

INSTITUTE FOR Evidence-Based Healthcare

ROLFING FOR ANY INDICATION IN HUMANS: A SYSTEMATIC REVIEW

Prepared for the National Health and Medical Research Council

Prepared by: Institute for Evidence-Based Healthcare, Bond University, Australia



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Report information

Authors

Sharon Sanders Anna Scott Mina Bakhit Zoe Michaleff Justin Clark Paul Glasziou

Contact person

Please send all correspondence to: ComplementaryMedicine@nhmrc.gov.au

Dates

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Membership and other details of the Panel and Committee can be found at:

https://www.health.gov.au/committees-and-groups/natural-therapies-review-expert-advisory-panel

https://www.nhmrc.gov.au/about-us/leadership-and-governance/committees/natural-therapiesworking-committee

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Plain Language summary

What was the aim of this review?

The aim of this review was to identify eligible studies and assess whether they demonstrate that Rolfing is effective in preventing and/or treating health outcomes for conditions where studies are available. Rolfing is a bodywork therapy which involves massage of connective tissues, guided movement, and movement education to improve posture, bodily ease, and alignment. This review is targeted for the Australian Government Department of Health and Aged Care to assist in their Natural Therapies Review, which is designed to determine whether certain natural therapies, including Rolfing, have enough evidence of effectiveness to be considered re-eligible for private health insurance rebates. This review is not intended to inform decisions about whether an individual or practitioner should use Rolfing.

Key messages

The effects of Rolfing on the populations and conditions assessed in this review are unknown, as the evidence provides very low certainty about the effect of Rolfing on the outcomes assessed. There were four populations and six randomised controlled trials included in this review. It was not possible to assess whether the results of this review are consistent with previous reviews, as no other systematic reviews of Rolfing were found.

What was studied in this review?

This review identified studies using a planned literature search, with no limit on publication date, or specific populations or conditions. Studies needed to compare the results of people receiving Rolfing to people who did not receive Rolfing (but could have received another intervention). Studies published in languages other than English, were listed, but not included in the assessment. Studies of healthy populations were not included. Assessment of harms or cost effectiveness was out of scope of this review.

Studies were assessed using the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) framework. GRADE is a method to assess how confident (or certain) systematic review authors can be that the estimates of the effect (reported in studies) are correct. The assessment made by the reviewer is then described as either very low certainty – meaning the true effect is probably markedly different from the estimated effect; low certainty – meaning the true effect might be markedly different from the estimated effect; moderate certainty – meaning that the true effect is probably close to the estimated effect; and high certainty – meaning the authors have a lot of confidence that the true effect is similar to the estimated effect.

What studies did we identify in this review?

Using a planned approach, 65 studies from 11 databases were identified as possibly eligible for inclusion and examined in full-text. No studies of Rolfing were submitted by the public via the Department's public call for evidence. Out of the 65 studies identified, six randomised controlled trials (reported in nine reports) covering four populations, were assessed in the evidence evaluation and included in the results. Studies were eligible if they defined Rolfing as Rolfing[®] Structural Integration (SI) and/or Rolf Movement[®] Integration, Studies of Structural Integration or Myofascial Structural Intervention. The number of people included in the studies was between 8 to 60 participants, with a total of 216 participants across all studies. Two studies with titles only (one with English title and one with a non-English title and both with no abstract or full text available) could not be assessed for eligibility. There were no trials of Rolfing compared with placebo and only 1 vs

no treatment (waitlist control), 4 versus another active intervention and 1 assessing value of adding it to rehabilitation alone.

What were the main results of the review?

The evidence regarding effectiveness of Rolfing is limited and provides very low certainty about the effects of Rolfing for the outcomes assessed in this review.

The evidence provides very low certainty for the effect of Rolfing on: gross motor function in children with spastic cerebral palsy (two studies; one of Rolfing versus waitlist in 26 participants and one study of Rolfing versus interactive play in 8 participants); pain, quality of life, mental health, physical function and social function in low back pain (two studies; one study of Rolfing plus outpatient rehabilitation versus rehabilitation alone in 46 participants and one study of Rolfing versus Fascial Fitness in 36 participants); pain and quality of life in fibromyalgia (one study versus acupuncture in 60 participants); and flexibility in hamstring tightness (one study versus Active Release Technique in 40 participants).

Implications for health policy and research

This review assesses the available evidence on Rolfing to inform the Australian Government about health policy decisions for private health insurance rebates. The review is not designed to cover all the reasons that people use, or practitioners prescribe Rolfing and is not intended to inform individual choices about using Rolfing.

The results of this review indicate that the current evidence base for Rolfing is too limited to determine if Rolfing is effective for any condition. These conclusions are based on six randomised controlled trials, with a limited number of participants. Outcomes relevant to patients were often not reported. Studies addressing more conditions and patient-relevant outcomes for which Rolfing is used in clinical practice, are needed.

How up to date is this review?

This review includes studies published up until 27 July 2021. Studies published after this date are not included in this review.

Executive summary

Background

Rolfing is a bodywork therapy that incorporates manipulation of the fascia, guided movement, and movement education to improve overall body alignment, and biomechanical functioning. In clinical practice, Rolfing is used to treat a variety of conditions, including musculoskeletal pain, chronic pain, stress, chronic fatigue syndrome and cerebral palsy.

Objectives

The aim of this review was to assess the clinical effectiveness of Rolfing for any condition. This information will be used by the Australian Government in deciding whether to reinclude Rolfing as eligible for private health insurance rebates, after it was excluded in 2019. This review was not designed to assess all the reasons that people use Rolfing, or the reasons practitioners prescribe Rolfing and is not intended to inform individual treatment choice.

Search methods

Literature searches were conducted in MEDLINE, Embase, CINAHL, AMED, PsycINFO, PEDro, Cochrane library, the WHO Virtual Health Library (which includes LILACS and other sources), and WHO ICTRP and ClinicalTrials.gov databases (via Cochrane CENTRAL), from inception to 26 July 2021. The Ida P. Rolf Library of Structural Integration was searched from inception to 27 July 2021. No limitations on date, language, or publication status were applied to the searches. The reference lists of included studies and related reviews were obtained using Scopus on 27 July 2021, and searches for studies published subsequent to and citing the included studies were conducted in Scopus on 27 July 2021.

Selection criteria

Randomised controlled trials (RCTs), non-randomised, quasi-randomised controlled trials, and non-randomised controlled trials studies of interventions (NRSI) were eligible for inclusion.

There was no restriction on eligible comparators. Inactive comparators (including placebo, no intervention, sham intervention, wait list and usual care if considered inactive) and active comparators (including another intervention or interventions) were eligible for inclusion.

Eligible studies included participants of any age with any injury, disease, medical condition, or preclinical condition. Healthy participants seeking health improvement were not eligible for inclusion.

Studies were eligible if they evaluated an intervention that meets the definition of Rolfing[®] Structural Integration (SI) and/or Rolf Movement[®] Integration, Studies of Structural Integration or Myofascial Structural Intervention. Outcomes were not used to decide eligibility of studies. Studies were not excluded based on country of origin or language of publication, but studies published in a language other than English were not translated. Harms and cost effectiveness were out of scope.

Data collection and analysis

Two review authors independently screened reports. After initial searching and screening, and to determine what data to extract, a blinded outcome prioritisation process was developed for NHMRC's Natural Therapies Working Committee (NTWC) to complete. Data collection and screening of full-text articles for inclusion was performed by two researchers.

Studies were assessed for risk of bias using the Risk of Bias (RoB) 2 tool, and certainty of evidence using GRADE. Study characteristics, intervention and results data were tabulated and described narratively for each study. No meta-analyses were conducted, as either only one study was available evaluating Rolfing for a condition, or the outcomes were not consistently reported in studies evaluating Rolfing for the same condition.

Main results

Six studies (9 reports) evaluating Rolfing for three conditions (Cerebral Palsy, Low back pain, Fibromyalgia) and one precondition (Hamstring tightness), were included in the review. The certainty of the evidence was very low for all studied outcomes, meaning the true effect is probably markedly different from the estimated effect and the effectiveness of Rolfing for these conditions is unknown.

- *Cerebral Palsy* (2 RCTs, one of Rolfing versus waitlist in 26 participants and one RCT of Rolfing versus interactive play in 8 participants)
- Low Back Pain (2 RCTs, one of Rolfing plus outpatient rehabilitation versus rehabilitation alone in 46 participants and one RCT of Rolfing versus Fascial Fitness in 36 participants)
- Fibromyalgia (1 RCT, versus acupuncture in 60 participants)
- Hamstring tightness (1 RCT, versus Active Release Technique in 40 participants).

