI, State Trait Anxiety Inventory. VAS, Visual Analogue Scale.

[220] The two groups statistically significantly differed in the pre testing.

Excerpt extraction tables of the excluded studies

Table A-22: Excerpt extraction table: summary of effectiveness on pain of excluded studies: neck part 1

Author, year [reference]	Brück 2021 [79]	Cholewicki 2021 [80]	El-Gendy 2019 [81]	Groisman 2019 [82]
Indication	Neck pain	Neck pain	Neck pain	Neck pain
Number of randomised patients	60	97	60	90
Intervention/technique	Fascial treatment	OMT	Myofascial release	OMT combined with exercise
Intervention applied by (profession)	Osteopathic practitioners	Osteopathic physicians	Therapist	Osteopaths
Comparison	Manual therapy; control group (untreated)	Waiting list	Electrotherapy; non-guideline approach (stretch and strength)	Exercises group
Effectiveness outcomes	**Pain** (pre-post group difference; mean ± SD; p-value): IG: -2.3 ± 2.3; **p<0.000** Manual therapy: -2.8 ± 2.0; **p<0.000** CG: 0.0 ± 1.7; n.s. *Mixed-design ANOVA:* significant time effect (F = 41.57; **p<0.001**; η^2=0.42) significant time*group interaction (F = 10.12; **p=0.001**; η^2=0.26) **Neck pain and disability** (group difference; mean ± SD; p-value): IG: -11.3 ± 14.1 **p<0.002** Manual therapy: -11.3 ± 12.4; **p<0.002** CG: 1.1 ± 4.6; n.s. *Mixed-design ANOVA:* significant time effect (F = 24.66; **p<0.001**; η^2=0.30) significant time*group interaction (F = 8.21; **p=0.001**; η^2=0.22)	**Average pain** (between-group difference; mean (95% CI; p-value): -0.90 (-1.75, -0.05); **p<0.05** **Current pain** (between-group difference; mean (95% CI; p-value): -1.28 (-2.21, -0.36); **p<0.05** **Pain interference** (between-group difference; mean (95% CI; p-value): -1.47 (-4.56, 1.63); n.s.	**Pain** (between-group differences; p-value): Electrotherapy vs IG: pre: 0.567; post: 0.46; n.s. IG vs CG: pre: 0.567; post: 0.001; **p<0.05**	**Pain** (between-group difference; mean ± SD (95% CI); p-value): -1,4 ± 0,5 (-2,4 to -0,3); **p=0.007**
Conclusion	The results demonstrated fascial treatment's effectiveness and clinical relevance for patients with chronic neck pain. Furthermore, the results confirmed the effectiveness of manual therapy on pain and severity of illness.	OMT is relatively safe and effective in reducing pain and disability along with improving sleep, fatigue, and depression in patients with chronic neck pain.	Both multimodal approaches of electrotherapy and myofascial release therapy are effective in treating patients with chronic mechanical neck pain.	The association between OMT and exercises reduces pain and improves functional disability more than only exercise for individuals with non-specific chronic neck pain.

Abbreviations: CG, control group. CI, confidence interval. IG, intervention group. n.s., not significant. OMT, osteopathic manipulative treatment. SD, standard deviation.

Table A-23: Excerpt extraction table: summary of effectiveness on pain of excluded studies: neck part 2

Author, year [reference]	Leaver 2010 [83]	Martínez-Segura 2006 [84]	McReynolds 2005 [85]	Osama 2021 [86]
Indication	Neck pain	Neck pain	Neck pain	Neck pain
Number of randomised patients	182	70	58	78
Intervention/technique	Neck manipulation (high-velocity, low-amplitude thrust)	Cervical high-velocity low-amplitude manipulation	OMT	Autogenic inhibition muscle energy techniques; reciprocal inhibition muscle energy techniques
Intervention applied by (profession)	Practitioners with physiotherapy, chiropractic, and osteopathy professions	Therapist	Physician	NR
Comparison	Neck mobilisation	Control mobilisation	Intramuscular ketorolac	Static stretching (CG)
Effectiveness outcomes	**Pain** (mean difference; mean (95% CI); p-value): *Week 2:* -0.1 (-0.7 to 0.6); n.s. *Week 12:* 0.2 (-0.4 to 0.7); n.s.	**Neck pain at rest** (intergroup comparison (pre-post scores); mean (95% CI); p-value): IG: 3.5 (3.9-3.1) CG: 0.4 (0.5-0.2) **p<0.001**	**Pain intensity** (total change; mean ± SD, p-value): IG: 2.8 ± 1.7 CG: 1.7 ± 1.6 Group difference: **p=0.02** **Pain relief** (n (%)): No relief: IG: 1 (3); CG: 5 (17) Some relief: IG: 10 (34); CG: 9 (31) Moderate amount of relief: IG: 7 (24); CG: 9 (31) A lot of relief: IG: 10 (34); CG: 6 (21) Complete relief: IG: 1 (3); CG: -	**Pain** (comparison; post hoc; p-value): *1. session:* CG vs autogenic inhibition muscle energy: n.s. CG vs reciprocal inhibition muscle energy: n.s. *5. session:* CG vs autogenic inhibition muscle energy: **p<0.001** CG vs reciprocal inhibition muscle energy: **p<0.001**
Conclusion	Neck manipulation is not appreciably more effective than mobilisation. The use of neck manipulation, therefore, cannot be justified based on superior effectiveness.	Our results suggest that a single cervical high-velocity low-amplitude manipulation was more effective in reducing neck pain at rest and in increasing active cervical ROM than a control mobilisation procedure in subjects suffering from mechanical neck pain.	OMT is a reasonable alternative to parenteral non-steroidal anti-inflammatory medication for patients with acute neck pain in the emergency department setting.	Autogenic inhibition muscle energy techniques are more effective than static stretching and inhibition muscle energy techniques in improving isometric muscle strength in patients with mechanical neck pain.

Abbreviations: CG, control group. CI, confidence interval. IG, intervention group. n.s., not significant. OMT, osteopathic manipulative treatment. ROM, range of motion. SD, standard deviation.

Table A-24: Excerpt extraction table: summary of effectiveness on pain of excluded studies: neck part 3

Author, year [reference]	Rezkallah 2018 [87]	Rodríguez-Fuentes 2016 [90]	Rotter 2020 [89]
Indication	Neck pain	Neck pain	Neck pain
Number of randomised patients	70	59	62
Intervention/technique	Myofascial release techniques combined with exercises	Myofascial release	Osteopathic medicine
Intervention applied by (profession)	Therapist	Physiotherapist	Medical doctor (and osteopath)
Comparison	Sustained natural apophyseal glides combined with exercises; CG	Manual therapy	CG[221]
Effectiveness outcomes	**Pain** (mean (SD)): IG: pre: 8.15 (1.007); post: 3.23 (1.24) Sustained natural apophyseal glides: pre: 7.73 (1.05); post: 2.69 (0.97) CG: pre: 7.71 (1.1); post: 5.14 (1.35) Group-difference (p-value): **p=0.0001**	**Pain intensity** (median (95% CI); p-value): IG: mid: 4.00 (3.8); post: 2.00 (1.8) CG: mid: 4.00 (2.8); post: 2.00 (2.00) Group-difference (p-value): n.s. **Bodily pain** post intervention (median (95% CI); p-value): IG: 15.00 (12.88) CG: 15.00 (0.00) Group-difference (p-value): n.s.	**Pain** (group-difference; mean (95% CI); p-value): *6 weeks:* −20.9 (−30.7; −11.1); **p<0.001** *12 weeks:* −26.2 (−35.2; −17.2); **p<0.001**
Conclusion	Sustained natural apophyseal glides with exercise and myofascial release with exercise offered short-term statistically significant improvements in pain, neck ROM and functional disability in non-specific neck pain patients.	The treatment of occupational mechanical neck pain by myofascial release therapy seems to be more effective than manual therapy for correcting the advanced position of the head, recovering ROM in side bending and rotation, and improving QoL.	The results of this study suggest that osteopathic medicine might effectively reduce pain intensity in adults with non-specific chronic neck pain.

Abbreviations: CG, control group. CI, confidence interval. IG, intervention group. n.s., not significant. QoL, quality of life. ROM, range of motion. SD, standard deviation.

Table A-25: Excerpt extraction table: summary of effectiveness on pain of excluded studies: shoulder

Author, year [reference]	Ajimsha 2012 [63]	Geldschläger 2004 [65]	Iqbal 2020 [64]	Schwerla 2020 [23]
Indication	Lateral epicondylitis	Chronic epicondylopathia humeri radialis	Adhesive capsulitis	Shoulder pain
Number of randomised patients	65	53	60	70
Intervention/technique	Myofascial release	Osteopathic treatment	Spencer muscle energy technique	Osteopathic treatment
Intervention applied by (profession)	Therapist	Osteopath	Therapist	Osteopathic practitioners
Comparison	Sham ultrasound therapy	Orthopaedic treatment	Passive stretching	Waiting list

[221] Patients of the control group started to receive osteopathic medicine treatment after week 12.

