ROLFING FOR ANY INDICATION IN HUMANS: A SYSTEMATIC REVIEW (RESEARCH PROTOCOL)

Prepared for the National Health and Medical Research Council

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Rolfing for any indication in humans: a systematic review (research protocol)

Background

Description of the condition

Rolfing is a bodywork therapy (therapy that involves manipulative therapy, breath work or energy medicine) that 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 though 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 well-being.(1)

Description of the intervention

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. 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)

While only therapists trained and certified by The Rolf Institute® may use the Rolfing® Service Mark, other institutions provide training in this approach.(3) In the 1960's, Dr Rolf informally established the Guild for Structural Integration from which The Rolf Institute® arose. Since this time 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 clear definition of SI and scope of practice for its members.(5)

The practice of Rolfing stems from Dr Rolf's hypothesis that optimal physical and psychological well-being 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 duration and consists of: 1) observation and assessment of posture and movement, 2) manual soft-tissue techniques including mobilisation/release of the myofascia and visceral facia, 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.

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)

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. The 2015 Review "An overview of the effectiveness of Rolfing for any clinical condition in humans"(13) included one systematic review of randomised trials 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 quality of Rolfing from systematic reviews of randomised trials of the therapy's effectiveness.

The present review will consider the evidence about the effectiveness of Rolfing, conducting a systematic review of randomised and non-randomised studies of interventions. The present document is the Research Protocol for this review and describes the proposed review objectives and methods.

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 randomised controlled trials and non-randomised studies of interventions.

Methods

Criteria for considering studies for this review

Types of study: study designs

The review will include evidence for Rolfing from randomised controlled trials (RCTs) and non-randomised studies of interventions (NRSIs). The Cochrane Handbook (Section 24.1.1) provides two main justifications for inclusion of NRSIs in a systematic review: 1) the available RCTs address the question indirectly or incompletely, 2) RCT study design is unsuitable.(14) The RCT study design is suitable for studies of the Rolfing intervention, however, the inclusion of NRSI studies in addition to RCTs will allow for an assessment of the effectiveness of Rolfing across a wider range of conditions and reflect the full breadth of the scope of practice.

We will include randomised controlled trials that use a truly random sequence to allocate participants to study groups. We will include controlled trials where participants are allocated to an intervention based on methods that are pseudo random (e.g. alternate allocation, or allocation by date of birth), or not random (a non-randomised controlled trial), and other non-randomised studies of interventions (NRSIs) with the design features tabulated below (Table 1). We will exclude non-randomised studies that do not include a contemporaneous control group, as well as those which have a relatively limited ability to estimate the causal effect of an intervention based on key design features related to the availability of outcome data and means for estimating intervention effect (e.g. timing of outcome measurement in relation to intervention, number of timepoints and measurement in the same or different individuals).(15) This will result in the exclusion from the review of studies without a control group that obtain outcome data from the same study participants at a single point in time before, and a single point in time after an intervention, and studies that examine associations between receipt of an intervention and outcomes at a point in time.

Table 1: Description and design features of non-randomised studies that will be included and excluded from the review (table is based on descriptions provided in the Cochrane Handbook Version 5)(14)

Design features of non-randomised studies that will be **included** in the review*	
	- observations are made at a single time point before and a single time point after the implementation of an intervention in a study group that receives the intervention and a study group that does not
	- a defined group of people is followed over time and associations between different interventions received and subsequent outcomes is examined. A prospective study of this design will recruit participants before an intervention and follow them forward in time. A retrospective study of this design identifies participants from past records which describe the interventions received, and follows them from the time of those records
	- a group of people with and without a specific outcome of interest are included and the association between the outcome and prior receipt of an intervention is examined
	- observations are made in a study group at multiple time points before and after an intervention with or without a control group
Design features of non-randomised studies that will be **excluded** from the review	
	- information on interventions received and current health outcomes are obtained from a group of participants at a single point in time
	- observations are made on participants receiving the same intervention, at a single point before and a single point after the intervention but with no control group
	-observations are made at a single time point before and a single time point after the implementation of an intervention in a study group that receives the intervention

*The results of non-randomised studies that are assessed as being at critical risk of bias on one of the domains of the ROBINS-I tool will not be reported in the review results, syntheses or conclusions (see section "Tools to assess risk of bias in individual studies").

Systematic reviews *as a study type* will be excluded. However, for any systematic reviews identified that would meet the inclusion criteria, the list of primary studies included in that systematic review will be checked for primary studies not identified in our database and other source searches. If any such primary studies are identified, and these studies meet the inclusion criteria for the present review, the studies will be included in the present review.

We will exclude expert opinion articles, editorials, and letters.

We will not exclude studies based on their size.

Types of study: study reports

Database searches will not exclude studies based on language of publication. Databases in languages other than English will not be searched, however, where studies in languages other than English are identified through searches in the English language databases, they will be dealt with via a process outlined in Appendix 3.