Limitations

The outcomes assessed in this review were limited to those deemed critical or important by NTWC for the included conditions, and did not include consideration of harms or cost-effectiveness.

The existing evidence for Rolfing is limited to a small number of studies, all at high risk of bias. It is unclear whether other studies have been done and not published (common when no effect of a treatment is found) or whether very few studies have been conducted. Two studies with title only information (one with an English title and one with a non-English title for which an abstract or full text could not be obtained) could not be assessed for eligibility. It is unknown whether these studies would be eligible for inclusion in the review.

Conclusions

The volume of evidence for the effectiveness of Rolfing is currently limited to six trials (with a total of 216 participants). The certainty of evidence (GRADE) for the outcomes of interest was very low. This evidence is very uncertain about the effect of Rolfing on outcomes for children with spastic cerebral palsy and people with low back pain, fibromyalgia, and hamstring tightness. Larger, robustly designed trials, addressing a greater breadth of conditions for which Rolfing is used in clinical practice in Australia are needed.

Protocol registration on PROSPERO PROSPERO (CRD42020191251)

1. Background

1.1. Description of the intervention

Rolfing is a bodywork therapy that involves manipulative therapy, breath work, or energy therapy. It incorporates manipulation of the fascia, guided movement and movement education to improve overall body alignment, and biomechanical functioning.(1) Rolfing is used for the treatment of numerous conditions, including musculoskeletal pain and dysfunction, chronic pain, stress, chronic fatigue syndrome and cerebral palsy.(2, 3) Other reasons for the use of Rolfing, include: to enhance performance through improved biomechanical functioning of the body as a whole, to learn and promote body awareness, alignment and balance, and as a psychological therapy.(4) Rolfing has been suggested for "anyone and everyone" suffering from any limiting physical discomfort, for those who have not experienced injury or trauma to enhance overall body conditioning and functionality, and for those who feel physical limitations have prevented attainment of spiritual or emotional wellbeing.(1)

Named after its founder, Dr. Ida P. Rolf (PhD), 'Rolfing' is the abbreviated term used to describe a system of bodywork commonly referred to as Rolfing[®] Structural Integration (SI), Rolf Movement[®] Integration and Myofascial Structural Integration (hereafter, collectively referred to as Rolfing). Rolfing is delivered over a series of sessions; it utilises manual therapy of the fascial matrix, guided movement and somatic movement education with the aim to systematically balance and optimise both the structure (shape) and function (ease of movement) of the entire body.(1, 5)

In the 1960s, Dr Rolf informally established the Guild for Structural Integration from which The Rolf Institute® arose. While only therapists trained and certified by The Rolf Institute® may use the Rolfing® trade mark, other institutions provide training in this approach.(3) The International Association of Structural Integrators®(IASI) certifies a number of professional bodies and schools as being compliant with current educational and professional practice standards for Structural Integration; these include the Hellerwork International®, The Guild for Structural Integration® and Soma Institute of neuronal Integration®.(6) The IASI provides a definition of Structural Integration (SI) and scope of practice for its members.(5)

The practice of Rolfing stems from Dr Rolf's hypothesis that optimal physical and psychological wellbeing is achieved when structure and movement are aligned and integrated with gravity. Dr Rolf identified gravity as an important lifelong stressor on the body's alignment that can result in soft tissue imbalances, compensatory and inefficient movement patterns, and dysfunction. In response, Dr Rolf developed the Classic Rolfing[®] Series delivered as a standardised 'recipe' known as the Ten-Series.(7) The series combines manual hands-on methods with somatic movement education, specifically, Rolf Movement Integration. Rolf Movement Integration is a form of movement education and feature of Rolfing Structural integration that aims to optimise and sustain structural ease through balanced movement behaviour.(1)

The aim of the Ten-Series is to systematically balance and optimise the structure and function of the entire body through a sequential education process that can be divided into three distinct sections: Sessions 1-3 focus on the superficial layers of connective tissue, Sessions 4-7 focus on the 'core' between the bottom of the pelvis and top of the head, and Sessions 8-10 focus on 'Integration' which aims to relate the body segments in an improved relationship bringing physical balance in the gravitational field.(2, 3)

Whilst the Ten-Series is typically delivered over ten sessions, the total number of sessions can vary, depending on the person's progress in achieving each series' outcomes. Different versions of the original Ten-Series 'recipe' are also employed by Rolfing therapists and taught by some of the Structural Integration institutions.(8, 9) Examples include: single SI session, a shorter series of SI

sessions, SI delivered by two therapists simultaneously or in large group clinic settings, and movement integration sessions delivered to individuals or groups.

Typically, a Rolfing session lasts a little over one hour, and consists of: 1) observation and assessment of posture and movement, 2) manual soft-tissue techniques including mobilisation/release of the myofascia and visceral fascia, 3) joint mobilisations and adjustments mostly of the appendicular skeleton and sacrum, but also the cranium, 4) active movement participation (AMP) such as stretching, resisting and isometric releases, 5) active movement education and demonstrations, and 6) homework/self-care such as AMP and somatic movement activities, to reinforce what has been achieved in the sessions.(10) Rolfing is commonly delivered in private clinics. Clinic equipment includes cushioned treatment tables and chairs, mats on the floor and floor space for movement. Therapists use taping/strapping, foam rollers and soft rubber balls as aids during the session or for take home self-care.(10)

1.2. How the intervention might work

Rolfing is performed with the aim of enhancing the structural and functional integrity of the human body and restoring proper alignment and coordination. This is proposed to occur through the manipulation and stretching of soft tissue, primarily the interconnected fascia of the body, which may alter its length and biomechanical properties.(3, 11) Manipulation of the fascia is thought to: stimulate the intra-fascial mechanoreceptors that interface with the nervous system to reduce the tension in the muscles and fascia, increase in the pliability of these tissues; enable adjacent soft tissues to move independently, and stimulate the sensory nerves responsible for increasing body awareness and perception.(1, 3, 12) The manipulation of soft tissue is also thought to improve the flow of interstitial fluid which may improve perfusion, removal of endogenous markers associated with inflammation and nociception.(1, 3, 12)

1.3. Why it is important to do this review

The Institute of Evidence-Based Healthcare (IEBH) has been contracted by the National Health and Medical Research Council (NHMRC), to perform a review of the evidence for the clinical effectiveness of Rolfing. This evidence evaluation is part of the Review of the Australian Government Rebate on Private Health Insurance for Natural Therapies 2019-2020.

This Review supplements the 2015 Review of the Australian Government Rebate on Natural Therapies for Private Health Insurance (2015 Review) which included Rolfing as one of the reviewed therapies. The 2015 Review, "An overview of the effectiveness of Rolfing for any clinical condition in humans," (13) included one systematic review of RCTs published between 2008 and mid-2013, which evaluated the effect of Rolfing. The systematic review included in the overview did not identify any eligible trials. As a result, the overview was unable to determine the efficacy, safety, or certainty of Rolfing from systematic reviews of RCTs of the therapy's effectiveness.

The present review considered the evidence about the effectiveness of Rolfing, conducting a systematic review of both RCTs and NRSIs.

2. Objectives

To assess the clinical effectiveness of Rolfing for any condition, or pre-clinical condition, or in individuals at risk for becoming ill or injured, compiling evidence from both RCTs and NRSIs. The populations for which evidence was identified are identified in Table 1.

3. Summary of Methods

For expanded description of the review's methods, please see the Appendices A and B.

3.1. Search methods

The following bibliographic databases were searched, from inception to 26 July 2021: MEDLINE (via Ovid), Embase (via Elsevier), CINAHL (via EBSCO), AMED (via OVID), PsycINFO (via Ovid), PEDro (http://www.pedro.org.au), Cochrane library (via Wiley) and the WHO Virtual Health Library (via BIREME) (which includes LILACS and other sources). The WHO ICTRP and ClinicalTrials.gov were searched via the Cochrane CENTRAL database within the Cochrane Library. Records in the Ida P. Rolf Library of Structural Integration were hand-searched from inception to 27 July 2021. The reference lists of included studies and related systematic reviews (6 literature and systematic reviews, identified during screening of the databases and reference list searches) were obtained using Scopus on 27 July 2021 ("backward searching"). Scopus was also used to search for studies published subsequent to and citing included studies on 27 July 2021 ("forward searching"). Evidence reviews commissioned by Australian government bodies and other national or international bodies that are recommended by NTREAP or NTWC members, were to be considered for inclusion in the review, however none were provided. In accordance with the Official Order, grey literature was considered out of scope. No language restrictions were applied, however, studies in languages other than English were dealt with via a process outlined in the Appendices.

3.2. Selection criteria

The inclusion criteria specified inclusion of both RCTs and NRSI.