Author, year [reference]	Ajimsha 2012 [63]	Geldschläger 2004 [65]	Iqbal 2020 [64]	Schwerla 2020 [23]
Effectiveness outcomes	**Pain severity and functional disability:** *Week 4:* IG: 78.7% reduction CG: 6.8% reduction Group difference (95% CI): 43.95 to 48.42 IG vs CG: **p<0.001** *Week 12:* IG: 63.1% reduction CG: 2.2% increase Group difference (95% CI): 39.5 to 43.98 IG vs CG: **p<0.001**	**Pressure pain** (mean difference (SD)): IG: -17 (19); **p<0.01** CG: -16 (27); **p<0.03** IG vs CG: n.s.	**Shoulder pain** (mean rank; p-value)**:** IG: pre: 28.53, post: 19.90 CG: pre: 32.47, post: 41.10 IG vs CG: **p=0.000** **Shoulder pain and disability** (mean rank; p-value)**:** IG: pre: 32.77, post: 40.03 CG: pre: 23.27, post: 28.53 IG vs CG: **p=0.000**	**Pain intensity** (inter-group difference of longitudinal changes (95% CI); p-value): *Average pain:* -40.4 (-33.2 to -47.5); **p<0.0005** *Worst pain:* -41.5 (-34.6 to -48.3); **p<0.0005** **Shoulder pain and disability** (difference of longitudinal changes, mean ± SD; p-value): -27.2 (-19.3 ± 31.1) **p<0.005**
Conclusion	Myofascial release is more effective than a control intervention for lateral epicondylitis.	An osteopathic approach successfully treated chronic epicondylopathia humeri radialis. A significant difference to an orthopaedic treatment could not be proved.	Spencer technique was found to be more effective than passive stretching in treating patients with adhesive capsulitis.	Five osteopathic treatments over a period of eight weeks led to statistically significant and clinically relevant positive changes of pain and disability in patients suffering from shoulder pain.

Abbreviations: CG, control group. CI, confidence interval. IG, intervention group. n.s., not significant. SD, standard deviation.

Table A-26: Excerpt extraction table: summary of effectiveness on pain of excluded studies: foot

Author, year [reference]	Eisenhart 2003 [77]	Renan-Ordine 2011 [78]
Indication	Ankle injuries	Plantar heel pain
Number of randomised patients	55	60
Intervention/technique	OMT	Myofascial trigger point manual therapy combined with a self-stretching
Intervention applied by (profession)	Osteopathic physician	Clinician with orthopaedic manual therapy training
Comparison	CG (standard of care)	Self-stretching programme
Effectiveness outcomes	**Pain** (mean ± SD; p-value): *1 session:* IG: pre: 6.50 ± 2; post: 4.1 ± 1.7; **p<0.001** *1 week:* IG: 3.15 ± 1.4 CG: 3.5 ± 2.8 Between-group difference: n.s.	**Bodily pain** (between-group difference; mean (95% CI); p-value): 7.8 (2.5, 13.3); **p<0.05**
Conclusion	A single session of OMT in the emergency department can have a significant effect on the management of acute ankle injuries.	The addition of trigger point manual therapies to a self-stretching protocol resulted in superior short-term outcomes as compared to a self-stretching program alone in the treatment of patients with plantar heel pain.

Abbreviations: CG, control group. CI, confidence interval. IG, intervention group. n.s., not significant. OMT, osteopathic manipulative treatment. SD, standard deviation.

Table A-27: Excerpt extraction table: summary of effectiveness on pain of excluded studies: fibromyalgia

Author, year [reference]	Castro-Sanchez 2011b [43]	Castro-Sanchez 2011c {Castro-Sanchez, 2011 #33}	Coste 2021 [37]
Indication	Fibromyalgia	Fibromyalgia	Fibromyalgia
Number of randomised patients	92	64	101
Intervention/technique	Craniosacral therapy	Massage-myofascial release therapy	Osteopathic medicine
Intervention applied by (profession)	Craniosacral therapists	Physiotherapist specialised in massage myofascial therapy	Medical doctors with diplomas in manual medicine – osteopathy
Comparison	Sham treatment (disconnected magnetotherapy)	Sham treatment (disconnected magnetotherapy)	Sham treatment
Effectiveness outcomes	**Pain at 18 different tender points** (p-value): right occiput: *20 weeks:* **p<0.05**; *2 months:* **p<0.05**; *1 year:* n.s. left occiput: *20 weeks:* **p<0.05**; *2 months:* **p<0.05**; *1 year:* **p<0.05** lower cervicals (righ-side): *20 weeks:* **p<0.05**; *2 months*: n.s.; *1 year:* n.s. lower cerivicals (left-side): *20 weeks:* **p<0.05**; *2 months:* **p<0.05**; *1 year:* **p<0.05** right trapezius muscle: *20 weeks:* **p<0.05**; *2 months:* n.s.; *1 year:* n.s. left trapezius muscle: *20 weeks:* **p<0.05**; *2 months:* **p<0.05**; *1 year:* n.s. right supraspinatus muscle: *20 weeks:* **p<0.05**; *2 months:* **p<0.05**; *1 year:* n.s. left supraspinatus muscle: *20 weeks:* n.s.; *2 months:* n.s.; *1 year:* n.s. second right rib: *20 weeks:* n.s.; *2 months:* n.s.; *1 year:* n.s. second left rib: *20 weeks:* **p<0.05**; *2 months:* n.s.; *1 year:* n.s. right lateral epicondyle: *20 weeks:* **p<0.05**; *2 months:* **p<0.05**; *1 year:* n.s. left lateral epicondyle: *20 weeks:* **p<0.05**; *2 months:* **p<0.05**; *1 year:* **p<0.05** right gluteal muscle: *20 weeks:* n.s.; *2 months:* **p<0.05**; *1 year:* n.s. left gluteal muscle: *20 weeks:* **p<0.05**; *2 months:* n.s.; *1 year:* n.s. right greater trochanter: *20 weeks:* **p<0.05**; *2 months:* n.s.; *1 year:* n.s. left greater trochanter: *20 weeks:* **p<0.05**; *2 months:* **p<0.05**; *1 year:* **p<0.05** right knee: *20 weeks:* n.s.; *2 months:* n.s.; *1 year:* n.s. left knee: *20 weeks:* n.s.; *2 months:* n.s.; *1 year:* n.s.	**Pain intensity** (p-value of group difference): *20 weeks:* **p<0.05**; *1 month:* **p<0.05**; *6 months:* n.s. **Body pain** (p-value of group difference): *20 weeks:* **p<0.05**; *1 month:* **p<0.05**; *6 months:* n.s. **Pain at 18 different tender points** (p-value of group difference): right occiput: *20 weeks:* **p<0.05**; *1 month:* **p<0.05**; *6 months:* n.s. left occiput: *20 weeks:* **p<0.05**; *1 month:* **p<0.05**; *6 months:* **p<0.05** lower cervicals (righ-side): *20 weeks:* n.s.; *1 month:* n.s.; *6 months:* n.s. lower cerivicals (left-side): *20 weeks:* **p<0.05**; *1 month:* **p<0.05**; *6 months:* n.s. right trapezius muscle: *20 weeks:* **p<0.05**; *1 month:* **p<0.05**; *6 months:* **p<0.05** left trapezius muscle: *20 weeks:* n.s.; *1 month:* n.s.; *6 months:* n.s. right supraspinatus muscle: *20 weeks:* n.s.; *1 month:* n.s.; *6 months:* n.s. left supraspinatus muscle: *20 weeks:* n.s.; *1 month:* n.s.; *6 months:* n.s. second right rib: *20 weeks:* n.s.; *1 month:* n.s.; *6 months:* n.s. second left rib: 2*0 weeks:* n.s.; *1 month:* n.s.; *6 months:* n.s. right lateral epicondyle: *20 weeks:* n.s.; *1 month:* n.s.; *6 months:* n.s. left lateral epicondyle: *20 weeks:* **p<0.05**; *1 month:* **p<0.05**; *6 months:* n.s. right gluteal muscle: *20 weeks:* **p<0.05**; *1 month:* **p<0.05**; *6 months:* n.s. left gluteal muscle: *20 weeks:* **p<0.05**; *1 month:* n.s.; *6 months:* n.s. right greater trochanter: *20 weeks:* **p<0.05**; *1 month:* **p<0.05**; *6 months:* **p<0.05** left greater trochanter: *20 weeks:* n.s.; *1 month:* n.s.; *6 months:* n.s. right knee: *20 weeks:* n.s.; *1 month:* n.s.; *6 months:* n.s. left knee: *20 weeks:* n.s.; *1 month:* n.s.; *6 months:* n.s.	**Pain intensity** (mean differences between groups; mean (95% CI); p-value): During treatment: −2.2 (−9.1 to 4.6); n.s. *Week 6:* −2.7 (−11.0 to 5.6); n.s. *Week 12:* 0.6 (−10.9 to 12.1); n.s. *Week 24:* −5.6 (−22.1 to 10.8); n.s. *Week 52:* −5.0 (−24.8 to 14.7); n.s.
Conclusion	Craniosacral therapy improved medium-term pain symptoms in patients with fibromyalgia.	A massage-myofascial release program significantly improved the pain, anxiety, quality of sleep, and QoL. The treatment reduced the sensitivity to pain at sensitive points, mainly at the lower cervicals, gluteal muscles, and right greater trochanter.	Osteopathy conferred no benefit over sham treatment for pain, fatigue, functioning, and QoL in patients with fibromyalgia. These findings do not support the use of osteopathy to treat these patients.