We will not exclude studies based on their publication status. For studies reported only as an abstract (e.g. a conference abstract) that provide author information, we will contact the authors to seek full information on the study. If no contact information for the study author is provided, the study will be noted in an Appendix, but it will not be included in the analysis.

Types of participants

To capture the wide range of populations and conditions commonly seen by practitioners of Rolfing, the population of the included studies will comprise people of any age with any injury, disease, medical condition, or pre-clinical condition. This includes disease prevention in at-risk healthy populations, broadly defined as those who are at increased risk of becoming ill or injured based on

social, biomedical, or behavioural risk factors. For the purposes of this review, social determinants include factors such as income, education, employment and social support; biomedical factors include a person's age, genetic make-up and health status (such as obesity, high blood pressure, high cholesterol, vitamin deficiency); and behavioural factors include a person's lifestyle choices (e.g. alcohol consumption, diet, exercise, tobacco and other drug use).(16) Healthy participants seeking health improvement (such as general wellbeing, fitness, aesthetic improvements, resilience and cognitive or emotional intelligence) are not eligible for inclusion. A study with eligible and ineligible populations will be included if separate data is available for the eligible populations.

Types of interventions

We will include studies that evaluate an intervention that meets the definition of Rolfing® Structural Integration (SI) and/or Rolf Movement® Integration as stated in the Official Order 2019-20P027 (page 17):

> *Rolfing is the abbreviated term used to describe Rolfing® Structural Integration (SI) and Rolf Movement® Integration. Named after its founder, Dr. Ida P. Rolf, SI is a form of bodywork that aims to reorganize the connective tissues, called fascia, so that body is more at ease and its structure is balanced in gravity. The aim is to restore postural efficiency and freedom of movement, improve flexibility, resolve discomfort, release tension, alleviate pain and revitalise energy. The hallmark of Rolfing SI is a standardized "recipe" known as the Ten-Series, the goal of which is to systematically balance and optimize both the structure (shape) and function (movement) of the entire body over the course of ten Rolfing sessions.*
>
> *Rolf Movement® Integration, a somatic sensory-motor approach to movement education, aims to help clients optimize and sustain structural ease through balanced movement behaviour. Originally developed by mandate from Dr. Rolf, who believed that movement education was a valuable adjunct to the hands-on structural work, Rolf Movement® Integration has evolved into both a therapy in its own right, and an inherent feature of the Rolfing Structural Integration process.*

We will also include studies of Structural Integration or Myofascial Structural Intervention, as these are considered synonymous with Rolfing, but we will exclude studies of individual component techniques (such as myofascial release, active functional technique, and others) in isolation, unless these interventions are identified as Rolfing/Structural Integration/Myofascial Structural Integration.

Studies will be included regardless of who delivers the intervention (e.g. a provider certified by the Rolfing Institute, the Guild for Structural Integration, the International Association of Structural Integrators or a similar body; or one who is not certified), although if the intervention is delivered by a certified provider, this information will be extracted as part of the description of the intervention (see further detail in "Data Items" section, below).

(Throughout the rest of the text of the Protocol, we will refer to the included interventions collectively as "Rolfing").

Types of comparators

We will include studies with the following comparators: placebo, no intervention, sham intervention, wait list, usual care, or another intervention or interventions.

Studies evaluating Rolfing as a co-intervention will be included as long as the effect of Rolfing is not confounded. Studies where Rolfing is being used as an adjunct intervention to another intervention will also be included, providing that the specific effect of Rolfing can be determined. For the purposes of the analysis, the comparisons will be grouped into the following: control (inactive), placebo/sham (if relevant), or other ('active') comparator.

Types of outcome measures

The outcomes reported by studies will not be used as a criterion for inclusion or exclusion from the review (at the title and abstract, or full text screening stage). Given the range of conditions for which Rolfing may be evaluated, the outcome measures to be reported in this review for each condition will be determined and prioritised by the NTWC. This will entail NTWC considering a list of populations, outcome domains and outcome measurements for prioritisation, with the list derived from the eligible studies and core outcome set/s for a particular condition (where available).

Throughout the outcome prioritisation exercise, the NTWC will have no knowledge of study results or details other than those stated above. In determining the critical and important outcomes, the NTWC will be guided by GRADE, and focus on the relevance and validity of outcome measures.

The NTWC decision on outcomes and their prioritisation will inform the study data extraction. For each condition, up to 7 critical, and important but not critical outcomes, will be extracted and presented in Summary of Findings Tables. Any other outcomes reported by the included studies will be listed in the Characteristics of included studies table, but data on these outcomes will not be extracted or reported.

Patient-Reported Experience Measures (PREMs), such as satisfaction with experience or preferences, will be excluded. Safety, quality or economic outcomes will be excluded.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases, from inception until present: MEDLINE, Embase, CINAHL, AMED, PsycInfo, PEDro, Cochrane library, Ida P. Rolf Library of Structural Integration and the WHO Virtual Health Library (which includes LILACS and other sources).