Included studies comprised of people of any age with any injury, disease, medical condition, or preclinical condition. Healthy participants seeking health improvement were not eligible for inclusion. A study with eligible and ineligible populations was included if separate data were available for the eligible population.

Included studies evaluated an intervention that meets the definition of Rolfing[®] Structural Integration (SI) and/or Rolf Movement[®] Integration as stated in the Official Order 2019-20P027 (full text of the definition is reproduced in Appendix A). Studies of Structural Integration or Myofascial Structural Intervention were also included. Studies of individual component techniques (such as myofascial release) were excluded, unless identified as Rolfing or Rolfing Structural Integration or Rolf Movement or Myofascial Structural Integration.

Studies with the following comparators were included: placebo, no intervention, sham intervention, wait list, usual care, or another intervention or interventions.

The outcomes reported by studies were not used as a criterion for inclusion or exclusion from the review. The outcome measures reported in this review for each condition were determined and prioritised by the NTWC. Patient-Reported Experience Measures (PREMs), such as satisfaction with experience or preferences, were excluded. Safety, quality, or economic outcomes were also excluded.

3.3. Data collection

Two reviewers independently screened the identified literature against the inclusion criteria. One reviewer retrieved full-text of eligible articles, and two reviewers then independently screened the full-text articles for inclusion. Disagreements were resolved by discussion, or reference to a third reviewer if required.

Two reviewers independently extracted data from reports of included studies using pre-piloted data extraction forms. If key information was missing from reports of the included studies, the study authors were contacted.

Two reviewers independently assessed risk of bias in the included studies using the Cochrane risk-ofbias 2 (RoB 2) tool. For each result, the effect of assignment to intervention (the 'intention to treat' effect) was assessed. Risk of bias judgments were compared by the two reviewers to identify discrepancies. Any discrepancies were reconciled by discussion between the two reviewers, or by referring to a third reviewer. Risk of bias in randomised and quasi-randomised controlled trials were assessed with the RoB 2 tool for randomised trials. The use of ROBINS-I tool for the assessment of risk of bias in non-randomised studies, was pre-specified. However, no NRSIs met the inclusion criteria for the review. GRADE was used to assess the certainty of the body of evidence for each outcome.

3.4. Data analysis

Meta-analyses could not be conducted due to the small number of studies evaluating Rolfing for each condition and large variation in outcomes measured by the included studies. The protocol prespecified that where meta-analysis was not possible, the findings from a large study at low risk of bias would be emphasised. However, none of the included studies are at low risk of bias. The protocol prespecified that if no large study at low risk of bias was available, vote counting based on direction of effect would be conducted. However, more than one study was available for only two conditions (low back pain, cerebral palsy; both 2 studies each), and they did not report the same outcomes consistently, precluding vote counting. The results of included studies are therefore tabulated and described narratively, as prespecified in the protocol, with studies grouped by condition, comparison, and outcome domain. As all of the included studies were RCTs, the studies were not grouped by study design. As all of the included studies were at high risk of bias, they were not ordered by the risk of bias rating. Although it was prespecified in the protocol that only studies judged to be low or unclear risk of bias would be reported in the text, none of the included studies were judged to be at low or unclear risk of bias (i.e., all were judged to be at high risk of bias). Therefore, all of the included studies were reported in the text.

If effect estimates were not provided by the study, these were calculated if possible and standardised across studies to aid interpretation (where noted); otherwise, study results were reported as presented in each study. The analysis approach (intention to treat, modified intention to treat, per protocol) used by each study for each outcome was documented in the results section of the report. When more than one approach was used by the study, or it was possible to reanalyse data using an intention to treat analysis, both analyses were presented, and the type of analysis stated.

The protocol specified that non-reporting bias would be assessed using funnel plots and statistical tests for funnel plot asymmetry. This could not be conducted due to the small number of studies. Trial register records of included studies were checked for selective non-reporting or under-reporting of results in the publication.

The GRADE approach was used to assess the certainty of the body of evidence for each outcome. For each comparator within each clinical condition, GRADEpro GDT (<u>www.gradepro.org</u>) was used to create summary of findings (SOF) tables to present information about the body of evidence, key numerical results and a summary judgment about the certainty of the underlying evidence for each outcome. Evidence statements for each outcome within each comparator and condition were written based on guidance for communicating findings of systematic reviews of interventions and using wording templates from GRADE guidance.

4. Results

4.1. Literature search results (PRISMA flow diagram)

Six studies described in 9 reports (14-22) were included in this review after screening 2948 records retrieved by database and trial registry searches and 1934 records retrieved via other methods, and assessing 65 reports in full text. Fifty six of the 65 reports assessed in full text were excluded from the review including 2 reports that could not be assessed for eligibility (noted as Records awaiting classification). Full reference details for each excluded study, the source of the study and reason for exclusion, are provided in the Appendix C.

No additional records were provided by the Natural Therapies Review Expert Advisory Panel or by the Natural Therapies Working Committee.



The PRISMA flowchart in Figure 1 summarises the screening process.

The conditions for which Rolfing has been evaluated and the number of RCTs and NRSIs evaluating Rolfing for these conditions are listed in Table 1, below. All of the included studies were RCTs,

Figure 1: PRISMA Flow chart

evaluating Rolfing in populations with spastic cerebral palsy, low back pain, fibromyalgia and hamstring tightness.

ICD-11^	POPULATION	# RCTs	# NRSI				
VIII	Diseases of the nervous system						
	Spastic cerebral palsy	2	0				
XV	Diseases of the musculoskeletal system or connective tissue						
	Low back pain	2	0				
	Fibromyalgia	1	0				
XXI	Symptoms, signs or clinical findings, not elsewhere classified	<u>.</u>					
	Hamstring tightness	1	0				

Table 1: Studies evaluating Rolfing by condition and ICD-11 disease classification

^International Statistical Classification of Diseases and Related Health Problems 11th Revision (ICD-11)-WHO Version (2021)

4.2. Cerebral palsy

4.2.1. Description of the condition

Cerebral palsy (CP) is defined as "a group of permanent disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing foetal or infant brain."((23) p 11) CP is the most common physical disability seen in childhood, with the overall birth prevalence of approximately 2 per 1,000 live births,(24) although the prevalence varies by geographical location, birthweight and gestational age.(25-27) Clinical presentation of CP can vary considerably, and clinical expression may change over time, as the central nervous system matures. The motor impairment associated with CP results in limitations in functional abilities and activities which can vary greatly in severity. The primary impairments associated with CP include reduced muscle strength, (28, 29) reduced cardiorespiratory fitness, (28, 30, 31) and poor selective motor control. (32) As a result of these impairments, people with CP may have difficulty performing everyday activities such as eating, dressing, walking, running, jumping, and negotiating stairs. (32-35) Motor abnormalities may be accompanied by multiple additional symptoms including altered sensation or perception, intellectual disability, communication difficulties, seizure disorders and musculoskeletal complications.(23) Traditionally, CP has been classified according to the type (e.g., spasticity), distribution (bilateral or unilateral), and description of the motor disturbance (e.g., dyskinesia). More recent classification systems allow categorisation of people with CP according to their level of functional impairment. These include the Gross Motor Function Classification System which is used to categorise functional motor impairment in children and may be used to track responses to interventions and for comparing groups of children in research, and the Manual Ability Classification System. (36, 37)

4.2.2. <u>Description of studies</u>

Two RCTs (in four records) including a total of 34 children with spastic cerebral palsy in the United States were identified.(15, 16, 19, 20)

One trial was a parallel-2 arm trial (n=26) comparing myofascial structural integration (MSI) to waitlist.(19) The other trial was a 2-arm crossover trial (n=8) comparing MSI to interactive play (IP).(16) In both trials, 10 weekly sessions of MSI were provided by an experienced Rolfer and children continued to receive their usual treatment regimen (comprising physical therapy +/- occupational therapy, medication or other treatments, and usual recreational activities).

The trials reported results for the following outcomes identified as of interest by the NTWC: gross motor function, (16, 19) integration/participation, (16) and physical function/impairment. (16, 19) The

following outcomes identified as of interest to the NTWC but not measured in the trials included: activities of daily living, fine motor skills/self-care, quality of life and self-efficacy/self-perception.

For all results reported, the overall risk of bias was high.

4.2.3. <u>Main Comparison: Structural integration vs waitlist (+ usual treatment in both</u> <u>groups) (19)</u>

Gross motor function

Gross motor function was measured with the Gross Motor Function Measure-66 (GMFM-66, where higher scores denote better performance). The trial did not report GMRM-66 scores at follow-up for the randomised sample. The trial states there was 'no significant effect of group' (p=0.537). That is, there was with no difference between Rolfing and control groups. The analysis was per-protocol (participants were analysed according to the intervention received rather than the intervention to which they were randomised).