Abbreviations: CI, confidence interval. n.s., not significant. QoL, quality of life.

Country selection for part 2

Table A-28: Overview of the country selection for part 2

	National association(s) of osteopaths	Statutory regulation	More than 5.5 Mio inhabitants
Albania	NI	x	x
Austria	√	x	√
Belgium	√	x	√
Bulgaria	NI	x	√
Croatia	NI	x	x
Cyprus	√	√	x
Czech Republic	NI	x	√
Denmark	√	√	√
Estland	√	x	x
Finland	√	√	√
France	√	√	√
Germany	√	x	√
Greece	√	x	√
Iceland	√	√	x
Ireland	√	x	x
Italy	√	**Regulation in work**	√
Lettland	√	x	x
Lithuania	√	x	x
Luxembourg	√	√	x
Malta	√	√	x
Netherlands	√	x	√
Norway	√	**Regulation in work**	√
Poland	NI	x	√
Portugal	√	√	√
Romania	NI	x	√
Slovakia	NI	x	x
Slovenia	√	x	x
Spain	√	x	√
Sweden	√	x	√
Switzerland	√	√	√
UK	√	√	√
Ukraine	NI	x	√
Hungary	NI	x	√

The highlighted countries indicate the included countries.
Abbreviations: NI, no information. UK, United Kingdom

Extraction tables for part 2

Factsheets on regulation, education and practice of osteopathy in the selected countries

Table A-29: Information on regulation, education and practice of osteopathy in Denmark

Denmark [1, 91, 92]	
Population	5.8 million [1]
Practising osteopaths in total	Approx. *270*
Osteopaths per 100.000 people (self-calculated)	5
Regulation	
National association(s) of osteopathy	Danske Osteopater [1]
Title ‚osteopath' protected	Yes [1]
Who is recognised as an osteopath?	Only persons who have been granted authorisation as an osteopath have the right to use the title ‚osteopath' [1, 91]
Information on regulation (official documents)	Legislation came into force on the 1st of July 2018* [1] (https://www.danskeosteopater.dk/autorisation-information-in-english/)
Legislation based on CEN/WHO Benchmark	Yes [1]
Authorisation and registration	Educational level and content must be approved by the Patient Safety Authority (Styrelsen for Patientsikkerhed)** There is an official register on The Patient Safety Authority website of all healthcare professionals in Denmark, holding a Danish license to practise within their profession, including osteopaths [1, 91]
Education	
Education level required to practise	Bachelor level*** [1]
Type of education offered	Type II [1]
Further information on education	*Two educational programmes, on top of prior healthcare profession, are offered in Denmark by ‚The International Academy of Osteopathy', IAO, and ‚The European School of Osteopathy', ESO****
Practice of osteopathy	
Patients can self-refer	Yes [1]
Osteopathy located in primary healthcare	Yes [1]
Practice execution	Private practice [1]
Reimbursement	*Either by private health insurance companies (almost all private Danish health insurance companies***** reimburse (partly or fully) osteopathic treatment) or work-related insurance under certain circumstances*
When are the costs reimbursed and for which indicators	*When people need osteopathic treatment and have private health insurance that covers osteopathic treatment, they usually get reimbursed. That could be due to back pain, postpartum problems, headaches etc. Furthermore, if treatment by an osteopath is necessary due to a recognised occupational accident, the costs can be covered under the Occupational Accident Insurance Act if the treatment is carried out by a registered osteopath.*
Restrictions to practise	No [1]
Continuing professional development (CPD)	There are currently no mandatory requirements for CPD, but there are plans to implement CPD in the future. [1]

The sentences (or passages) in italics are comments/additions by Hanna Tómasdóttir, DO M.R.O.DK (Autoriseret Osteopat, Master I Positiv Psykologi, Formand for Danske Osteopater, President of European Federation & Forum for Osteopathy (EFFO)), written contact 11th July and 22nd July 2022

** "Until 1st July 2023, osteopaths who had completed their training and were already practising as osteopaths before the legislation came into force on 1st July 2018 can continue to practise as osteopaths under the transitional arrangement, and thus without authorisation. These osteopaths have until 1st July 2023, after which they must be issued with authorisation to continue practising as osteopaths. Osteopaths who have completed their training after 1st July 2018, or have moved to Denmark after 1st July 2018, must wait for an official license to practise as an osteopath – an official authorisation from the Patient Safety Authority before they can use the title 'osteopath' and practise as osteopaths in Denmark."*

*** For non-EU citizens, a Danish language test must be passed, and evaluation employment must be completed*

**** A Bachelor's degree or equivalent to a Bachelor's level, which corresponds to level 6 of the European Qualifications Framework (EQF), is required to obtain a license to practise Osteopathy in Denmark. The total amount of hours should be no less than 4200, incl. 1000 hours of supervised clinical practice (adopted from The WHO Benchmarks)*

**** *Further information about education can be found here:*
https://www.danskeosteopater.dk/wp-content/uploads/2020/01/Executive-order-on-the-Authorisation-of-Osteopaths.pdf
***** *The following health insurance companies in Denmark cover osteopathy (partly or fully): Alm. Brand, If forsikring, Topdanmark, Codan, PFA, Dansk Sundhedssikring, Danica, Lærerstandens Brandforsikring, Runa, Bauta, Sygeforsikringen 'danmark', AP Pension, Gjensidige, Skandia, Tryg*
Abbreviations: approx., approximately. CEN, Comité Européen de Normalisation. CPD, Continuing Professional Development. ESO, European School of Osteopathy. IAO, The International Academy of Osteopathy. WHO – World Health Organisation

Table A-30: Information on regulation, education and practice of osteopathy in Germany

Germany [93-97]	
Population	83.2 million [96]
Practising osteopaths in total	approx. 10,000 (Status 2018) [93]
Osteopaths per 100.000 people (self-calculated)	12
Regulation	
National association(s) of osteopathy	*In Germany, many different associations exist* (e.g. Konsensgruppe Osteopathie Deutschland with its members Verband der Osteopathen Deutschland e.V. (VOD), Akademie für Osteopathie e.V. (AFO), Bundesarbeitgemeinschaft Osteopathie (BAO), Deutscher Verband für Osteopathische Medizin e.V. (DVOM), Register der traditionellen Osteopathen in Deutschland GmbH (ROD), additionally there are other groups Verband für Osteopathie und ganzheitliche Therapie e.V. (VOgT), Bundesverband Osteopathie e.V. (bvo), Verband Freier Osteopathen e.V. (VFO), Verband für Osteopathie und ganzheitliche Therapie e.V., Verband wissenschaftlicher Osteopathen Deutschlands (VWOD))*
Title ‚osteopath' protected	No [97]
Who is recognised as an osteopath?	*Osteopathy in Germany has been defined as a medicine system that can only be applied by physicians or state-approved alternative practitioners (‚Heilpraktiker')*
Information on regulation (official documents)	*No regulation of the profession in Germany – osteopaths can work in first access under the ‚Heilpraktiker Law' or as a medical doctor* (https://www.bundestag.de/resource/blob/710020/60d8de59f2d4e5f98f5ce9f25f8df1e6/WD-9-043-20-pdf-data.pdf)
Legislation based on CEN/WHO Benchmark	*No*
Authorisation and registration	*‚Heilpraktiker' must register with the local health authority as a Heilpraktiker practice* Various associations for osteopathy (e.g. VOD and bvo) maintain a register of practising osteopaths
Education	
Education level required to practise	*There is no legal regulation on the necessary training, but most physicians or Heilpraktiker** perform osteopathy*
Type of education offered	Due to the lack of regulation, no uniform training or curriculum exists. Different osteopathic schools in Germany offer apprenticeships [97]. *Training as an osteopath is always additional training for a doctor, physiotherapist or alternative practitioner.*
Further information on education	Osteopathic training in Germany mostly takes place at private schools or universities that are partially and voluntarily supervised through associations of osteopaths or alternative practitioners. The curricula and the extent of training hours show a high variation among schools [94, 97].
Practice of osteopathy	
Patients can self-refer	*Yes*
Osteopathy located in primary healthcare	*Yes*
Practice execution	*Private practice*
Reimbursement	Many German (private) health insurance organisations reimburse the costs for osteopathic treatment partially if a physician recommends this kind of treatment [95], and *statutory health insurance funds may give a subsidy*
When are the costs reimbursed and for which indicators?	*Costs are covered by insurance if patients are referred by a doctor* *The costs will be reimbursed when the osteopath is a member of an osteopathic organisation, as the VOD*
Restrictions to practise	*No*
Continuing professional development	*There are no regulations for CPD, however, the various associations may give regulations so that osteopaths can remain members*

The sentences (or passages) in italics are comments/additions by Kerstin Ceglie (Verband der Osteopathen Deutschland e.V), written contact, 14th of July and personal contact, 21st of July 2022
** No guarantee for completeness. The various associations have different requirements for becoming a member of an osteopathic association.*
*** To become a ‚Heilpraktiker', you have to make a ‚Heilpraktiker'-examination.*

Abbreviations: AFO, Akademie für Osteopathie e.V. approx., approximately. BAO, Bundesarbeitgemeinschaft Osteopathie. BVO, Bundesverband Osteopathie e.V. CEN, Comité Européen de Normalisation. CPD, Continuing Professional Development. DVOM, Deutscher Verband für Osteopathische Medizin e.V. NI, no information. ROD, Register der traditionellen Osteopathen in Deutschland GmbH. VOD, Verband der Osteopathen Deutschland e.V. VFO, Verband für Osteopathie und ganzheitliche Therapie e.V. VOgT, Verband für Osteopathie und ganzheitliche Therapie e.V. VWOD, Verband wissenschaftlicher Osteopathen Deutschlands. WHO, World Health Organisation.