The following search string will be used to search Ovid MEDLINE:

(exp Fascia/ and exp Massage/) or Rolfing.ti,ab. or Rolf.ti,ab. or Structural integration.ti,ab. or Applied kinesiology.ti,ab. or Deep tissue massage.ti,ab. or ((myofascial or fascial) adj2 (Release or Massage or Manipulation or Manipulations)).ti,ab. OR (Hellerwork or Structural Visceral Integration or Pelvic lift or Diaphragm* release or Somatic movement education).ti,ab.

This search string has been modified to run in other databases and the search strings for those databases are provided in Appendix 1.

We will also check the reference lists of all included studies (backwards citation search), and we will check studies citing the included studies (forwards citation search) for additional studies.

Search restrictions

We will not impose language or publication date restrictions on the searches.

Searching other resources

In accordance with the Official Order, grey literature will be considered out of scope. However, evidence reviews commissioned by Australian government bodies and other national or international bodies that are recommended by the Natural Therapies Review Expert Advisory Panel (NTREAP) or NTWC members, will be considered in the review as a source of eligible RCTs and NRSIs, which will be assessed for inclusion against the above criteria (see "Criteria for considering studies for this review").

The Department of Health will also be inviting the public and key stakeholders to provide additional published research evidence on the effectiveness of Rolfing. The NTREAP and NTWC will also submit evidence it had identified or been provided with.

Data collection and analysis

Inclusion decisions

Two reviewers will independently screen the titles and abstracts identified in the database searches, citation searches, and those provided by NTREAP for eligibility against the inclusion criteria. One reviewer will retrieve full-text of eligible articles, and two reviewers will independently screen the full-text articles for inclusion. Any disagreements will be resolved by discussion, or reference to a third reviewer. The selection process will be recorded in sufficient detail to complete a PRISMA flow diagram. Full text studies which do not meet the inclusion criteria will be tabulated, and reasons for exclusion provided.

Evidence provided through the Department's call for evidence or by NTREAP or NTWC will be assessed according to the inclusion criteria. Evidence not meeting the inclusion criteria will be tabulated with reason for exclusion provided. Eligible studies that have not been identified in database searches and other search processes will be incorporated into the review.

Data collection process

Two reviewers will independently extract data from reports of included studies using pre-piloted data extraction forms (Appendix 2). During piloting, the reviewers will jointly extract the data from two studies into the extraction forms to ensure consistent understanding and suitability of the data extraction forms. The remainder of the studies will be extracted by two authors independently. Data extractions will be compared by a third reviewer to identify discrepancies in extractions, and discrepancies will be reconciled by discussion, or by referring to a third reviewer.

Requests for data

If key information is missing from reports of the included studies, we will contact the corresponding authors.

Data items

We will collect information on study design, location and setting and participant characteristics including health status (healthy, disease or condition), age and number of participants. Descriptions of the key characteristics of the interventions (including comparator) will also be extracted and reported using the Template for Intervention Description and Replication (TIDieR) checklist.(17) We will extract data for the critical, and important but not critical, outcomes assessed at each time point including the number of participants with events and number of participants for dichotomous outcomes, means and standard deviations for continuous outcomes, and point estimates and confidence intervals (Appendix 2).

Dealing with missing data

If numerical outcome data such as standard deviations are missing from reports of the included studies, and they cannot be obtained from the authors, where feasible, we will calculate them from other available statistics, such as P values, according to the methods described in the Cochrane Handbook for Systematic Reviews of Interventions.(14) Where data has been calculated, this will be noted in the evaluation report for transparency. Where the information cannot be obtained from authors or calculated, the data will be reported as per original studies, and its incompleteness will be noted.

Tools to assess risk of bias in individual studies

Randomised and pseudo-randomised controlled trials will be assessed for risk of bias with the Cochrane risk-of-bias 2 (RoB 2) tool for randomised trials. This tool considers biases arising from the following domains: randomisation process, deviation from intended intervention, missing outcome data, measurement of the outcome, selection of the reported result and overall bias. Each domain will be assessed and judged as being at: 1) low risk of bias, 2) some concerns, 3) high risk of bias.(18)

Non-randomised studies of interventions will be assessed for risk of bias with the Risk-of-bias in non-randomised studies of interventions (ROBINS-I) tool. This tool views each study as an attempt to emulate a hypothetical randomised trial and assesses bias in seven domains: confounding, selection bias, bias in measurement classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes, and bias in selection of the reported result.(19) Each domain will be assessed and judged as being at: 1) low risk of bias, 2) moderate risk of bias, 3) serious risk of bias, 4) critical risk of bias, or 5) no information to base a judgment. When a domain is assessed as being at critical risk of bias (the study is too problematic in this domain to provide any useful evidence on the effect of the intervention), the study will not be further assessed. The results of the risk of bias assessment for such a study (the reason for critical rating) and characteristics of that study will be reported, but the results of the study will not be reported and it will not be included in any synthesis or review conclusions.