Physical function/impairment

Physical function/impairment was measured with the GAITRite[®] electronic walkway. No results were reported for the randomised sample for this outcome.

4.2.4. <u>Other Comparison: Myofascial Structural integration vs Interactive Play</u> Sessions (+ usual treatment in both groups) (16)

Gross motor function

Gross motor function was measured with the Gross Motor Function Measure-66 (GMFM-66 where higher scores denote better performance). The trial reports increased gross motor function scores with both interventions (4.49 points for MSI and 1.52 points on the GMFM-66 for IP). The analysis was a modified intention to treat (participant with missing outcome data was excluded). Using individual participant data provided in the publication, intention-to-treat analysis was conducted of the first crossover phase data (as the methods of cross-over analysis used by trialists was not reported and a participant was excluded from analysis). This analysis found an increase in GMFM-66 scores from baseline of 5.19 (SD 3.88) for MSI and 0.73 (SD 2.05) for IP. There was no significant difference in mean change between the MSI and IP interventions (difference in mean change -4.47 points (94%CI -9.84 to +0.90).

Integration / participation

The method of measurement of participation is not clearly reported but appears to have been via parent completion of the WHODAS 2.0 (an assessment tool directly linked to the International Classification of Functioning, Disability and Health). The trial reports that there was 'No trend observed in the International Classification of Functioning Interview responses.'

Physical function/impairment

Physical function was measured by passive ankle range of motion (method of measurement not reported). The trial reports 'We did not observe consistent improvements in ankle range of motion (ROM) across the group. However, three children showed considerable improvements in ankle dorsiflexion after myofascial structural integration treatment.'

Summary of findings:

Myofascial Structural Integration compared to Waitlist for Spastic cerebral palsy

Patient or population: Spastic cerebral palsy in children Setting: University medical clinic Intervention: Myofascial Structural Integration Comparison: Waitlist

	Anticipated	absolute effects* (95% CI)	Relative	Nº of	Cortainty of the	
Outcomes	Risk with Waitlist	Risk with Myofascial Structural Integration	(95% CI)	nts (studies)	evidence (GRADE)	Evidence statement
Activities of daily living	The included this outcome	study did not measure		-	-	No studies found. The effect of Myofascial Structural Integration on activities of daily living in spastic cerebral palsy is unknown
Fine motor skills/self-care	The included this outcome	study did not measure		-	-	No studies found. The effect of Myofascial Structural Integration on fine motor skills in spastic cerebral palsy is unknown
Gross motor function assessed with: Gross Motor Function Measure – 66 (GMGM-66) (score out of 100 with higher scores denote better performance) follow-up: 9 months	No follow-up randomised s	data was reported for the ample.		26 (1 RCT)	⊕⊖⊖⊖ Very low ^{a,b}	The evidence is very uncertain about the effects of Myofascial Structural Integration on gross motor function
Integration/participation	The included this outcome	study did not measure		-	-	No studies found. The effect of Myofascial Structural Integration on integration/participation in spastic cerebral palsy is unknown
Physical Function/Impairment	No result was randomised s	s reported for the ample		-	-	No studies found. The effect of Myofascial Structural Integration on physical function in spastic cerebral palsy is unknown
Quality of life	The included this outcome	study did not measure		-	-	No studies found. The effect of Myofascial Structural Integration on quality of life in spastic cerebral palsy is unknown

Myofascial Structural Integration compared to Waitlist for Spastic cerebral palsy

Patient or population: Spastic cerebral palsy in children Setting: University medical clinic Intervention: Myofascial Structural Integration Comparison: Waitlist

	Anticipated absolute effects* (95% Cl)		Relative	Nº of	Containty of the	
Outcomes	Risk with Waitlist	Risk with Myofascial Structural Integration	effect (95% CI)	nts (studies)	Certainty of the evidence (GRADE)	Evidence statement
Self-efficacy/Self-perception	The included this outcome	study did not measure		-	-	No studies found. The effect of Myofascial Structural Integration on self-efficacy in spastic cerebral palsy is unknown

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: confidence interval

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. Downgraded twice for study limitations associated with high risk of bias arising from the randomisation process and deviations from intended interventions

b. Downgraded twice for imprecision associated with small sample size and no data on which to assess precision

Summary of findings:

Myofascial Structural Integration compared to Interactive Play for Spastic cerebral palsy

Patient or population: Spastic cerebral palsy in children Setting: Outpatients Intervention: Myofascial Structural Integration

Comparison: Interactive Play

	Anticipated absolute effects* (95% CI)		Dalatha	Nº of		
Outcomes	Risk with Interactive Play	Risk with Myofascial Structural Integration	effect (95% CI)	nº of participan ts (studies)	Certainty of the evidence (GRADE)	Evidence statement
Activities of daily living - not measured	The included stu outcome	udy did not measure this		-	-	No studies found. The effect of Myofascial Structural Integration on activities of daily living in spastic cerebral palsy is unknown

Myofascial Structural Integration compared to Interactive Play for Spastic cerebral palsy

Patient or population: Spastic cerebral palsy in children Setting: Outpatients Intervention: Myofascial Structural Integration Comparison: Interactive Play

	Anticipated a	Pelative				
Outcomes	Risk with Interactive Play	Risk with Myofascial Structural Integration	effect (95% CI)	nº of participan ts (studies)	Certainty of the evidence (GRADE)	Evidence statement
Fine motor skills/self- care - not measured	The included str outcome	udy did not measure this		-	-	No studies found. The effect of Myofascial Structural Integration on fine motor skills in spastic cerebral palsy is unknown
Gross motor function assessed with: Gross Motor Function Measure - 66 (GMFM- 66) (score out of 100 with higher scores denote better performance) follow-up: Unclear (post-intervention, possibly 10 weeks)	The mean chan in GMFM-66 sc in the active pla group was 0.73 points	ge The mean change in GMFM-66 score in the myofascial structural integration group was 5.19 points which is 4.47 points higher than the change in the interactive play group (0.90 lower to 9.84 higher) The MID of GMGM-66 is 1.0 and 0.7 for a medium effect size in people at GMFCS level II and III (children in the study were GMFCS level II, III and IV)		8 (1 RCT)	⊕⊖⊖⊖ Very low ^{a,b}	The evidence is very uncertain about the effects of Myofascial Structural Integration on gross motor function
Integration/Participation assessed with: Parent report of participation on WHODAS 2.0 follow-up: Unclear (post-intervention, possibly 10 weeks)	No data was rep	ported.		8 (1 RCT)	⊕⊖⊖⊖ Very low ^{a,c}	The evidence is very uncertain about the effect of Myofascial Structural Integration on integration/participation
Physical Function/Impairment assessed with: Passive ankle range of motion follow-up: Unclear (post-intervention, possibly 10 weeks)	No data was rep	ported.		8 (1 RCT)	⊕⊖⊖⊖ Very low ^{c,d}	The evidence is very uncertain about the effect of Myofascial Structural Integration on physical function/impairment

Myofascial Structural Integration compared to Interactive Play for Spastic cerebral palsy

Patient or population: Spastic cerebral palsy in children Setting: Outpatients Intervention: Myofascial Structural Integration

Comparison: Interactive Play

	Anticipated al	osolute effects* (95% CI)	Deletive	e Nº of participan ts (studies)		
Outcomes	Risk with Interactive Play	Risk with Myofascial Structural Integration	effect (95% CI)		Certainty of the evidence (GRADE)	Evidence statement
Quality of life - not measured	The included stu outcome	udy did not measure this		-	-	No studies found. The effect of Myofascial Structural Integration on quality of life in spastic cerebral palsy is unknown
Self-efficacy/Self- perception	The included stu outcome	udy did not measure this		-	-	No studies found. The effect of Myofascial Structural Integration on self-efficacy in spastic cerebral palsy is unknown

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: confidence interval; MID: minimum important difference; GMRCS: Gross Motor Function Classification System

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. Downgrade twice for study limitations associated with high risk of bias arising from deviations from intended intervention and measurement of outcome and some concerns from the randomisation process

b. Downgraded once for imprecision associated with small sample size

c. Downgraded twice for imprecision associated with small sample size and no outcome data for the treatment groups reported (narrative statement only provided by investigators)

d. Downgraded twice for study limitations associated with high risk of bias arising from deviations from intended intervention and measurement of outcome and some concerns from the randomisation process and missing outcome data

4.2.4.2. <u>Evidence statements</u>

The evidence is very uncertain about the effect of Myofascial Structural Integration when compared to waitlist on gross motor function.