Table A-31: Information on regulation, education and practice of osteopathy in Italy

Italy [1]	
Population	60.4 million
Practising osteopaths in total	Approx. 12,000
Osteopaths per 100.000 people (self-calculated)	20
Regulation	
National Association(s) of osteopathy	Registro degli Osteopati d'Italia, ROI, Federazione Sindacale Italiana Osteopat, Fe.s.i.os, Associazione professionale degli osteopati, APO
Title ‚osteopath' protected	Not yet – Italy is in the process of regulation
Who is recognised as an osteopath?	*At this moment, since the law is not complete, there are no official requirements ‚to be an osteopath'.* *In the future, there will be requirements one has to meet to get the title (which will be protected)*
Information on regulation (official documents)	A law is in place, but there are no implementing decrees yet* (https://www.gazzettaufficiale.it/eli/id/2018/1/31/18G00019/sg)
Legislation based on CEN/WHO Benchmark	No – but CEN has been presented to the Ministry during the discussions about recognition
Authorisation and registration	*The Ministry of Health is responsible for authorisation* Associations for osteopathy (e.g. RIO) maintain a register of practising osteopaths. *An official national register of practising osteopaths will be created at the end of the regulatory process*
Education	
Education level required to practise	Due to the ongoing regulation process, no requirements have been set as yet, but it will change to a university degree (Bachelor's equivalent) when regulation is implemented
Type of education offered	Type I and Type II**
Further information on education	More than 40 educational institutions offer training in osteopathy right now; some are validated by foreign institutions (e.g. UCO, BNU)
Practice of osteopathy	
Patients can self-refer	Yes
Osteopathy located in primary healthcare	Not yet – Italy is in process of regulation
Practice execution	Private practice National Health Services***
Reimbursement	Some private insurance cover treatments After the regulation process is over also, the State will reimburse
When are the costs reimbursed and for which indicators	*Not defined yet*
Restrictions to practise	The professional profile that has just been approved does not allow osteopaths to use internal and invasive techniques.
Continuing professional development (CPD)	There are currently no mandatory requirements for CPD

The sentences (or passages) in italics are comments/additions by Giacomo Consorti (Consigliere Macroregione Nord-Ovest ROI – Registro degli Osteopati d'Italia), written contact, 13th July 2022

** There are 3 decrees which need to be done before the law will be active. 1) definition of professional profile (done), 2) definition of the university curriculum (work in progress), 3) definition of the criteria of equivalence and equipollence (not started yet)*

*** Type II is currently offered in Italy, but on regulation, only Type I university programmes will be offered.*

**** when the regulation process is over*

Abbreviations: APO, Associazione professionale degli osteopati. approx., approximately. BNU, Buckinghamshire New University. CEN, Comité Européen de Normalisation. CPD, Continuing Professional Development. e.g. for example. Fe.s.i.os, Federazione Sindacale Italiana Osteopati. ROI, Registro degli Osteopati d'Italia. UCO, University College of Osteopathy. WHO, World Health Organisation.

Table A-32: Information on regulation, education and practice of osteopathy in Norway

Norway [1]	
Population	5.5 million
Practising osteopaths in total	Approx. *550*
Osteopaths per 100.000 people (self-calculated)	10
Regulation	
National association of osteopathy	Norsk Osteopatforbund (NOF)
Title ‚osteopath' protected	*Title regulated and protected as from 1st of July 2022. There is a transition period ending 1st of July 2023, until then, osteopaths can use the title as long as they present a formal application. From 1st of July 2023, only registered osteopaths can use the title.*
Who is recognised as an osteopath?	*When the profession is fully regulated, and the legislation takes effect, the title 'osteopath' will be protected and will consequently ensure that only qualified osteopaths can deliver osteopathy/osteopathic treatment.*
Information on regulation (official documents)	Osteopaths will be included in Health personnel law* (https://lovdata.no/dokument/NL/lov/1999-07-02-64, *Chapter 9, § 48. ‚Autorisasjon')*
Legislation based on CEN/WHO benchmark	Yes – in process of regulation *referring to accredited education programme delivered in Norway by a registered university college*
Authorisations and registration	When regulation is in place, the profession will be regulated by the common regulatory body for all healthcare professions in Norway, Helsedirektoratet, and all licensed osteopaths will need to be registered on the national ‚Helsepersonellregisteret'. Actually, the national association for osteopathy maintains a register for all practising osteopaths (https://osteopati.org/finn-din-osteopat/)
Education	
Education level required to practise	Bachelor/DO**
Type of education offered	Type I***
Further information on education	*After fulfilling sixth form/A-levels, students can enter a full-time 4-year programme at Kristiania University College*
Practice of osteopathy	
Patients can self-refer	Yes
Osteopathy located in primary healthcare	Yes – in process of regulation, *osteopaths can deliver their service anywhere within the healthcare system, mainly osteopaths work in private primary healthcare*
Practice execution	Private practice National Health Services
Reimbursement	*By several major private health insurance companies, no state funding/reimbursement*
When are the costs reimbursed and for which indicators?	*Reimbursement depends on individual coverage from (private) health insurance and applies to patients who have been referred by their insurer*
Restrictions to practise	No
Continuing professional development	*When regulated, CPD is part of any healthcare professional's individual responsibility; there is no specific number of hours or credits*

The sentences (or passages) in italics are comments/additions by D.O. Tomas Collin (Leder Norsk Osteopatforbund), written contact, 6th and 11th of July

* *See* https://lovdata.no/dokument/NL/lov/1999-07-02-64

** *About 200 osteopaths in NOF are Type I educated, and around 175 are Type II educated*

*** *Full-time, 4-years, see* https://www.kristiania.no/en/

Abbreviations: approx., approximately; CEN, Comité Européen de Normalisation; CPD, Continuing Professional Development; DO, doctor of osteopathic medicine; NOF, Norsk Osteopatforbund; WHO, World Health Organisation

Table A-33: Information on regulation, education and practice of osteopathy in Portugal

Portugal [1]	
Population	Approx. *10.3 million*
Practising osteopaths in total	*3,102**
Osteopaths per 100.000 people (self-calculated)	550
Regulation	
National association(s) of osteopathy	*Currently, there are two associations with expression in the field of Osteopathy: AOST – Associação dos Osteopatas de Portugal, the largest, and AIO – Associação Independente de Osteopatia*
Title ‚osteopath' protected	Yes
Who is recognised as an osteopath?	*After a transitory process of DO practitioner's recognition until 7th August 2020, the ACSS – Central Administration of Health Services, I.P./Ministry of Health, only recognised osteopaths with a BSc Hons in osteopathy who are able to practise in Portugal, or if they come from European Union (EU) countries where Osteopathy is recognised as a health profession, and are registered as osteopaths in EU health state bodies. Only with an official licence in osteopathy issued by ACSS/ Ministry of Health, osteopaths can work in Portugal.*
Information on regulation (official documents)	Osteopathy has been officially considered as a Healthcare Profession since 2003. *The recognised practitioners may, in principle, exercise in Portugal under Directive 2005/36/EC of the European Parliament and of the Council, of 7th September, amended by Directive 2013/55/EU of the European Parliament and of the Council, of 20th November, transposed into Portuguese domestic law, submitting the application to the ACSS – Central Administration of Health Services, I.P./Ministry of Health.* The practice of osteopathy performed by non-osteopaths is punishable by law (limits access to the regulated profession or its exercise). (https://www.acss.min-saude.pt//wp-content/uploads/2016/09/Lei-45_2003.pdf, https://www.acss.min-saude.pt//wp-content/uploads/2016/09/Lei-71_2013.pdf, https://www.acss.min-saude.pt//wp-content/uploads/2016/09/Portaria-207_B-2014.pdf, https://www.acss.min-saude.pt//wp-content/uploads/2016/09/Portaria-172_E2015.pdf)
Legislation based on CEN/WHO Benchmark	*Yes (partially) – considering the proposals and recommendations of the World Health Organisation, with the necessary adaptations to Portuguese domestic law.*
Authorisations and registration	Only osteopaths accredited and registered in the ACSS – Portuguese Central Administration of the Health System, I.P./Ministry of Health, can practise osteopathy in Portugal
Education	
Education level required to practise	Bachelor of Science Hons
Type of education offered	Type I**
Further information on education	*The teaching of osteopathy in Portugal began in 1981 with DO programmes. Portuguese Degrees in Osteopathy (BSc Hons, with 240 ECTS) started in 2016. There are currently eight colleges across the country that offer osteopathic degrees programmes*
Practice of osteopathy	
Patients can self-refer	Yes
Osteopathy located in primary healthcare	Yes
Practice execution	Private practice
Reimbursement	Partly covered by the three major private insurance companies
When are the costs reimbursed and for which indicators	*The co-payment, i.e. the amount receivable from the insurer, will depend on what is contractually defined for the osteopathic appointment.*
Restrictions to practise	No
Continuing professional development (CPD)	There are no mandatory requirements for CPD

The sentences (or passages) in italics are comments/additions by Dr Fernando L. Diniz Baptista, DEA, MSc, BSc Ost, DO (UK), written contact, 13th July 2022

** Official data collected on 26th May 2022*

***About 90% of all osteopaths in AOST are Type I educated, and about 10% are Type II educated*

Abbreviations: ACSS, Central Administration of Health System. AIO, Associação Independente de Osteopatia. AOST, Associação dos Osteopatas de Portugal. approx., approximately. BSc, Bachelor of Science. CEN, Comité Européen de Normalisation. CPD, Continuing Professional Development. DO, Diploma Osteopath. ECTS, European Credit Transfer and Accumulation System. EU, European Union. WHO, World Health Organisation.