The ROBINS-I tool requires pre-specification of confounding domains and co-interventions that could differ between intervention groups. ROBINS-I guidance suggests that these are likely to be identified both through the expert knowledge of the subject matter and initial review of the literature. To identify potential confounding domains and co-interventions relevant to most or all studies in the review, a two-step process will be used. During data extraction, prognostic factors and co-interventions considered in the introduction and/or discussion sections of the included studies will be recorded and tabulated according to the condition or health status of the study population. This list will then be provided to the NTWC who may suggest any additional confounders or relevant co-interventions. The potential confounders and co-interventions identified by this approach will be used during the application of the ROBINS-I tool.

The ROBINS-I tool is currently most closely aligned with study designs that are “cohort-like”, specifically concurrently controlled studies in which individuals who have received different interventions are followed up over time.(19) The non-randomised studies potentially eligible for inclusion in this review are consistent with this design. For study designs where some components of the ROBINS-I are less relevant (e.g. case-control studies) and modifications to ROBINS-I signalling questions are being considered by the developers, guidance on issues of bias specific to these designs that is currently provided by the Cochrane Handbook for Systematic Reviews of Interventions will be used when applying ROBINS-I and the limitations of the tool acknowledged.(14)

Risk of bias assessment process

Two reviewers will independently assess risk of bias in the included studies. Risk of bias judgments will be compared by a third reviewer to identify discrepancies. Any discrepancies will be reconciled by discussion between the two reviewers, or by referring to a third reviewer.

Data synthesis

Measures of effect

We will use risk ratios for dichotomous outcomes where the results are reported as the number of individuals with an event. Count data (e.g. the number of events in each group, such as the number of illness episodes) will be analysed using methods for dichotomous, continuous, time-to-event, or rate data – as appropriate (Cochrane Handbook Section 9.4.8).(14) For continuous outcomes (e.g. severity of illness, gross motor function measures, etc.), we will use mean difference or standardised mean difference as appropriate (Cochrane Handbook Section 9.2.3).(14)

Given the breadth of this review, it is not practical at the Protocol stage to pre-specify the minimally important differences (MID) for interpreting the size of the intervention effect.

Unit of analysis

The individual will be used as the unit of analysis, where possible. However, where data on the number of individuals with outcomes of interest is not available, we will extract the information as it is presented (e.g. the number of events in each group).

If any included studies are cluster RCTs that report data only on a cluster level (rather than individual level), we will conduct the analysis at a cluster level, considering each cluster as if it were 'an individual' (so the sample size is the number of clusters) and using the summary measurement from each cluster. Alternately, analysis will be conducted at the level of the individual whilst accounting for the data clustering, if the study reports data which properly accounts for the clustered design. Statistical advice will be sought to determine appropriate methods as recommended by the Cochrane Handbook (Section 16.3.3).(14)

An additional source of clustering in individually randomised trials is centre effects in multicentre trials and therapist effects in studies where groups of patients are treated by the same therapist. Often these cluster effects are ignored in trial analysis. For individually randomised trials with these types of potential clustering effects, if possible, analysis will be conducted at the level of the individual whilst accounting for the clustering. If this is not possible then we will still potentially include the study in the meta-analysis but note a limitation that the study's standard error may be inaccurate.

Studies with more than two groups

If studies with more than two arms are included in the review, where all study arms assess includable interventions and need to be retained (e.g. Rolfing group vs Structural Integration group vs Placebo) we will analyse groups in a way that avoids arbitrary omission or double counting. Where possible, we will combine groups to create a single pair-wise comparison (preferable approach); alternatively we will select one pair of interventions and exclude others (if preferable approach not possible); or split the 'shared' comparator group into two (or more if required) groups of smaller sample size and include two (or more if required) comparisons (least preferable approach) (Cochrane Handbook Section 16.5.4).(14)

Quantitative synthesis

We will undertake meta-analyses of RCTs when two or more trials report the same outcome for a comparator within a condition, and if the trials are sufficiently homogeneous with respect to participants and interventions. Pseudo-randomised trials will be analysed with RCTs. NRSIs may be meta-analysed when two or more studies for the same condition report the same outcome for a comparator, and are judged to be at overall low to moderate risk of bias, and are homogeneous with respect to participants and interventions. NRSIs will be analysed separately to RCTs, with NRSIs of different design features analysed separately to each other. Meta-analyses will be conducted using *Review Manager 5*.

Anticipating considerable heterogeneity among the included studies, we will use a random effects model.

When meta-analysis of RCTs is not possible or appropriate, we will follow the guidance for synthesising and presenting quantitative effects of interventions using other methods provided by the Cochrane Collaboration (Cochrane Handbook Section 12.2).(14) When meta-analysis is not possible due to incompletely reported outcome or effect estimates, the following approach will be adopted: first, if available, findings from a large study at low risk of bias will be emphasised, with the remaining results being summarised using vote-counting approach (based on direction of effect); second, if no large study at low risk of bias is available, vote counting based on direction of effect will be conducted.