The evidence is very uncertain about the effect of Myofascial Structural Integration when compared to interactive play on physical function/impairment.

The evidence is very uncertain about the effect of Myofascial Structural Integration when compared to interactive play on gross motor function.

The evidence is very uncertain about the effect of Myofascial Structural Integration when compared to interactive play on integration/participation and physical function/impairment.

4.3.Low back pain

4.3.1. <u>Description of the condition</u>

Low back pain is a common condition that many individuals will experience at some stage of life. Low back pain is defined as pain or discomfort that is located on the back below ribs and above the gluteal crease, which could be with or without referred leg pain.(38) Non-specific low back pain is most common (around 85%) and it is defined as a low back pain without any known pathological cause (e.g., cancer, fracture).(39) According to the European Guidelines,(40) low back pain is frequently classified according to the pain duration, as follows: acute <6 weeks, subacute 6-12 weeks, and chronic > 12 weeks.

4.3.2. <u>Description of studies</u>

Two RCTs (in 3 reports) evaluating the effectiveness of Rolfing in populations with low back pain (82 participants in aggregate) were identified.(14, 17, 18) One trial was conducted in a Rehabilitation Hospital in Boston, USA,(18) and the other at a university sports complex in Austria.(14) Both were two-arm, parallel, RCTs. Duration was 3 weeks in one trial (14) and 20 weeks in the second trial.(18)

In the trial by Jacobson et al (2015),(18) the participants in the intervention group received outpatient rehabilitation in addition to ten sessions of Structural Integration which was delivered in accordance with the Rolf Ten Series protocol; the comparator group received outpatient rehabilitation alone. In the trial by Baur et al (2017),(14) Structural Integration was compared against fascial fitness sessions involving specific stretching exercises and springy movements provided by a trained fascial fitness coach.

The reported outcomes identified as of interest to the NTWC included: pain, physical functioning/ disability, quality of life, mental health, and social function. Overall symptom improvement and work status were not measured in either trial.

Risk of bias for both studies, overall, was high.

4.3.3. <u>Main Comparison: Structural integration in addition to outpatient</u> rehabilitation vs outpatient rehabilitation alone

Pain

Jacobson et al (2015) found greater within group change in median VAS pain bothersomeness and SF-36 bodily pain subscale in the intervention group (structural integration + outpatient rehabilitation group) compared to control (outpatient rehabilitation), however, no significant between group difference was identified.(18) A significant difference in favour of the intervention group was found for SF-36 item bodily pain subscale. In the trial by Jacobson et al (2015),(18) it is important to note that participants in the control intervention (outpatient rehabilitation) did not change from baseline to follow up (VAS bothersomeness 0 IQR -24.5 to 6.5; SF36 bodily pain subscale median change 0 IQR 0 to 11).(18)

Physical functioning / disability

Jacobson et al (2015)(18) found a significant between group difference in favour of the intervention group (structural integration + outpatient rehabilitation group) for median change on Roland-Morris Disability Questionnaire (RMDQ) scores.(18) The reduction in RMDQ score with structural integration + outpatient rehabilitation (median 2 points) is at the lowest level of difference that would be considered clinically relevant. However, no 95% confidence interval was reported, and the lower limit of inter-quartile range of difference included no between-group difference (-4.5 to -1.0). No between group difference was found for median change of SF-36 item role physical subscale

(p=0.84), for the number of days/half days disabled over the past week (p=0.45), or for the physical function subscale (p=0.35).

Quality of life:

Jacobson et al (2015) found no between group difference for median change in SF-36 item general health subscale, or for the SF-36 physical composite score.(18)

Mental Health:

Jacobson et al (2015) found no between group difference for median change in SF-36 mental composite score, SF-36 item role emotional subscale, or for the SF-36 item mental health subscale.(18)

Social functioning:

Jacobson et al (2015) found a statistically significant (p=0.041), but not clinically relevant, between group difference in social functioning score in favour of Structural Integration + Outpatient Rehabilitation. For the Structural Integration + Outpatient Rehabilitation group there was a median change from baseline score of 0 (IQR 0 to 16) and for the Outpatient Rehabilitation group alone the median change from baseline was also 0 (with an IQR of -13 to 0).(18)

Analyses were a modified intention to treat, with data for participants lost to follow up analysed in the group to which participants were randomised, and imputation of data using the last observation carried forward method.

4.3.4. <u>Other Comparison: Structural integration vs Fascial Fitness</u>

Pain

Baur et al (2017) found pain (measured on a 0-10 cm VAS scale) improved equally over time in both the Structural Integration group (intervention, baseline: 2.9 ± 1.6 ; follow up: 1.8 ± 1.4), and in the Fascial Fitness group (control, baseline: 2.5 ± 1.9 ; follow up: 1.6 ± 1.5) but identified no time by group interaction effect (p=0.83 for group difference).(14) There was insufficient information to definitively determine the method of analysis (intention-to-treat, modified-intention-to-treat, per protocol) used in this study, but it was possibly a modified intention to treat analysis.

Summary of findings 4.3.4.1.

Summary of findings:

Structural Integration in addition to outpatient rehabilitation compared to Outpatient Rehabilitation alone for Low Back Pain

Patient or population: Low Back Pain Setting: Outpatients

Intervention: Structural Integration in addition to outpatient rehabilitation Comparison: Outpatient Rehabilitation alone

	Anticipated a	bsolute effects* (95% CI)				
Outcomes	Risk with Outpatient Rehabilitation alone	Risk with Structural Integration in addition to outpatient rehabilitation	Relative effect (95% CI)	Nº of participan ts (studies)	Certainty of the evidence (GRADE)	Comments
Bothersomeness of pain assessed with: Visual analogue scale (0-100mm with higher scores indicating more pain) follow-up: 20 weeks	Mean change wa study.	as not reported for this		46 (1 RCT)	⊕⊖⊖⊖ Very low ^{a,b,c}	The evidence is very uncertain about the effect of Structural Integration on bothersomeness of pain
Physical functioning/disability assessed with: Roland-Morris Disability Questionnaire (0-24 points with higher scores indicate greater level of disability) follow-up: 20 weeks	Mean change wa study.	as not reported for this		46 (1 RCT)	⊕⊖⊖⊖ Very low ^{ab.c}	The evidence is very uncertain about the effect of Structural Integration on physical functioning
Quality of life assessed with: Short Form Health Survey (SF-36) General health subscale (0-100 with higher score indicating more favourable health state) follow-up: 20 weeks	Mean change wa study.	as not reported for this		46 (1 RCT)	⊕⊖⊖⊖ Very low ^{a,b,c}	The evidence is very uncertain about the effect of Structural Integration on quality of life
Overall symptom improvement	The included stu outcome	dy did not measure this		-	-	No studies found. The effect of Structural Integration in addition to outpatient rehabilitation on overall symptom improvement in low back pain is unknown

Structural Integration in addition to outpatient rehabilitation compared to Outpatient Rehabilitation alone for Low Back Pain

Patient or population: Low Back Pain

Setting: Outpatients

Intervention: Structural Integration in addition to outpatient rehabilitation

Comparison: Outpatient Rehabilitation alone

	Anticipated a	Anticipated absolute effects* (95% CI)				
Outcomes	Risk with Outpatient Rehabilitation alone	Risk with Structural Integration in addition to outpatient rehabilitation	Relative effect (95% CI)	Nº of participan ts (studies)	Certainty of the evidence (GRADE)	Comments
Work status	The included stu outcome	dy did not measure this		-	-	
Social functioning assessed with: Short Form Health Survey (SF-36) Social function subscale (0-100 with higher score indicating more favourable health state) follow-up: mean 20 weeks	Mean change wa study.	as not reported for this		46 (1 RCT)	⊕⊖⊖⊖ Very low ^{a,b,c}	The evidence is very uncertain about the effect of Structural integration on social functioning
Mental health assessed with: Short Form Health Survey (SF-36) mental composite score with higher score indicating more favourable health state follow-up: 20 weeks	Mean change wa study.	as not reported for this		46 (1 RCT)	⊕⊖⊖⊖ Very low ^{a.b,c}	The evidence is very uncertain about the effect of Structural Integration on mental health

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% Cl).