Table A-34: Information on regulation, education and practice of osteopathy in Switzerland

Switzerland [1, 98, 99]	
Population	8.6 million [1]
Practising osteopaths in total	Approx. 1,300 [1]
Osteopaths per 100.000 people (self-calculated)	15
Regulation	
National association(s) of osteopathy	*SuisseOsteo, Fédération Suisse d'Ostéopathiee, Schweizerischer Verband der Osteopathie*
Title ‚osteopath' protected	Yes [1]
Who is recognised as an osteopath?	Osteopaths with a cantonal licence to practise [98, 99]
Information on regulation (official documents)	2006: Intercantonal recognition of osteopathy 2020: Inclusion in the Health Professions Act (GesBG) [98, 99] (https://fedlex.data.admin.ch/filestore/fedlex.data.admin.ch/eli/cc/2020/16/20200201/de/pdf-a/fedlex-data-admin-ch-eli-cc-2020-16-20200201-de-pdf-a.pdf)
Legislation based on CEN/WHO Benchmark	No – legislation passed prior to CEN publication [1]
Authorisation and registration	To work as an osteopath in Swiss, a cantonal licence to practise is required, which is granted to holders of the Master of Science FH in Osteopathy or an equivalently recognised foreign diploma [98, 99] *Registration in the ‚nationalen Gesundheitsberuferegister (GesReg:* https://www.gesreg.admin.ch/)*'* *to practise is needed for activity in own responsibility or in responsibility for a company*
Education	
Education Level required to practise	Master* [1]
Type of education offered	Type I [1]
Further information on education	Osteopathic training is provided at the ‚Hochschule für Gesundheit in Fribourg' (HEdS-FR). It is bilingual (French and German) training. The title ‚Master of Science HES in Osteopathy' is awarded after ten semesters or five years of full-time study. The ‚Fernfachhochschule Schweiz' (FFHS) offers a Bachelor's degree and is in the process of offering a Master's degree in osteopathy (from 2026).* [99]
Practice of osteopathy	
Patients can self-refer	Yes [1]
Osteopathy located in primary healthcare	Yes [1]
Practice execution	Private practice [1]
Reimbursement	By private insurance [1]
When are the costs reimbursed and for which indicators	*Each insurance company knows its own products, which have very different regulations for the participation or assumption of costs.*
Restrictions to practise	No [1]
Continuing Professional development (CPD)	*No statutory CPD but members of the SuisseOsteo, Fédération Suisse d'Ostéopathiee, Schweizerischer Verband der Osteopathie are required to do 30 hours of CPD per year*

The sentences (or passages) in italics are comments/additions by Christian Streit (Geschäftsführer SuisseOsteo), written contact, 12th July 2022

** 5 years of full-time study*

*** See:* https://www.ffhs.ch/de/bachelor/bsc-in-osteopathie#aufbau, https://www.heds-fr.ch/de/ausbildung/osteopathie/der-beruf/

Abbreviations: Approx., approximately. CEN, Comité Européen de Normalisation. CPD, Continuing Professional Development. FH, University of Applied Sciences. GesBG, Gesundheitsberufegesetz. NAREG, nationales Gesundheitsberuferegister. WHO, World Heath Organisation.

Table A-35: Information on regulation, education and practice of osteopathy in the United Kingdom (UK)

United Kingdom [1, 100]	
Population	68 million [1]
Practising osteopaths in total	approx. 5,500 [1]
Osteopaths per 100.000 people (self-calculated)	8
Regulation	
National association(s) of osteopathy	Institute of Osteopathy (iO) [1]
Title ‚osteopath' protected	Yes [1]
Who is recognised as an osteopath?	*Individuals who successfully complete a degree level qualification programme that is recognised by the government regulator, the General Osteopathic Council (GOsC) can then go on to join the official Register. This is renewable on an annual basis.*
Information on regulation (official documents)	Osteopathy has been regulated since 1993 [1] (https://www.osteopathy.org.uk/news-and-resources/document-library/legislation/osteopaths-act-1993-as-amended/)
Legislation based on CEN/WHO Benchmark	No – legislation passed prior to CEN publication* [1]
Authorisation and registration	Recognition of qualification from the GOsC Official register of osteopaths operated by the UK regulator (GOsC) [1, 100]
Education	
Education Level required to practise	Bachelor [1]
Type of education offered	Type I** and Type II [1]
Further Information on education	*Only people who meet the Osteopathic Practice Standards are able to graduate with a recognised qualification enabling them to apply for registration with the GOsC. At present, the majority of osteopaths qualify with integrated Master's degrees (M Ost).*
Practice of osteopathy	
Patients can self-refer	Yes [1]
Osteopathy located in primary healthcare	Yes, and *also in secondary care and hospital settings.*
Practice execution	Private practice National Health Service [1]
Reimbursement	*By all insurance companies, but coverage varies depending on the type of scheme. There is no general reimbursement for osteopathic care by the NHS or government, although there is a small number of historical or local schemes where a patient can access an osteopath in independent practice, with some or all costs reimbursed.*
When are the costs reimbursed and for which indicators	*Patient fees are reimbursed (typically up to a specified maximum set by the insurance company) when the patient has asked for osteopathic care. Depending on the case, this may have required preapproval through the insurer's triage process.*
Restrictions to practise	No [1]
Continuing professional development (CPD)	*CPD is mandatory for practising osteopathy in the UK. CPD requirements are specified by the regulator and require 90 hours of study over a three-year period, with a particular focus on addressing key osteopathic practice standards. Peer review was recently introduced as a key element.*

The sentences (or passages) in italics are comments/additions by Maurice Cheng (Chief Executive Institute of Osteopathy, iO), written communication, 14th July 2022

** although the UK were key contributor to CEN*

*** including Type I part-time programmes*

Abbreviations: approx., approximately. CEN, Comité Européen de Normalisation. CPD, Continuing Professional Development. GOsC, General Osteopathic Council. iO, Institute of Osteopathy. NHS, National Health Services. UK, United Kingdom. WHO, World Health Organisation.

Table A-36: Information on regulation, education and practice of osteopathy in Austria

Austria [101, 102]	
Population	8.9 million [102]
Practising osteopaths in total	approx. *2,000*
Osteopaths per 100.000 people (self-calculated)	22
Regulation	
National Association(s) of osteopathy	Österreichische Gesellschaft für Osteopathie (OEGO) Österreichische Ärztegesellschaft für Osteopathie, osteopathische Medizin und klinische Osteopathie (OEÄGO)* [101]
Title ‚osteopath' protected	No
Who is recognised as an osteopath?	The term 'osteopathy' and the title of 'osteopath' are currently not legally protected in Austria and are used by various professional groups with different training standards** [101]
Information on regulation (official documents)	No information
Legislation based on CEN/WHO Benchmark	No
Authorisations and registration	At present, there is no regulation regarding authorisation and registration *The OEGO maintains a register of members with a minimum qualification*
Education	
Education Level required to practise	At present, there is no legal regulation about education level requirements*** [101]
Type of education offered	*Type II*
Further Information on education	Currently, various training and further education courses are offered in the field of osteopathy in Austria, including Master's courses by the Wiener Schule für Osteopathy (WSO) and the International Academy of Osteopathy (IAO). For Master's degrees: Doctors, dentists, physiotherapists and medical students from SIP (Summative integrated exam) 4 onwards are allowed to participate**** [101]
Practice of osteopathy	
Patients can self-refer	Yes, and *in case of prevention, for curative interventions, a physician's referral is required*
Osteopathy located in primary healthcare	*No defined standards for primary healthcare applicable in Austria; newly created primary healthcare centres may offer osteopathy at their discretion*
Practice execution	Private practice
Reimbursement	*Osteopathic treatments are only covered by some private health insurances if osteopathy is listed; in rare cases, by regional health insurances*
When are the costs reimbursed and for which indicators?	*Partly reimbursement is possible after individual prior sickfund approval; no country-wide standards for reimbursement applicable*
Restrictions to practise	The practice without restriction is allowed for physicians and dentists. Osteopaths with a non-medical basic profession are allowed to practise osteopathy on the basis of their professional law (mostly the Medical-Technical Services Act (MTD Act)) after being referred by a doctor [101]
Continuing Professional Development (CPD)	No CPD requirements for osteopaths*****

The sentences (or passages) in italics are comments/additions by Margit Halbfurter (Chair of Österreichische Gesellschaft für Osteopathie), written contact 16th August 2022

** All members of this organisation are also members of the OEGO*

*** In Austria, osteopathy is mainly practised by doctors and physiotherapists with extensive osteopathic training.*

**** See for minimum qualification to be registered as OEGO member:* https://www.oego.org/home/wie-werde-ich-mitglied/

**** https://www.wso.at/index.php/lehrgaenge-kurse/master-of-science-msc
https://www.osteopathie.eu/de/master-of-science-in-osteopathie

***** *In Austria WSO and the IAO offer many post-graduate courses for specialisation in osteopathy*

Abbreviations: approx., approximately. CEN, Comité Européen de Normalisation. CPD, Continuing Professional Development. IAO, International Academy of Osteopathy. MTD Act, Medical-Technical Services Act. OEÄGO, Österreichische Ärztegesellschaft für Osteopathie, osteopathische Medizin und klinische Osteopathie. OEGO, Österreichische Gesellschaft für Osteopathie. SIP, Summative integrated exam. WHO, World Health Organisation. WSO, Wiener Schule für Osteopathy.

