Systematic review of evidence on the clinical effectiveness of kinesiology

Technical report prepared by Cochrane Australia

4 November 2024

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# Scope of the technical report

This Technical Report includes a complete description of the methods for the review (Appendices A, B and G), results of the search and prioritisation process (Appendix A), citation for the included study (Appendix D), differences between the protocol and the review and methods not used (Appendix G), and abbreviations used in the report (Appendix I).

It also includes an overview of Appendices C, E and F which are listed below but presented in separate files.

Appendices contained in this file are in light grey rows. Those in separate files are in blue rows.

|  |
| --- |
| Appendix A. Study eligibility criteria, identification and selection |
| Appendix B. Data collection, analysis and interpretation of findings |
| Appendix C. Lists of excluded studies, public submissions, studies awaiting classification (1 file) |
| Appendix D. Citation for included study |
| Appendix E. Characteristics of included study (1 file) |
| Appendix F. Risk of bias assessments for included study (1 file) |
| Appendix G. Differences between the protocol and the review and methods not used |
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# Appendix A. Study eligibility criteria, identification and selection

## Overview of Appendix A

Appendix A is comprised of Appendices A1-A7 (below). These Appendices report the methods (grey rows) and results (blue rows) from the first four stages of the review (Figure A, 1-4). These stages encompass the initial specification of questions to be addressed in the synthesis and criteria for including studies in the review, the specification and implementation of search methods, and the selection of studies. From this set of studies, we compiled information about the populations and outcomes addressed in studies eligible for the review. This information was reviewed by NHMRC, NTWC and NTREAP in order to confirm outcomes for inclusion in the evidence synthesis.

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| Appendix A1. Review questions and criteria for considering studies for this review |
| Appendix A2. Search methods for identification of studies |
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| Appendix A5. Prioritisation process: methods used to refine the questions addressed in the synthesis |
| Appendix A6. Final framework: synthesis questions and criteria for including studies in each synthesis |
| Appendix A7. Summary of inclusion decisions based on the final framework |

Appendices A1-A3 and A5 report the pre-specified methods from the protocol endorsed by NTWC with input from NTREAP, prospectively registered on the International prospective register of systematic reviews (PROSPERO ID [CRD42024528900](https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=528900)). Appendix A6 reports the framework that resulted from the prioritisation process shown in Figure A and described in Appendix A5. The framework was finalised prior to commencing data extraction (Figure A, panel 5). It defines the scope of the evidence synthesis and specifies the synthesis questions and associated PICO (population, intervention, comparator, outcome) criteria for including studies in each synthesis.



**Fig A** | Staged approach for developing the questions and analytic framework for this review.

# Appendix A1. Review questions and criteria for considering studies

The overall objective of this systematic review is to examine the evidence for the clinical effectiveness of specialised kinesiology in preventing and/or treating injury, disease, medical conditions or preclinical conditions [1]. The questions for the review follow (framed as primary and secondary objectives). An initial analytic framework for the review was presented in the protocol to illustrate the breadth of questions and a possible structure for the synthesis, with indicative populations and outcome domains (Figure A1.1). The framework was refined through the prioritisation process (described in Appendix A5) leading to the final framework and criteria for including studies in the synthesis (Appendix A6). Outcomes listed in the objectives were agreed through the prioritisation process.

## Primary objective was to answer the following question

1. What is the effect of *specialised* *kinesiology* compared to an inactive control (no intervention, sham, placebo, wait list control, or a co-intervention offered to both groups, or continuation of usual care) on outcomes for each underlying condition, pre-condition, injury or risk factor? (see Appendix G)

## Secondary objectives related to the following questions

1. What is the effect of *specialised* *kinesiology* compared to evidence-based treatments (active comparators) on outcomes for each underlying condition, pre-condition, injury or risk factor (see Appendix G)?
2. What evidence exists examining the effects of *specialised* *kinesiology* compared to other active comparators?