Synthesis will be undertaken for comparisons of Rolfing with control (inactive), and comparisons with placebo/sham (if relevant) interventions. Results data from studies comparing Rolfing with other active comparisons (e.g. manual therapies, exercise, pharmacological treatments, etc.) will be extracted but not synthesised further, except where requested by the NTWC. Instead, this data will form an 'evidence inventory' to provide readers with a snapshot of available evidence comparing Rolfing with other comparisons.

The NTWC may request that data comparing Rolfing with another active intervention be synthesised, where:

1) at least two studies compare the effect of Rolfing with the same active comparator, and the comparator is sufficiently homogenous across studies to support synthesis, and
2) at least two of these studies are at low or moderate risk of bias, and
3) the comparator represents an accepted, evidence-based 'gold standard' of care for the population in question.

Where relevant, such instances will be identified by the NTWC through blinded discussions with the evidence reviewer at the data synthesis stage, or prior to provision of the first draft evaluation report.

Assessment of heterogeneity

If meta-analyses are performed, we will use the I^2 statistic to measure heterogeneity among the included studies. In addition, we will visually examine the effect sizes and their confidence interval to verify whether high I^2 values suggest a potential problem, and consider the p-value from the Chi^2 test for heterogeneity to aid in the interpretation.

Non quantitative synthesis

When meta-analysis or other methods of statistical synthesis cannot be used, the results of included studies will be displayed in tables and or plots, and in text. The results of included studies will be tabulated with studies grouped by condition, study design characteristics (e.g. RCTs and NRSIs), comparison and outcome domain. If effect estimates are not provided by the study, these will be calculated if possible and standardised across studies to aid interpretation, otherwise study results will be reported as presented in each study. If there are sufficient studies and data, study results may be presented in forest plots (without the summary diamond) or box-and-whisper plots. When reporting the results of studies textually, the studies will be ordered by study design characteristics (e.g. RCTs and NRSIs) and according to the assessment of risk of bias, with reporting in text limited to studies judged to be at low or unclear risk of bias only.

Risk of reporting bias across studies

It is considered very unlikely that any meta-analysis will include more than 10 trials. Therefore, the creation of funnel plots (including contour-enhanced funnel plots) would be inappropriate.

Should a meta-analysis with more than 10 trials be performed, we will create a funnel plot to assess the potential for reporting biases (Cochrane Handbook Section 10.4.3.1).(14) If small study effects are suspected, they will be tested using the approach appropriate to outcome type (i.e. continuous, dichotomous): for continuous outcomes reported as mean differences, Egger's test will be used; for continuous outcomes measured as standardised mean differences, the small effects will not be tested (as no guidance from Cochrane Handbook is available); for dichotomous outcomes reported as odds ratios, the tests proposed by Harbord and Peters will be used; for dichotomous outcomes reported as risk ratios or risk differences, the small effect sizes will not be tested (as no guidance from Cochrane Handbook is available). A statistician will be consulted prior to undertaking any of these tests (Cochrane Handbook Section 10.4.3.1). If there is evidence of small-study effects, we will conduct a sensitivity analysis using trim and fill (Cochrane Handbook Section 10.4.4.2).(14)

Addressing risk of bias

If meta-analysis can be conducted, we will perform sensitivity analysis to determine the size and direction of effect when excluding studies in which any risk of bias domain has been graded as 'high risk'.

Subgroup analyses

If sufficient data is available, we plan to carry out the following subgroup analyses:

1) Effectiveness of Rolfing in participants who are "at risk" healthy vs in those diagnosed with a condition/illness
2) Type of Rolfing intervention (e.g. Rolfing vs Structural integration vs Myofascial structural integration)
3) Treatment provider (e.g. Certified Rolfing/SI practitioner vs non-certified)
4) Age of participants (<18 years, 18-65 years, > 65years)

Certainty of the evidence

The GRADE approach will be used to assess the certainty of the body of evidence for each outcome. Using this approach, certainty will be rated as very low (the true effect is probably markedly different from the estimated effect), low (the true effect might be markedly different from the estimated effect), moderate (the authors believe that the true effect is probably close to the estimated effect) or high (the authors have a lot of confidence that the true effect is similar to the estimated effect).(20)