Cl: confidence interval; RR: risk ratio

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. Downgraded one for study limitation associated with high risk of bias arising from measurement of the outcome

b. Downgraded twice for imprecision associated with small sample size and large variation in scores

c. Single study with investigator conflict of interest

Structural Integration compared to Fascial Fitness for Low Back Pain

Patient or population: Low Back Pain Setting: University sports centre Intervention: Structural Integration Comparison: Fascial Fitness

	Anticipated a	bsolute effects* (95% CI)				
Outcomes	Risk with Fascial Fitness	Risk with Structural Integration	Relative effect (95% CI)	nº of participa nts (studies)	Certainty of the evidence (GRADE)	Evidence statement
Perception of pain assessed with: Visual analogue scale (VAS) (0-10cm with higher scores indicating more pain) follow-up	The mean perception of p was 1.6	MD 0.2 higher (0.75 lower to 1.15 higher) The MID of VAS for pain is 1.0		36 (1 RCT)	⊕⊖⊖⊖ Very low ^{a,b}	The evidence is very uncertain about the effect of Structural Integration on perception of pain
Physical functioning/disability	The included s outcome	tudy did not measure this		-	-	No studies found. The effect of Structural Integration on physical functioning/disability in low back pain is unknown
Overall symptom improvement	The included study did not measure this outcome			-	-	No studies found. The effect of Structural Integration on overall symptom improvement in low back pain is unknown
Quality of life	The included s outcome	tudy did not measure this		-	-	No studies found. The effect of Structural Integration on quality of life in low back pain is unknown
Work status	The included study did not measure this outcome			-	-	No studies found. The effect of Structural Integration on work status in low back pain is unknown
Social function	The included study did not measure this outcome			-	-	No studies found. The effect of Structural integration on social function in low back pain is unknown
Mental health	The included s outcome	tudy did not measure this		-	-	No studies found. The effect of Structural Integration on mental health in low back pain is unknown

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% Cl).

CI: confidence interval; MD: mean difference; MID: minimum important difference

Structural Integration compared to Fascial Fitness for Low Back Pain

Patient or population: Low Back Pain Setting: University sports centre Intervention: Structural Integration Comparison: Fascial Fitness

	Anticipated a	bsolute effects* (95% CI)	Deletive	No of		
Outcomes	Risk with Fascial Fitness	Risk with Structural Integration	effect (95% CI)	participa nts (studies)	Certainty of the evidence (GRADE)	Evidence statement

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect. Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. Downgraded twice for study limitations associated with high risk of bias arising from the randomisation process and some concerns related to deviations from intended intervention, measurement of outcome and selection of reported result

b. Downgraded once for imprecision associated with small sample size

4.3.4.2. Evidence statements

The evidence is very uncertain about the effect of Structural Integration in addition to outpatient rehabilitation when compared to outpatient rehabilitation alone on bothersomeness of pain.

The evidence is very uncertain about the effect of Structural Integration in addition to outpatient rehabilitation when compared to outpatient rehabilitation alone on quality of life.

The evidence is very uncertain about the effect of Structural Integration in addition to outpatient rehabilitation when compared to outpatient rehabilitation alone on bothersomeness of mental health.

The evidence is very uncertain about the effect of Structural Integration in addition to outpatient rehabilitation when compared to outpatient rehabilitation alone on physical function.

The evidence is very uncertain about the effect of Structural Integration in addition to outpatient rehabilitation when compared to outpatient rehabilitation alone on social function.

The evidence is very uncertain about the effect of Structural Integration when compared to Fascial Fitness on perception of pain.

4.4. Fibromyalgia

4.4.1. <u>Description of the condition</u>

Fibromyalgia is a chronic pain disorder, estimated to affect approximately 2% of people globally, with variability across jurisdictions,(41) a greater prevalence among women,(41) and increasing prevalence with age.(42, 43) Aetiology is not completely clear, however, evidence suggests an abnormal operation of pain pathways, which results in the amplification of pain signals.(44)

Diagnostic criteria were initially published by the American College of Rheumatology in 1990, and included widespread musculoskeletal pain and tenderness; they were subsequently modified in 2010, to recognise a broader spectrum of symptoms, and also take into account: fatigue, problems with sleep, and cognitive disturbance.(45) Common features of fibromyalgia, include: musculoskeletal pain and tenderness, fatigue, poor quality sleep, problems with memory, cognition and concentration, and high levels of distress.(46) These symptoms result in physical as well as psychosocial disability, limit the individual's employment opportunities, and impact on the quality of life.(47)

Management of fibromyalgia is frequently multi-modal, involving a range of approaches, such as: pharmacological treatments, exercise, multi-modal cognitive therapy, education, and relaxation. (48)

4.4.2. Description of studies

One 3-arm, RCT of 60 individuals in Brazil was identified.(22) The study included participants diagnosed by a neurologist as having fibromyalgia syndrome (according to the American College of Rheumatology 1990 criteria). The trial compared the effectiveness of Rolfing alone, to acupuncture alone, to Rolfing + acupuncture.

The Protocol for the present review specified that studies where Rolfing was used as an adjunct intervention to another intervention are includable, provided that the specific effect of Rolfing could be determined. Therefore, the present study was included, and the results for the Rolfing study arm, and the acupuncture study arm were extracted and analysed. However, no analysis was conducted on the Rolfing plus acupuncture arm, as the specific effect of Rolfing could not be determined in this arm, in accordance with the Protocol.

The reported outcomes identified as of interest to the NTWC included: pain and quality of life. Other outcomes identified as of interest to the NTWC (physical function-global, fatigue, tenderness, sleep, and stiffness) were not reported by the study. The risk of bias of the study was overall high.

4.4.3. Main Comparison: Rolfing vs Acupuncture

Pain

The Pain Verbal Numeric Analogue Scale score for each group was reported at baseline, immediately post-intervention, and at 3 months post-intervention. Study authors did not assess the differences between groups at those time points. The differences between the Rolfing and Acupuncture groups were calculated. There was no difference between groups at baseline (MD 0.05, 95% CI -0.79 to 0.89, p=0.91), immediately post-intervention (MD -0.10, 95% CI -1.58 to 1.38, p=0.89), or at 3 months post-intervention (MD 0.25, 95% CI -1.21 to 1.71, p=0.74).

Quality of life

Quality of life was measured using the Fibromyalgia Impact Questionnaire (FIQ) score. The study authors reported the significance of the differences between groups but do not specify the time

point. The study reported no significant difference between acupuncture and Rolfing groups (p= 0.87; timepoint for measurement unclear). The differences between the Rolfing and Acupuncture groups at immediately post treatment and 3 months post treatment were calculated. There were no significant differences between the groups immediately post treatment (mean difference -7.1 95% CI -19.0 to 4.8) or at 3 months post treatment (mean difference -3.24 95% CI -14.1 to 7.6).

There was insufficient information to definitively determine the method of analysis (intention to treat, modified intention to treat, per protocol) used in this study but it was possibly an intention to treat analysis.

4.4.3.1. Summary of findings

Summary of findings:

Rolfing compared to Acupuncture for Fibromyalgia

Patient or population: Fibromyalgia Setting: Neurological clinic Intervention: Rolfing Comparison: Acupuncture

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect	Nº of participa	Certainty of the	Evideore statement	
Outcomes	Risk with Acupuncture	Risk with Rolfing	(95% CI)	nts (studies)	(GRADE)		
Pain assessed with: Verbal numeric analogue scale (0-10 with higher scores indicating more pain) follow up: post-treatment	The mean pain was 4.65	MD 0.1 lower (1.58 lower to 1.38 higher) The MID of VAS for pain is 1.0	-	40 (1 RCT)	⊕OOO VERY LOW a.b	The evidence is very uncertain about the effect of Rolfing on pain post-treatment	
Pain assessed with: Verbal numeric analogue scale (0-10 with higher scores indicating more pain) follow up: 3 months	The mean pain was 5.47	MD 0.25 higher (1.21 lower to 1.71 higher) The MID of VAS for pain is 1.0	-	40 (1 RCT)	⊕⊖⊖⊖ VERY LOW a.b	The evidence is very uncertain about the effect of Rolfing on pain 3 months post-treatment	
Physical function - Global	The included study did not measure this outcome			-	-	No studies found. The effect of Rolfing on physical function in fibromyalgia is unknown	
Quality of life (QOL) assessed with: Fibromyalgia Impact Questionnaire (FIQ) (0- 100 with lower scores indicating better quality of life) follow up: post-treatment	The mean quality of life was 46.13	MD 7.11 lower (19.01 lower to 4.79 higher) The MID for FIQ for QOL is 8.1	-	40 (1 RCT)	⊕OOO VERY LOW a.b	The evidence is very uncertain about the effect of Rolfing on quality of life post-treatment	
Quality of life (QOL) assessed with: Fibromyalgia Impact Questionnaire (FIQ) (0- 100 with lower scores indicating better quality of life) follow up: 3 months	The mean quality of life was 47.40	MD 3.24 lower (14.05 lower to 7.57 higher) The MID for FIQ for QOL is 8.1	-	40 (1 RCT)	⊕OOO VERY LOW a.b	The evidence is very uncertain about the effect of Rolfing on quality of life 3 months post- treatment	
Fatigue	The included study did not measure this outcome			-	-	No studies found. The effect of Rolfing on fatigue in fibromyalgia is unknown	
Tenderness	The included study did not measure this outcome			-	-	No studies found. The effect of Rolfing on tenderness in fibromyalgia is unknown	
Sleep	The included study did not measure this outcome					No studies found. The effect of Rolfing on sleep in fibromyalgia is unknown	
Stiffness	The included st measure this ou	udy did not utcome		-	-	No studies found. The effect of Rolfing on stiffness in fibromyalgia is unknown	