A complete description of the intervention components for the specialised kinesiology and the “sham” kinesiology intervention groups was not provided in the study reports. We could not confirm whether the “sham” content/protocol was sufficiently inactive to be combined with the wait list control group as per objective 1, or would be more appropriately categorised as an active intervention. Since this was the only study in this review, we considered it more informative to present the results separately for specialised kinesiology compared to either a “sham” intervention or wait list control. We used the terms reported by the trialists when describing comparator groups.



**Fig A1.1 |** Initial analytic framework for the review showing example population groups and outcome domains for the evidence synthesis. The framework was informed by research on the outcomes (and underlying conditions) for which specialised kinesiology is commonly sought or prescribed, a scoping search of studies evaluating specialised kinesiology, the wider literature on specialised kinesiology, and consideration of frameworks for classifying disease and outcomes [2, 3].

## A1.1 Criteria for considering studies for this review

### A1.1.1 Types of studies

We included randomised controlled trials (RCTs) (including individually and cluster randomised, and cross-over trials).

Controlled trials in which the allocation sequence did not include a truly random element, was predictable, or was not adequately concealed from investigators were eligible as long as there was an attempt to have some kind of ‘randomisation’ to groups. Examples included studies that used methods for sequence generation based on alternation, dates (of birth or attendance at a clinic) and patient record numbers [4].

Non-randomised studies of interventions (NRSIs) with specific design features that are suitable for estimating a causal effect were eligible for inclusion in the review, in line with current Cochrane guidance. While study design labels were used as an aid to communicating about eligible designs and for use in the review, eligibility decisions were based on assessment of the specific design features of each study rather than the label used by the study authors (see checklist Appendix 2 in protocol published on PROSPERO [CRD42024528900](https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=528900)) [5, 6].

Eligible non-randomised study designs were those in which the following features are present.

* The intervention may be allocated to individuals or clusters. We anticipated that kinesiology (or the control) would be allocated to individuals in most studies [7].
* Treatment groups may be formed by some action of the researchers or in the course of usual treatment decisions (including healthcare decision makers, practitioners or participants/patients/peoples’ choices).
* Studies must include a contemporaneous control.
* There must be an attempt to control for confounding (either by using methods that control in principle for confounding or that control for observed covariates)
* The design must be suitable for estimating a causal effect.

We excluded:

* Studies for which available reports had not been peer reviewed (grey literature, including theses).

#### Date and language restrictions.

There were no restrictions on publication date.

Potentially eligible studies published in languages other than English were not eligible for synthesis. In accordance with the protocol, these studies were to be included in the list of studies ‘Awaiting classification’ and coded according to whether they were likely to be eligible or whether eligibility could not be determined.

### A1.1.2 Types of participants

Studies involving participants with any disease, medical condition, injury, or preclinical condition were eligible for the review. This included healthy participants with clearly-identified risk factors (evident from study eligibility criteria or baseline data). There were no restrictions on age.

We expected that studies would include participants that fall within broad population groups as indicated in the initial framework Figure A1.1. The population groups encompass conditions for which specialised kinesiology is commonly sought or prescribed. Decisions about which populations to include in the evidence synthesis and how these populations would be grouped for synthesis were made through the prioritisation process (see Appendix A5) and reported in the final framework (see Appendix A6).

**Excluded populations.** Healthy populations seeking health improvement.

Studies that included both healthy participants and participants eligible for the review were to be included if separate data were available or a majority of participants met the review eligibility criteria [8]. No such studies were included.

### A1.1.3 Types of interventions

For the purpose of this review, eligible interventions were specialised or energy kinesiology as per the description provided by NHMRC [9]:

A system that involves the use of manual muscle testing techniques

* “… to elicit a yes/no response in muscles via a strong/ weak bio-feedback mechanism … to reveal imbalances within the body; for example, sources of pain, allergies, and digestive and mental health disturbances”, and
* “facilitate a person’s natural healing process” by bringing “the root cause of any ‘imbalance’ to a person’s conscious attention” and identifying tools needed to correct any imbalances (extracts from [9]).