Certainty of the evidence for each outcome will be determined by considering eight GRADE factors; five of which may result in rating down certainty (risk of bias, indirectness, inconsistency, imprecision and publication bias), and three which may result in rating up certainty (large effect, dose response, all plausible confounding and bias). Reasons for downgrading the evidence will be classified as 'serious' (downgrading the certainty rating by one level), or 'very serious' (downgrading the certainty by two levels) (when the reason is not serious enough to warrant downgrading it will be classified as 'no limitation'). Certainty of the evidence may be rated up one level when a large magnitude of effect exists, when there is a dose-response gradient, and when all plausible confounders or other biases would reduce a demonstrated effect or suggest a spurious effect when no effect was observed, as per guidance outlined in GRADE Guideline 9.(21) Using the GRADE approach, the baseline certainty rating for RCTs is high. Based on recent advice from the GRADE Working Group, the baseline certainty rating for NRSIs will also be high.(22)

In this review, risk of bias in randomised trials will be assessed using Cochrane risk of bias tool 2 (RoB 2), and non-randomised studies with ROBINS-I, with movement from assessment of risk of bias to judgments about study limitations based on guidance provided by the Cochrane Collaboration (Cochrane Handbook Table 14.2.a).(14) Inconsistency of results will be assessed as per GRADE guidance by considering similarity of point estimates, overlap of their confidence intervals and statistical criteria for heterogeneity (23). Indirectness will be assessed across the domains of population, intervention, comparator, direct comparison and outcome as recommended in the Cochrane Handbook (Table 14.2.b).(14) To assess imprecision, we will consider the number of events, the size of the confidence intervals and a calculation of the optimal information size. Thresholds for appreciable benefit for dichotomous outcomes and size of the difference for continuous outcomes will be determined to facilitate decisions to rate down for imprecision. This will be achieved through a combination of focused searching of literature for studies providing credible estimates and consultation with the NTWC. Where a compelling rationale for a threshold for a dichotomous outcome cannot be determined, the relative reduction or increase of >25% will be used as per guidance from the GRADE handbook.(24)

'Summary of Findings' table and evidence statements

For each comparator within each clinical condition, GRADEpro GDT (www.gradepro.org) will be 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. For each clinical condition, up to 7 critical, and important but not critical, outcomes will be presented in the SOF table. Description of the methods to be used to identify and prioritise outcomes for each clinical condition is provided in the Study eligibility criteria 'Types of outcome measures' section of the protocol. Where both RCTs and NRSIs provide data for the same outcome and comparator within a condition we will follow GRADE Guideline 18 about how the results should be presented in the SOF.(22) According to this guidance, if certainty of evidence differs in the body of randomised trials and the body of NRSIs, only the higher certainty evidence will be presented in the SOF table. If certainty ratings are the same for the RCT and NRSI body of evidence, the results from both will be presented in the same SOF table but on separate rows of the table. When the certainty ratings of the two bodies of evidence are the same, if the results are consistent, then the overall certainty assessment is that of the two bodies of evidence. If the results are inconsistent and it is determined that both bodies of evidence should be taken into consideration, the overall certainty will be rated down further for this inconsistency. Detailed explanations to support judgments (e.g. the GRADE assessment of certainty) will be provided as footnotes in the SOF table using guidance from Cochrane (Cochrane Handbook Section 14.1.6.10).(14)

Evidence statements will be written from narrative comments provided by GRADEpro GDT.

Differences between the protocol and systematic review

Differences between the protocol and the systematic review (if any) will be documented in the "Differences between the protocol and systematic review" section of the systematic review, together with reasons for the differences.

Protocol registration

On final approval by the NHMRC, the protocol will be registered on the International Prospective Register of Systematic Reviews (PROSPERO).

Acknowledgements

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Contributions to the Protocol and Review

Draft the protocol: SS, AS, JC, MB, ZM, PG
Develop the search strategy: JC
Run the search strategy: JC
Obtain copies of studies: JC
Select which studies to include: SS, AS, MB, ZM
Extract data from studies: SS, AS, MB, ZM
Enter data into Review Manager 5: SS, AS
Carry out the analysis: SS, AS, PG
Interpret the analysis: SS, AS, PG
Draft the final review: SS, AS, JC, MB, ZM, PG

SS and AS are the guarantors of the review

Declarations of interest

All authors report no known conflicts of interest.

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APPENDIX 1 – Database search strings

Database search strings

Ovid MEDLINE

(exp Fascia/ and exp Massage/) or Rolfing.ti,ab. or Rolf.ti,ab. or Structural integration.ti,ab. or Applied kinesiology.ti,ab. or Deep tissue massage.ti,ab. or ((myofascial or fascial) adj2 (Release or Massage or Manipulation or Manipulations)).ti,ab. OR (Hellerwork or Structural Visceral Integration or Pelvic lift or Diaphragm* release or Somatic movement education).ti,ab.