Table A-37: Information on regulation, education and practice of osteopathy in Finland

Finland [1]	
Population	5.5 million
Practising osteopaths in total	approx. 500
Osteopaths per 100.000 people (self-calculated)	9
Regulation	
National Association(s) of osteopathy	Suomen Osteopaattiliitto ry/Finlands Osteopatförbund rf and Suomen ortopediset osteopaatit ry (Soory) *
Title ‚osteopath' protected	Yes
Who is recognised as an osteopath?	Persons licensed or authorised to practise by the national supervisory authority
Information on regulation (official documents)	Osteopathy has been officially considered a Healthcare Profession since 1994 (https://finlex.fi/en/laki/kaannokset/1994/en19940564 https://finlex.fi/en/laki/kaannokset/1994/en19940564)
Legislation based on CEN/WHO Benchmark	No – legislation passed prior to CEN publication
Authorisations and Registration	The National Supervisory Authority for Welfare and Health (Valvira) grants, upon application, the right to practise as a licensed or authorised healthcare professional and authorises the use of the occupational title of healthcare professional** The national association maintains a register of practising osteopaths (https://osteopaattiliitto.fi/loydameidat/)
Education	
Education Level required to practise	Bachelor***
Type of education offered	Both Type I & Type II (according to the CEN-standard are offered in Finland)
Further Information on education	The degree programmes are part of the Osteopathic European Academic Network (OsEAN) Member Schools. The Master's Degree Programme in Osteopathy (Metropolia University of Applied Sciences) is open to osteopaths with at least 2 years of professional experience.
Practice of osteopathy	
Patients can self refer	Yes
Osteopathy located in primary healthcare	Yes
Practice execution	Private practice
Reimbursement	By a couple of private insurance companies, there is a possibility of being reimbursed when presenting a doctor's referral
When are the costs reimbursed and for which indicators	NI
Restrictions to practise	No
Continuing Professional Development	There are currently no mandatory requirements for Continuing Professional Development

** About 60% of osteopaths in the Finnish Osteopathic Association are Type I educated, and about 40% of osteopaths in the association are 2 Type II educated*

***Comité Européen de Normalisation (CEN), the European standard for osteopathic practice and training, is utilised by the National Supervisory Authority for Welfare and Health, Valvira, to asses the educational criteria for registering as an osteopath following their graduation*

**** The level of education required to practise osteopathy in Finland is either a 240 ECTS University of Applied Sciences diploma, Type I education or equal requirements, Type II education, 4 years part-time*

Abbreviations: approx., approximately. CEN, Comité Européen de Normalisation. CPD, Continuing Professional Development. NI, no information; OsEAN, Osteopathic European Academic Network. Soory, Suomen Osteopaattiliitto ry/Finlands Osteopatförbund rf and Suomen ortopediset osteopaatit ry. WHO, World Health Organisation.

Table A-38: Information on regulation, education and practice of osteopathy in France

France [1]	
Population	67 million
Practising osteopaths in total	approx. 25,600
Osteopaths per 100.000 people (self-calculated)	38
Regulation	
National Association(s) of osteopathy	Ostéopahtes de France, UFOF/ODF Association Française d'Ostéopathie, AFO Chambre Nationale des Ostéopathes, CNO Registre Des Ostéopahtes de France, ROF Syndicat Français Des Ostéopahtes, SFDO
Title ‚osteopath' protected	Yes
Who is recognised as an osteopath?	Doctors, midwives, masseur-physiotherapists and nurses authorised to practise, holders of a university or inter-university diploma sanctioning training followed within a medical training and research unit issued by a medical university and recognised by the National Council of the Order of Doctors, holders of a diploma issued by an approved establishment, holders of an authorisation to practise osteopathy or to use the title of osteopath delivered by the administrative authority
Information on regulation (official documents)	Recognised since March 2002, decrees dated 2007 and 2014 regulate practice and education (https://www.legifrance.gouv.fr/loda/article_lc/LEGIARTI000031549014/)
Legislation based on CEN/WHO Benchmark	No – legislation passed prior to CEN publication
Authorisation and registration	Osteopaths wishing to practise must submit a request to the Regional Health Agency to register his/her degree or diploma from an approved school in the Adeli (Automation of Lists) Directory. Various associations (e.g. AFO and ROF) maintain a register of practising osteopaths
Education	
Education Level required to practise	Approved degree or diploma
Type of education offered	Type I and Type II
Further Information on education	Only the Ministry of Health accredits osteopathy programmes.* The training does not have university equivalence, and the level of training required to practise osteopathy in France has been defined since 2014 by the publication of decrees: ■ A training framework ■ 4,860 hours for high school graduates ■ 1,894 hours for physiotherapists ■ 700 hours for physicians
Practice of osteopathy	
Patients can self-refer	Yes
Osteopathy located in primary healthcare	No
Practice execution	Private practice National Health Services**
Reimbursement	By 80% of private insurance companies. The level and the number of refunds depend on an individual contract most of the time, about three treatments a year are refunded
When are the costs reimbursed and for which indicators	NI
Restrictions to practise	Yes***
Continuing Professional Development (CPD)	There are no mandatory requirements for CPD yet

** 31 schools are approved:* https://www.afosteo.org/espace-etudiants/etablissements-agrees/

*** Osteopaths only practice in private clinics or private maternity hospitals, usually being volunteers. Some physiotherapists and also osteopaths may practice osteopathy within the National Health Services but not under the title of osteopath*

****see Décret 2007-435 du 25 mars 2007 (actes et exercice) for more information, following information is translated from [1], page 44: "Practitioners with an osteopathic title are authorised to carry out manipulations with the sole aim of preventing or remedying functional disorders of the human body, to the exclusion of organic pathologies which require therapeutic, medical, surgical, medicinal or physical*

intervention. These manipulations are musculoskeletal and myofascial, exclusively manual and external. They cannot act when there are symptoms justifying paraclinical examinations. For the treatment of these functional disorders, the osteopath performs non-instrumental, direct and indirect, non-forced manipulations and mobilizations, in accordance with the recommendations of good practice established by the Haute Autorité de santé."

"… practitioners … are obliged, if they are not themselves doctors, to refer the patient to a doctor when the symptoms require a diagnosis or medical treatment when it is noted that these symptoms persist or worsen or when the disorders presented exceed their field of competence."

"I. – A practitioner who holds an osteopathic title may not perform the following acts:

1° Gynaeco-obstetrical manipulations;

2° Pelvic touching.

II – After a diagnosis established by a doctor attesting to the absence of medical contraindication medical contraindication to osteopathy, the practitioner with an osteopathic title is entitled to perform the following acts:

1° Manipulations of the cranium, the face and the rachis in infants under six months old;

2° Manipulations of the cervical rachis"

Abbreviations: *AFO, Association Française d'Ostéopathie. approx., approximately. CEN, Comité Européen de Normalisation. CNO, Chambre Nationale des Ostéopathes. CPD, Continuing Professional Development. NI, no information; ROF, Registre Des Ostéopahtes de France. SFDO, Syndicat Français Des Ostéopahtes. UFOF/ODF, Ostéopahtes de France. WHO, World Health Organisation.*