Summary of findings:

Rolfing compared to Acupuncture for Fibromyalgia

Patient or population: Fibromyalgia Setting: Neurological clinic Intervention: Rolfing Comparison: Acupuncture

Outcomes	Anticipated absolute effects* (95% Cl)		Relative effect	Nº of participa	Certainty of the	
	Risk with Acupuncture	Risk with Rolfing	(95% CI)	nts (studies)	(GRADE)	Evidence statement

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; MD: Mean difference; MID: Minimum important difference

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect Very low certainty: We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect

Explanations

a. Downgraded one for study limitation associated with high risk of bias arising from the randomisation process and some concerns related to deviations from the intended intervention and measurement of the outcome

b. Downgraded twice for imprecision associated with small sample size and wide confidence interval

4.4.3.2. Evidence statements

The evidence is very uncertain about the effects of Rolfing when compared to acupuncture on pain either immediately post-intervention or at 3 months post-intervention.

The evidence is very uncertain about the effects of Rolfing when compared to acupuncture on quality of life either immediately post-intervention or at 3 months post-intervention.

4.5. Hamstring tightness

Although hamstring tightness is not considered to be an injury, disease or condition, it may increase the risk of injury in healthy populations, i.e., is a pre-clinical condition and therefore meets the inclusion criteria for this review.

4.5.1. <u>Description of the condition</u>

The hamstrings are a group of muscles located down the back of the leg, which include the biceps femoris, semitendinosus, and semimembranosus muscles. Hamstring muscles support bodily movement and play a crucial role in many activities, such as, walking, running, and jumping.(49) Hamstring tightness can affect these daily activities and limit mobility.

Hamstring tightness, defined as a lack of range of motion (ROM) with a concomitant restriction down the back of the leg, can affect all age groups and is considered a potential cause of hip restricted movement or dysfunction.(50-52) Deficit in hamstring length has also been associated with an increased risk for hamstring strain,(53, 54) and may lead to the development of low back pain.(55)

Hamstring tightness may occur both from participating in sports that require powerful thrust (e.g., football or basketball), and under normal circumstances whilst engaging in non-strenuous activities (e.g., sitting for prolonged periods).(56)

4.5.2. <u>Description of studies</u>

One 2-arm, RCT of 40 individuals in India was identified.(21)

The study included participants diagnosed with hamstring tightness by criteria of limited extension range (<60 degrees), determined by active knee extension method. The trial compared the effectiveness of Rolfing alone to Active Release Technique (ART) developed by Dr. Michael Leahy.

The reported outcomes identified as of interest to the NTWC included: flexibility popliteal angle, and flexibility sit and reach test. No other outcomes of interest were identified by the NTWC.

The risk of bias of the study was high overall.

4.5.3. Main Comparison: Rolfing alone vs Active Release Technique (ART)

Flexibility - Sit and Reach distance test

The mean change (in centimetres) between baseline measurement and immediately post treatment was 8.58 (SD 4.01) for the Rolfing structural integration group and 10.9 (SD 5.39) for the Active Release Technique group, with no significant difference between groups (P = 0.16). Study authors did not assess the differences between groups at those time points. The differences between the Rolfing Structural Integration and Active Release Technique were calculated assuming equal number of participants in both groups (this was not stated in the study). There was no difference between groups at baseline (MD 1.87 95% CI -2.60 to 6.34, p = 0.41) or post-treatment (MD -0.45, 95% CI -2.71 to 1.81), p = 0.70). The difference in mean change from baseline between the two groups is -2.32, 95% CI -5.26 to 0.62, p = 0.12).

Flexibility - Popliteal angle

Popliteal angle (right side): The mean change in degrees between baseline measurement and immediately post treatment was 21 (SD 5.47) for the Rolfing structural integration group and 27.35 (SD 5.89) for the Active Release Technique group. Study authors did not assess the difference between groups at those time points. The differences between the Rolfing Structural Integration and Active Release Technique were calculated assuming equal number of participants in both groups (this was not stated in the study). There was no difference between Rolfing and Active Release Technique at baseline (MD -3.93, 95% Cl -8.96 to 1.10, p=0.13) or at post-treatment (MD 2.42, 95% Cl -0.22 to 5.06, p= 0.07). The difference in mean change from baseline between groups is -6.35, 95%Cl -9.87 to -2.83), p=0.0004, in favor of Rolfing.

<u>Popliteal angle (left side)</u>: The mean change in degrees between the baseline measurement and immediately post treatment was 21.31 (SD 4.28) for the Rolfing structural integration group and 26.95 (SD 5.64) for the Active Release Technique group. Study authors did not assess the difference between groups at those time points. The differences between the Rolfing Structural Integration and Active Release Technique were calculated assuming equal number of participants in both groups (this was not stated in the study). There was no difference between Rolfing and Active Release Technique at baseline (MD -1.87, 95% CI -7.60 to 3.86, p= 0.52). However, at post-treatment, Active Release technique was better than Rolfing (MD 3.77, 95% CI 0.25 to 7.29, p= 0.07). The difference in mean change from baseline is -5.64, 95%CI -8.74 to -2.54), p=0.0004 in favor of Rolfing.

There was insufficient information to determine the method of analysis (intention to treat, modified intention to treat, per protocol) used in this study.

4.5.3.1. <u>Summary of findings</u>

Summary of findings:

Rolfing Structural Integration compared to Active Release Technique for Hamstring tightness

Patient or population: Hamstring tightness

Setting: University college of physiotherapy

Intervention: Rolfing Structural Integration

Comparison: Active Release Technique

	Anticipated absolute effects* (95% Cl)					
Outcomes	Risk with Active Release Technique	Risk with Rolfing Structural Integration	Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
Flexibility assessed with: Sit and Reach distance test (increased distance indicates increased hamstring flexibility) follow-up: Post intervention	The mean flexibility was 22.55 cm	MD 0.45 cm lower (2.71 lower to 1.81 higher)	-	40 (1 RCT)	⊕⊖⊖⊖ Very low ^{ab,c}	The evidence is very uncertain about the effect of Rolfing Structural Integration on flexibility
Flexibility assessed with: Popliteal angle (Right side) (smaller angle indicates increased hamstring flexibility) follow-up: Post intervention	The mean flexibility was 6.05 degrees	MD 2.42 degrees higher (9.22 higher to 5.06 higher)	-	40 (1 RCT)	⊕⊖⊖⊖ Very low ^{ab,c}	The evidence is very uncertain about the effect of Rolfing Structural Integration on flexibility
Flexibility assessed with: Popliteal angle (Left side) (smaller angle indicates increased hamstring flexibility) follow-up: Post intervention	The mean flexibility was 5.65 degrees	MD 3.77 degrees higher (0.25 higher to 7.29 higher)	-	40 (1 RCT)	⊕⊖⊖⊖ Very low ^{a,b,c}	The evidence is very uncertain about the effect of Rolfing Structural Integration on flexibility

Summary of findings:

Rolfing Structural Integration compared to Active Release Technique for Hamstring tightness

Patient or population: Hamstring tightness

Setting: University college of physiotherapy

Intervention: Rolfing Structural Integration

Comparison: Active Release Technique

	Anticipated absolute effects' (95% Cl)					
Outcomes	Risk with Active Release Technique	Risk with Rolfing Structural Integration	Relative effect (95% Cl)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: confidence interval; MD: mean difference

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect. Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. Downgraded two for study limitations associated with high risk of bias arising from deviations from intended interventions, missing outcome data and measurement of the outcome

b. Downgraded one for indirectness. The study appears to evaluate a single session Rolfing. This is not consistent with classical Rolfing which typically follows the 'Ten-Series' recipe

c. Downgraded two for imprecision associated with small sample size and wide confidence intervals

4.5.3.2. Evidence statements

The evidence is very uncertain about the effect of Rolfing Structural Integration when compared to Active Release Technique on flexibility assessed by the sit and reach distance test.