Cochrane Library

([mh Fascia] AND [mh Massage]) OR Rolfing:ti,ab OR Rolf:ti,ab OR "Structural integration":ti,ab OR "Applied kinesiology":ti,ab OR "Deep tissue massage":ti,ab OR ((myofascial:ti,ab OR fascial:ti,ab) NEAR/2 (Release:ti,ab OR Massage:ti,ab OR Manipulation:ti,ab OR Manipulations:ti,ab)) OR (Hellerwork OR "Structural Visceral Integration" OR "Pelvic lift" OR "Diaphragm* release" OR "Somatic movement education"):ti,ab

Embase

('rolfing'/exp OR ('Fascia'/exp/mj AND 'Massage'/exp/mj) OR Rolfing:ti,ab OR Rolf:ti,ab OR "Structural integration":ti,ab OR "Applied kinesiology":ti,ab OR "Deep tissue massage":ti,ab OR ((myofascial OR fascial) NEAR/2 (Release OR Massage OR Manipulation OR Manipulations)):ti,ab) OR (Hellerwork OR "Structural Visceral Integration" OR "Pelvic lift" OR "Diaphragm* release" OR "Somatic movement education"):ti,ab

CINAHL

((MH "Rolfing") OR ((MH "Fascia+") AND (MH "Massage+")) OR TI Rolfing OR AB Rolfing OR TI Rolf OR AB Rolf OR TI "Structural integration" OR AB "Structural integration" OR TI "Applied kinesiology" OR AB "Applied kinesiology" OR TI "Deep tissue massage" OR AB "Deep tissue massage" OR ((TI myofascial OR AB myofascial OR TI fascial OR AB fascial) N2 (TI Release OR AB Release OR TI Massage OR AB Massage OR TI Manipulation OR AB Manipulation OR TI Manipulations OR AB Manipulations))) OR (TI Hellerwork OR AB Hellerwork OR TI "Structural Visceral Integration" OR AB "Structural Visceral Integration" OR TI "Pelvic lift" OR AB "Pelvic lift" OR TI "Diaphragm* release" OR AB "Diaphragm* release" OR TI "Somatic movement education" OR AB "Somatic movement education")

AMED

((exp Fascia/ AND exp Massage/) OR Rolfing.ti,ab. OR Rolf.ti,ab. OR Structural integration.ti,ab. OR Applied kinesiology.ti,ab. OR Deep tissue massage.ti,ab. OR ((myofascial.ti,ab. OR fascial.ti,ab.) adj2 (Release.ti,ab. OR Massage.ti,ab. OR Manipulation.ti,ab. OR Manipulations.ti,ab.))) OR (Hellerwork or Structural Visceral Integration or Pelvic lift or Diaphragm* release or Somatic movement education).ti,ab.

PsycINFO

(Rolfing.ti,ab. OR Rolf.ti,ab. OR Structural integration.ti,ab. OR Applied kinesiology.ti,ab. OR Deep tissue massage.ti,ab. OR ((myofascial.ti,ab. OR fascial.ti,ab.) adj2 (Release.ti,ab. OR Massage.ti,ab. OR Manipulation.ti,ab. OR Manipulations.ti,ab.))) OR (Hellerwork or Structural Visceral Integration or Pelvic lift or Diaphragm* release or Somatic movement education).ti,ab.

PEDro

Rolfing OR Rolf OR Structural integration OR Myofascial release OR Myofascial massage OR Myofascial manipulation OR Myofascial manipulations OR Hellerwork OR "Structural Visceral Integration" OR "Pelvic lift" OR "Diaphragm* release" OR "Somatic movement education"

WHO Virtual Health Library (excluding MEDLINE)

Rolfing OR Rolf OR "Structural integration" OR "Applied kinesiology" OR "Deep tissue massage" OR ((myofascial OR fascial) AND (Release OR Massage OR Manipulation OR Manipulations)) OR (Hellerwork OR "Structural Visceral Integration" OR "Pelvic lift" OR "Diaphragm* release" OR "Somatic movement education")

Ida P. Rolf Library of Structural Integration

Search functionality limited, requires handsearching

APPENDIX 2 – Data extraction forms

Data Extraction Table: Characteristics of Included Studies

General information				Participants			Intervention	Comparator	Outcomes		Notes
Author & year	Country	Setting (e.g. clinic, home)	Study design (e.g. RCT, cohort, pre/post)	N (total, each group)	Type (e.g. healthy, health diagnosis / condition)	Age (mean/ median, SD / range)	Reported as per TIDIER checklist elements… please see below	Reported as per TIDIER checklist elements… please see below	Primary	Secondary	Other issues

TIDIER checklist elements for reporting components of interventions											
Brief name	Why	What	What	Who provided	How	Where	When & how much	Tailoring	Modification	How well	How well
Name or phrase that describes the intervention	Rationale, theory or goal of elements essential to the intervention	Materials used in the intervention	Procedures, activities and/or processes used in the intervention	Intervention provider, their expertise, background, and specific training	Modes of delivery (e.g. face to face), whether provided in group or individually	Types of locations where intervention occurred	Number of times intervention delivered, period of time, number of sessions, their schedule, duration, intensity or dose	Describe whether intervention was personalised, titrated or adapted; and how	Describe if the intervention was modified during the study (if so, what, why, when and how)	Was intervention adherence or fidelity assessed? (how, by whom, strategies used to maintain or improve fidelity)	Extent to which the intervention was delivered as planned?