Literature search strategies for part 1

Search strategy for Embase.com

Search date: 18.05.2022		
No.	Query Results	Results
#62.	#60 NOT #61	621
#61.	#60 AND 'Conference Abstract'/it	120
#60.	#59 AND ([english]/lim OR [german]/lim)	741
#59.	#17 OR #53 OR #58	756
#58.	#57 AND [2017-2022]/py	166
#57.	#54 OR #56	376
#56.	#16 AND #55	366
#55.	('meta analysis'/exp OR 'systematic review'/exp OR ((meta NEAR/3 analy*):ab,ti) OR metaanaly*:ab,ti OR review*:ti OR overview*:ti OR ((synthes* NEAR/3 (literature* OR research* OR studies OR data)):ab,ti) OR (pooled AND analys*:ab,ti) OR (((data NEAR/2 pool*):ab,ti) AND studies:ab,ti) OR medline:ab,ti OR medlars:ab,ti OR embase:ab,ti OR cinahl:ab,ti OR scisearch:ab,ti OR psychinfo:ab,ti OR psycinfo:ab,ti OR psychlit:ab,ti OR psyclit:ab,ti OR cinhal:ab,ti OR cancerlit:ab,ti OR cochrane:ab,ti OR bids:ab,ti OR pubmed:ab,ti OR ovid:ab,ti OR (((hand OR manual OR database* OR computer*) NEAR/2 search*):ab,ti) OR ((electronic NEAR/2 (database* OR 'data base' OR 'data bases')):ab,ti) OR bibliograph*:ab OR 'relevant journals':ab OR (((review* OR overview*) NEAR/10 (systematic* OR methodologic* OR quantitativ* OR research* OR literature* OR studies OR trial* OR effective*)):ab)) NOT ((((retrospective* OR record* OR case* OR patient*) NEAR/2 review*):ab,ti) OR (((patient* OR review*) NEAR/2 chart*):ab,ti) OR rat:ab,ti OR rats:ab,ti OR mouse:ab,ti OR mice:ab,ti OR hamster:ab,ti OR hamsters:ab,ti OR animal:ab,ti OR animals:ab,ti OR dog:ab,ti OR dogs:ab,ti OR cat:ab,ti OR cats:ab,ti OR bovine:ab,ti OR sheep:ab,ti) NOT ('editorial'/exp OR 'erratum'/de OR 'letter'/exp) NOT (('animal'/exp OR 'nonhuman'/exp) NOT (('animal'/exp OR 'nonhuman'/exp) AND 'human'/exp))	1,459,069
#54.	#16 AND ([cochrane review]/lim OR [systematic review]/lim OR [meta analysis]/lim)	181
#53.	#16 AND #52	601
#52.	#37 NOT #51	5,146,497
#51.	#38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50	3,981,020
#50.	'animal experiment'/de NOT ('human experiment'/de OR 'human'/de)	2,425,194
#49.	(rat:ti,tt OR rats:ti,tt OR mouse:ti,tt OR mice:ti,tt OR swine:ti,tt OR porcine:ti,tt OR murine:ti,tt OR sheep:ti,tt OR lambs:ti,tt OR pigs:ti,tt OR piglets:ti,tt OR rabbit:ti,tt OR rabbits:ti,tt OR cat:ti,tt OR cats:ti,tt OR dog:ti,tt OR dogs:ti,tt OR cattle:ti,tt OR bovine:ti,tt OR monkey:ti,tt OR monkeys:ti,tt OR trout:ti,tt OR marmoset*:ti,tt) AND 'animal experiment'/de	1,155,971
#48.	(databases NEAR/5 searched):ab	54,263
#47.	'update review':ab	123
#46.	'we searched':ab AND (review:ti,tt OR review:it)	41,678
#45.	review:ab AND review:it NOT trial:ti,tt	980,019
#44.	('random cluster' NEAR/4 sampl*):ti,ab,tt	1,555
#43.	'random field*':ti,ab,tt	2,661
#42.	nonrandom*:ti,ab,tt NOT random*:ti,ab,tt	17,786
#41.	'systematic review':ti,tt NOT (trial:ti,tt OR study:ti,tt)	208,879
#40.	'case control*':ti,ab,tt AND random*:ti,ab,tt NOT ('randomised controlled':ti,ab,tt OR 'randomized controlled':ti,ab,tt)	19,707
#39.	'cross-sectional study' NOT ('randomized controlled trial'/de OR 'controlled clinical study'/de OR 'controlled study'/de OR 'randomised controlled':ti,ab,tt OR 'randomized controlled':ti,ab,tt OR 'control group':ti,ab,tt OR 'control groups':ti,ab,tt)	331,157
#38.	((random* NEXT/1 sampl* NEAR/8 ('cross section*' OR questionnaire* OR survey OR surveys OR database OR databases)):ti,ab,tt) NOT ('comparative study'/de OR 'controlled study'/de OR 'randomised controlled':ti,ab,tt OR 'randomized controlled':ti,ab,tt OR 'randomly assigned':ti,ab,tt)	2,855
#37.	#18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36	5,808,135
#36.	trial:ti,tt	364,652
#35.	'human experiment'/de	576,775

#34.	volunteer:ti,ab,tt OR volunteers:ti,ab,tt	269,222
#33.	(controlled NEAR/8 (study OR design OR trial)):ti,ab,tt	415,712
#32.	assigned:ti,ab,tt OR allocated:ti,ab,tt	446,741
#31.	((assign* OR match OR matched OR allocation) NEAR/6 (alternate OR group OR groups OR intervention OR interventions OR patient OR patients OR subject OR subjects OR participant OR participants)):ti,ab,tt	418,365
#30.	crossover:ti,ab,tt OR 'cross over':ti,ab,tt	116,567
#29.	(parallel NEXT/1 group*):ti,ab,tt	29,355
#28.	'double blind procedure'/de	195,409
#27.	((double OR single OR doubly OR singly) NEXT/1 (blind OR blinded OR blindly)):ti,ab,tt	258,280
#26.	(open NEXT/1 label):ti,ab,tt	96,567
#25.	(evaluated:ab OR evaluate:ab OR evaluating:ab OR assessed:ab OR assess:ab) AND (compare:ab OR compared:ab OR comparing:ab OR comparison:ab)	2,493,827
#24.	compare:ti,tt OR compared:ti,tt OR comparison:ti,tt	587,566
#23.	placebo:ti,ab,tt	341,563
#22.	'intermethod comparison'/de	285,035
#21.	'randomization'/de	93,809
#20.	random*:ti,ab,tt	1,787,537
#19.	'controlled clinical trial'/de	436,903
#18.	'randomized controlled trial'/de	710,556
#17.	#16 AND [randomized controlled trial]/lim	297
#16.	#7 AND #15	2,447
#15.	#8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14	11,245
#14.	'myofascial release'	606
#13.	'myofascial release'/exp	138
#12.	(craniosacral OR 'cranio sacral') NEAR/1 (therap* OR treatment* OR manipulat*)	262
#11.	'craniosacral therapy'/exp	196
#10.	osteopat*:ti,ab,lnk,kw,de	10,536
#9.	'osteopathic manipulation'/exp	546
#8.	'osteopathic medicine'/exp	5,475
#7.	#1 OR #2 OR #3 OR #4 OR #5 OR #6	2,020,431
#6.	backache*	64,460
#5.	neckache*	36
#4.	headache*	328,548
#3.	pain* OR ache* OR aching OR sore*	1,769,208
#2.	'headache and facial pain'/exp	353,024
#1.	'musculoskeletal pain'/exp	174,096

Search strategy for MEDLINE via Ovid

Database: Ovid MEDLINE(R) and In-Process, In-Data-Review & Other Non-Indexed Citations and Daily <1946 to May 13, 2022>, Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations and Daily <2018 to May 13, 2022>	
Search date: 18.05.2022	
ID	Search
1	exp Pain/ (507674)
2	exp Musculoskeletal Pain/ (9796)
3	exp Shoulder Pain/ (6866)
4	exp Headache Disorders/ (44912)
5	(pain* or ache* or aching or sore*).mp. (1199383)
6	headache*.mp. (133229)
7	neckache*.mp. (33)
8	backache*.mp. (4434)
9	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 (1374797)
10	exp Osteopathic Medicine/ (3644)
11	exp Manipulation, Osteopathic/ (1404)
12	osteopat*.mp. (9819)
13	((craniosacral or cranio-sacral) adj (therap* or treatment* or manipulat*)).mp. (121)
14	exp Myofascial Release Therapy/ (28)
15	myofascial release.mp. (720)
16	10 or 11 or 12 or 13 or 14 or 15 (10515)
17	9 and 16 (1832)
18	limit 17 to randomised controlled trial (238)
19	((randomized controlled trial or controlled clinical trial).pt. or randomized.ab. or placebo.ab. or drug therapy.fs. or randomly.ab. or trial.ab. or groups.ab.) not (exp animals/ not humans.sh.) (5905382)
20	17 and 19 (710)
21	limit 17 to (meta analysis or "systematic review") (112)
22	(((comprehensive* or integrative or systematic*) adj3 (bibliographic* or review* or literature)) or (meta-analy* or metaanaly* or "research synthesis" or ((information or data) adj3 synthesis) or (data adj2 extract*))).ti,ab. or (cinahl or (cochrane adj3 trial*) or embase or medline or psyclit or (psycinfo not "psycinfo database") or pubmed or scopus or "sociological abstracts" or "web of science").ab. or ("cochrane database of systematic reviews" or evidence report technology assessment or evidence report technology assessment summary).jn. or Evidence Report: Technology Assessment*.jn. or ((review adj5 (rationale or evidence)).ti,ab. and review.pt.) or meta-analysis as topic/ or Meta-Analysis.pt. (888917)
23	17 and 22 (222)
24	21 or 23 (224)
25	limit 24 to yr="2017 - 2022" (140)
26	18 or 20 or 25 (760)
27	limit 26 to (english or german) (739)
28	remove duplicates from 27 (505)