The evidence is very uncertain about the effect of Rolfing Structural Integration when compared to Active Release Technique on flexibility assessed by the popliteal angle.

5. Discussion

5.1. Summary of main results

We conducted a systematic review of RCTs and NRSI to evaluate the effectiveness of Rolfing for any condition. The review identified six RCTs that evaluated the effectiveness of Rolfing and/or Structural Integration for four conditions: cerebral palsy (2 RCTs in 34 children), low back pain (2 RCTs in 82 participants), fibromyalgia (1 RCT in 60 participants), and hamstring tightness (1 RCT in 40 participants).

The evidence provides very low certainty for all outcomes prioritised as critical or important for patients by NTWC in this review. The main reason for the evidence being assessed as very low certainty was because results for all trials were judged to be at high risk of bias. Under GRADE, where evidence is assessed as very low certainty this means that the true effect in each study is probably markedly different from the estimated effect. Therefore, this review cannot conclude the effectiveness of Rolfing.

The outcomes prioritised as critical or important for patients by NTWC and therefore assessed in this review included:

- Myofascial Structural Integration for children with spastic cerebral palsy compared to waitlist or interactive play was assessed for gross motor function integration/participant and physical function.
- Structural Integration in addition to outpatient rehabilitation for low back pain was assessed for bothersomeness of pain, physical mental health, function, and quality of life compared to outpatient rehabilitation alone.
- Structural Integration for low back pain compared to Fascial Fitness was assessed for perception of pain.
- Rolfing for fibromyalgia compared to acupuncture was assessed for pain and quality of life immediately post-intervention or at 3 months
- Rolfing Structural Integration was compared to Active Release Technique for flexibility in adults with hamstring tightness.

5.2. Overall completeness and applicability of evidence

To locate studies evaluating the clinical effectiveness of Rolfing, multiple databases were searched, reference lists of included studies and related reviews were checked, studies published subsequently to the included studies were screened, and an intervention-specific library was hand-searched, with no restrictions on language or date. Outcomes reported by studies were not used as an inclusion or exclusion criteria, and studies in populations with any injury, disease, medical condition or pre-clinical condition were eligible for inclusion. As a result, 6 RCTs were found to be eligible for 3 conditions (spastic cerebral palsy, low back pain and fibromyalgia) and one preclinical condition that may increase risk of injury in healthy individuals (hamstring tightness). All included studies were published in English. Two studies with title only and no abstract of full-text available could not be assessed for inclusion. Translation of the non-English title of one of these studies (published in 2013) indicated the condition of interest in the study was 'shoulder limitation after breast cancer surgery'. The title of the second study (published in 1984) that could not be assessed for inclusion was 'Therapeutic renewal. Rolfing or structural integration.'

The studies were conducted in the USA (2 studies in spastic cerebral palsy and 1 study in low back pain), Austria (1 study in low back pain), Brazil (1 study in fibromyalgia) and India (1 study in hamstring tightness). Participants in the included studies are considered likely to be similar to those

who would be found in clinical practice in Australia. The included studies evaluated interventions variably described as Rolfing, Myofascial Structural Integration, Structural Integration and Rolfing Structural Integration, delivered alone or in addition to existing management, and of varying dose and duration, although the reporting of intervention details was often incomplete. Comparators included: wait list, usual care, or other active interventions. Details were generally not reported in sufficient detail to allow replication and assessment of generalisability. As there may be some variation in Rolfing practice, acceptance, and adherence to the intervention across countries, it is unclear how generalisable the findings are to the Australian context. Outcomes considered critical or important to patients by NTWC were not reported in most studies. Due to limited data, analysis exploring the impact of specific participant and intervention characteristics on study outcomes could not be conducted. Harms and cost-effectiveness were not assessed in this review.

5.3. Certainty of the evidence

The GRADE approach was used to assess the certainty of the body of evidence for each outcome as high, moderate, low, or very low certainty. The evidence for Rolfing was judged to be very low certainty for all outcomes reported in the included studies.

The risk of bias for the results reported in the included studies was high overall. Certainty of the evidence was rated down once or twice for study limitations associated with high risk of bias. For most results, the randomisation domain (domain 1) and deviations from intended interventions (domain 2) were rated as at high risk of bias or there were some concerns. In domain 2, this was because information was unavailable about whether the lack of blinding influenced the intended intervention and/or the analysis was considered inappropriate for assessing the effect of assignment to the intervention. Domain 3, missing outcome data, was generally rated at low risk of bias. For domain 4 (measurement of the outcome) and domain 5 (selection of the reported result) ratings of bias varied. Study outcomes were downgraded once or twice for imprecision due to small sample size, wide confidence intervals or lack of data to inform a judgment on precision.

5.4. Potential biases in the review process

Biases in the review process could have arisen from the differences between the protocol and the review. All deviations are reported in the Appendix G, together with the reasoning for the deviation. It was anticipated that the effect of Rolfing would be evaluated across a broad range of conditions. As such, outcomes against which studies could be assessed for inclusion were not pre-specified at the start of the review. Instead, outcome domains and measures for each condition were prioritised during the review. To mitigate the potential for biases arising from this, the complete list of outcomes identified for each eligible study by condition was provided in a blinded format (suppressing reference and outcomes of the study) to the NTWC, who prioritised the relevant outcomes and outcome measures.

5.5. Agreements and disagreements with other studies or reviews

No existing systematic reviews specifically evaluating the effect of Rolfing or Structural Integration were identified during the review process. A specific search for systematic reviews with the term "Rolfing" or "Structural Integration" in the title or abstract, conducted in PubMed on 25 August 2021, returned no (zero) results.

Six related reviews (2 systematic reviews and 4 literature reviews), that mentioned or potentially included Rolfing as one of multiple complementary, non-surgical, non-drug or alternative health practices of interest for specific populations (e.g. informal care givers) or conditions (e.g. scoliosis) or for unspecified populations or conditions, were identified whilst screening the results of searches conducted for the present review. (57-62)

The reference lists of these reviews were checked, but no studies assessing the effects of Rolfing were identified, or the studies evaluating Rolfing that were identified did not meet the inclusion criteria for this review. The review by Brekke et al (2020),(57) reviewed non-surgical interventions for excessive anterior pelvic tilt in symptomatic and non-symptomatic adults, and included one study on Rolfing.(63) However, this study did not meet the inclusion criteria for the present review. A systematic review by Carnes et al (2010) (58) focused on manual therapies but did not include any studies of Rolfing. Deutsch (2008) (59) is a broad review and discussion of Rolfing, however, none of the discussed Rolfing studies were found to meet the inclusion criteria for the present review. Van Tulder et al's evidence-based review (2016) (60) focused on the outcomes of non-invasive treatment modalities for back pain, however, none of the included studies were of Rolfing. Walter et al (2017) systematically reviewed the evidence for mind and body complementary health practices for informal caregivers, (61) and Zarzycka et al (2009) reviewed alternative methods of conservative treatment of idiopathic scoliosis. (62) Although Rolfing was one of the therapies of interest in both reviews, neither identified any includable studies of Rolfing. The agreement or disagreement of the findings of these reviews with the present review cannot be assessed, as none were focused specifically on Rolfing, and generally did not identify Rolfing studies.

5.6. Limitations of the review

The volume of evidence for the effectiveness of Rolfing is currently very limited, in terms of the number of trials (six were identified), conditions addressed by those trials (cerebral palsy, low back pain, fibromyalgia, and the preclinical condition, hamstring tightness), and study sizes (ranging from 8 to 60 participants). The identified trials were all rated at high risk of bias, and the certainty of the evidence is very low. Where more than one trial was available for a condition, each trial included different comparators and measured different outcomes, precluding meta-analyses of the evidence.

6. Authors' conclusions

Few studies have evaluated the effects of Rolfing in a limited number of conditions and the evidence from existing studies of Rolfing is of very low certainty. Larger and high quality randomised controlled trials are needed to evaluate and compare the safety and efficacy of Rolfing in populations in which it is used in clinical practice in Australia.

6.1. Implications for policy

This report was commissioned by the Australian Government as part of the Natural Therapies Review, with findings intended to inform decisions relating to whether private health insurance cover should be reinstated to Rolfing. As such, specific recommendations are not provided. Current evidence does not support the use of Rolfing in children with spastic cerebral palsy, people with low back pain or fibromyalgia or hamstring tightness.

6.2. Implications for research

The volume of evidence for the effectiveness of Rolfing is currently limited to six trials (total of 216 participants). The risk of bias for all included studies was overall high, and the certainty of evidence (GRADE) for the outcomes of interest that were reported was very low. Larger, robustly designed trials, addressing a greater breadth of conditions for which Rolfing is used in clinical practice, are needed.

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