Data Extraction Table: Outcomes

Dichotomous outcomes

Outcome: _____						
	Number of participants with outcome (intervention group)	Number of participants (intervention group)	Number of participants with outcome (comparison group)	Number of participants (comparison group)	Point estimate (Risk Ratio, Odds Ratio)	Variance (95% Confidence interval, p-value)
Time point 1						
Time point 2						
…						

Continuous outcomes

Outcome: _____						
	Mean (intervention group)	Standard Deviation	Mean (comparison group)	Standard Deviation	Point estimate (Mean Difference (MD), Standardised MD (SMD))	Variance (95% Confidence interval, p-value)
Time point 1						
Time point 2						
…						

Data Extraction Table: Risk of Bias

Randomised controlled trials: Cochrane Risk of Bias Tool 2

We will use the existing templates provided by Cochrane to extract this data:
https://drive.google.com/file/d/1KSFASeBJP8FjBMpEbNlDiYxp4CKuOZgM/view

Non-randomised studies of interventions: Risk of bias in non-randomised studies of interventions (ROBINS-I)

Reference	Bias due to confounding	Bias due to confounding rating	Bias in selection of participants into the study	Bias in selection of participants in to the study rating	Bias in classification of interventions	Bias in classification of interventions rating	Bias due to deviations from intended interventions	Bias due to deviations from intended interventions rating	Bias due to missing data	Bias due to missing data rating	Bias in measurement of outcomes	Bias in measurement of outcomes rating	Bias in selection of the reported result	Bias in selection of the reported result rating
Author & Year	*Quote supporting the rating*	*Rating: no information / low / moderate/ serious/ critical risk of bias*	*Quote supporting the rating*	*Rating: no information / low / moderate/ serious/ critical risk of bias*	*Quote supporting the rating*	*Rating: no information / low / moderate/ serious/ critical risk of bias*	*Quote supporting the rating*	*Rating: no information / low / moderate/ serious/ critical risk of bias*	*Quote supporting the rating*	*Rating: no information / low / moderate/ serious/ critical risk of bias*	*Quote supporting the rating*	*Rating: no information / low / moderate/ serious/ critical risk of bias*	*Quote supporting the rating*	*Rating: no information / low / moderate/ serious/ critical risk of bias*

APPENDIX 3 – Screening and selecting studies in languages other than English

We will follow the below approach for searching for, and selecting, studies published in languages other than English:

1. Database search or the Department's call for evidence will not be restricted by language of publication.[1]

2. If the title and abstract are not available in English, we will use Google translator or an equivalent method to translate the title and abstract. Then go to step 4.

3. If online translation doesn't facilitate understanding of the title and abstract, then these studies will be listed as 'studies unable to be translated or interpreted at the title/abstract stage' in the systematic review.

4. We will examine translated titles and abstracts and remove obviously irrelevant reports. The number of articles not published in English that were excluded at title and abstract screen will be reported in the 'Results of the search'

5. If the study is likely to meet the 'Criteria for considering studies for inclusion in the review' (based on title and abstract screen), or there is any uncertainty, the full-text report will not be translated to determine the studies' compliance with eligibility criteria. Go to step 6

6. For studies in languages other than English that are potentially relevant for inclusion:

    a) We will record these and available information in a 'Studies Awaiting Classification' table to inform readers of the review of the availability of other possibly relevant reports and reflect this information in the PRISMA flow diagram (https://training.cochrane.org/handbook/current/chapter-04)
    b) As soon as this table is finalised, we will provide a copy to the NHMRC, noting that the review is not expected to include any of these articles.
    c) We will appraise the potential risk of language bias and the implications in the Evidence Evaluation Report. It is suggested that 'Overall completeness and applicability of evidence'[2] and 'Agreements and disagreements with other studies or reviews'[3] may be the most appropriate subsections for this.
    d) Make appropriate qualifying statements throughout the protocol and Evidence Evaluation Report to acknowledge that only the evidence published in English will be/was reviewed.
    e) In the relevant sections of the Evidence Evaluation Report include the Author's conclusions/What does this mean sections, we will explicitly note any potential limitations due to language bias, amongst other things (e.g. the certainty of the evidence), that might influence the conclusions of the review.

[1] The implications of excluding databases with studies in languages other than English will be clearly articulated throughout the evidence evaluation report.
[2] Contractors should record and flag any 'seminal' works identified in the search, for example: SRs that would be relevant for comparisons, or RCTs referred to in the included studies as 'seminal' that aren't published in English and use this information to semi-quantify the literature that might exist in languages other than English.
[3] An initial search for Cochrane reviews should be conducted, noting that it is standard practice for Cochrane to incorporate studies in languages other than English. Comparison of SR findings with other SR which include studies in languages other than English may assist consideration of language bias and identifying gaps in English language research.