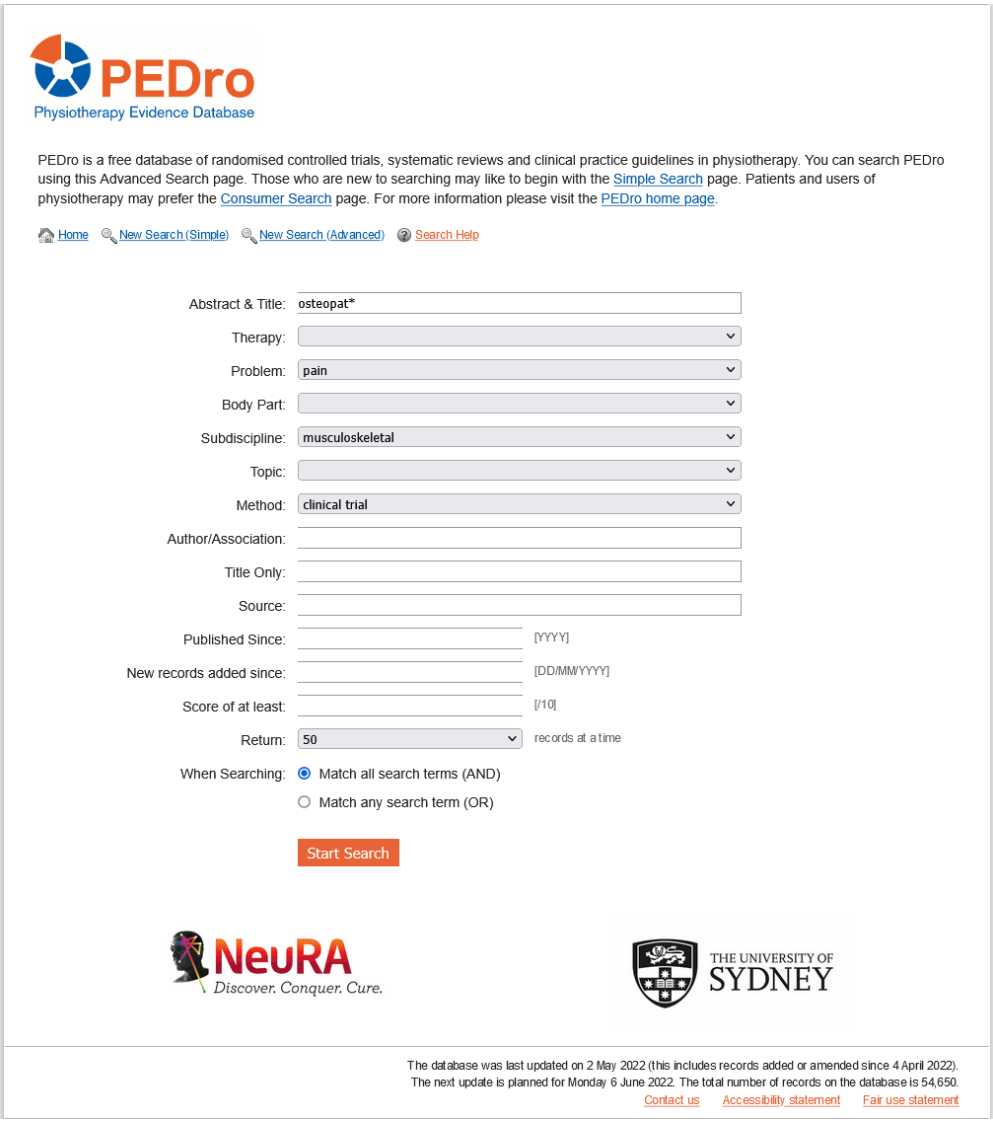
Search strategy for Cochrane Library

Search Name: Osteopathy for musculoskeletal pain	
Last saved: 18/05/2022 13:46:37	
Comment: LG/VH 180522	
ID	Search
#1	MeSH descriptor: [Pain] explode all trees
#2	MeSH descriptor: [Musculoskeletal Pain] explode all trees
#3	MeSH descriptor: [Shoulder Pain] explode all trees
#4	MeSH descriptor: [Headache Disorders] explode all trees
#5	((pain* OR ache* OR aching OR sore*)) (Word variations have been searched)
#6	(headache*) (Word variations have been searched)
#7	(neckache*) (Word variations have been searched)
#8	(backache*) (Word variations have been searched)
#9	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8
#10	MeSH descriptor: [Osteopathic Medicine] explode all trees
#11	MeSH descriptor: [Manipulation, Osteopathic] explode all trees
#12	(osteopat*) (Word variations have been searched)
#13	((craniosacral OR cranio-sacral) NEAR (therap* OR treatment* OR manipulat*)) (Word variations have been searched)
#14	MeSH descriptor: [Myofascial Release Therapy] explode all trees
#15	("myofascial release") (Word variations have been searched)
#16	#10 OR #11 OR #12 OR #13 OR #14 OR #15
#17	#9 AND #16
#18	#9 AND #16 in Trials
#19	#9 AND #16 with Cochrane Library publication date Between Jan 2017 and May 2022, in Cochrane Reviews, Cochrane Protocols
#20	#18 OR #19
#21	(conference abstract):pt
#22	(abstract):so
#23	(clinicaltrials OR trialsearch OR ANZCTR OR ensaiosclinicos OR Actrn OR chictr OR cris OR ctri OR registroclinico OR clinicaltrialsregister OR DRKS OR IRCT OR Isrctn OR rctportal OR JapicCTI OR JMACCT OR jRCT OR JPRN OR Nct OR UMIN OR trialregister OR PACTR OR R.B.R.OR REPEC OR SLCTR OR Tcr):so (Word variations have been searched)
#24	#21 OR #22 OR #23
#25	#20 NOT #24
Total hits: 458	

PEDro

Date of search: 19.05.2022

CT Search (69 Hits)



Suchstrategie HTA-INAHTA

Date of search: 18.05.2022	
ID	Search query,"Hits","Searched At"
18	(((backache*) OR (neckache*) OR (headache*) OR (pain* OR ache* OR aching OR sore*) OR ("Headache Disorders"[mhe]) OR ("Shoulder Pain"[mhe]) OR ("Musculoskeletal Pain"[mhe]) OR ("Pain"[mhe])) AND ((myofascial release) OR ("Myofascial Release Therapy"[mhe]) OR ((craniosacral OR cranio-sacral) AND (therap* OR treatment* OR manipulat*)) OR (osteopat*) OR ("Manipulation Osteopathic"[mhe]) OR ("Osteopathic Medicine"[mhe]))) AND (English OR German)[Language],"9","2022-05-18T13:11:06.000000Z"
17	((backache*) OR (neckache*) OR (headache*) OR (pain* OR ache* OR aching OR sore*) OR ("Headache Disorders"[mhe]) OR ("Shoulder Pain"[mhe]) OR ("Musculoskeletal Pain"[mhe]) OR ("Pain"[mhe])) AND ((myofascial release) OR ("Myofascial Release Therapy"[mhe]) OR ((craniosacral OR cranio-sacral) AND (therap* OR treatment* OR manipulat*)) OR (osteopat*) OR ("Manipulation Osteopathic"[mhe]) OR ("Osteopathic Medicine"[mhe])),"9","2022-05-18T13:09:58.000000Z"
16	(backache*) OR (neckache*) OR (headache*) OR (pain* OR ache* OR aching OR sore*) OR ("Headache Disorders"[mhe]) OR ("Shoulder Pain"[mhe]) OR ("Musculoskeletal Pain"[mhe]) OR ("Pain"[mhe]),"1427","2022-05-18T13:09:37.000000Z"
15	backache*,"1","2022-05-18T13:08:55.000000Z"
14	neckache*,"0","2022-05-18T13:08:44.000000Z"
13	headache*,"113","2022-05-18T13:08:27.000000Z"
12	pain* OR ache* OR aching OR sore*,"1232","2022-05-18T13:08:11.000000Z"
11	"Headache Disorders"[mhe],"58","2022-05-18T13:07:41.000000Z"
10	"Shoulder Pain"[mhe],"9","2022-05-18T13:07:09.000000Z"
9	"Musculoskeletal Pain"[mhe],"8","2022-05-18T13:06:36.000000Z"
8	"Pain"[mhe],"603","2022-05-18T13:05:27.000000Z"
7	(myofascial release) OR ("Myofascial Release Therapy"[mhe]) OR ((craniosacral OR cranio-sacral) AND (therap* OR treatment* OR manipulat*)) OR (osteopat*) OR ("Manipulation Osteopathic"[mhe]) OR ("Osteopathic Medicine"[mhe]),"33","2022-05-18T13:04:17.000000Z"
6	myofascial release,"0","2022-05-18T13:02:56.000000Z"
5	"Myofascial Release Therapy"[mhe],"0","2022-05-18T13:02:32.000000Z"
4	(craniosacral OR cranio-sacral) AND (therap* OR treatment* OR manipulat*),"29","2022-05-18T13:01:19.000000Z"
3	osteopat*,"4","2022-05-18T13:00:35.000000Z"
2	"Manipulation Osteopathic"[mhe],"2","2022-05-18T12:59:59.000000Z"
1	"Osteopathic Medicine"[mhe],"1","2022-05-18T12:59:26.000000Z"
Total hits: 9	

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