The latter is an essential component that differentiates specialised or energy kinesiology from similar but ineligible interventions (see Excluded therapies below). The selected tools may include a wide range of interventions commonly considered to be ‘tools of the trade’ in specialised kinesiology (e.g. acupressure, aromatherapy, myofascial interventions).

Because of the potential challenge of distinguishing components of specialised or energy kinesiology systems from related modalities such as applied kinesiology, and the likelihood of identifying studies in which the defining techniques and principles of specialised or energy kinesiology systems are incompletely reported, studies were included if the therapy was described as a specialised or energy kinesiology system, or any of the named variants of this system (Touch for Health, Professional Kinesiology Practice (PKP), Three in One, Integrative Kinesiology).

Except for the specific exclusions below, specialised kinesiology interventions were eligible irrespective of the mode of delivery (face-to-face or virtual), the training or qualifications of the teacher or practitioner (except if the training was Professional Applied Kinesiology™ – see Excluded therapies), the setting in which specialised kinesiology is used, and the dose and duration of treatment.

More details about each of these intervention features is provided under data extraction (see B1).

**Excluded therapies**

1. **Applied kinesiology (Professional Applied Kinesiology™)**[[1]](#footnote-2) refers to the original form of kinesiology that is used only as a diagnostic tool, not a treatment modality [10, 11]. While Professional Applied Kinesiology™ (PAK) is used to inform decisions about treatment, resulting treatments are not considered to be part of PAK, instead falling within the scope of practice of the registered health professionals that use kinesiology for diagnosis (mainly chiropractors). Nor is there a premise in PAK that the body can heal itself if the person is aware of what is needed to facilitate healing (i.e. awareness of the root cause of a condition will facilitate a person’s healing process). Practitioners of (PAK) must be certified by the International Board of Applied Kinesiology (IBAK). A prerequisite for PAK certification is completion of a tertiary qualification that fulfils requirements for registration in a relevant health profession (e.g. chiropractic, osteopathy, physiotherapy or medicine). [9-11]
2. **Educational kinesiology (Edu-K)** is an educational, movement-based program, with Brain Gym® activities forming the core program [12]. Although manual muscle testing techniques may be used by the educational kinesiologist to identify the learning difficulty to be addressed, the core intervention consists of “physical activities done in a specific sequence to improve focus, concentration, eye-hand coordination and brain integration” [13].
3. **Kinesiology** as used to refer to human movement science in North America (especially in Canada), and related terms for practitioners of human movement science.
4. **Kinesiology taping** as in a specific method used mainly by physiotherapists.
5. **Kinesiotherapy** which is sometimes used to refer to “the main, active component of physiotherapy and a means of restoring the range of movement, improving muscle strength and endurance, improving movement coordination, increasing the aerobic capacity and inducing a global sensation of wellness” [14].
6. **Other systems that use kinesiology muscle testing** (e.g. Total Body Modification, PSYCH-K, Body talk).

#### Comparisons

1. Specialised kinesiology *versus* any inactive comparator (no intervention, sham, placebo, wait list control, or a co-intervention offered to both groups, or continuation of usual care).
2. Specialised kinesiology *versus* evidence-based gold standard treatment(s)
3. Specialised kinesiology *versus* any active comparator (for inclusion in evidence inventory only, not the synthesis).

Any co-intervention was eligible (i.e. pharmacological or non-pharmacological). Usual care comparators were eligible if there was an explicit statement that indicated that participants could continue to access their routine care or therapy (including self-care). If a comparator labelled as ‘usual care’ involved a defined intervention (i.e. specific treatments and processes selected by the researchers), this was deemed to be either an active intervention (if restricted to the comparator group) or a co-intervention (if able to be accessed by both groups, e.g. continuation of a specific medication).

A complete description of the intervention components for the specialised kinesiology and the “sham” kinesiology intervention groups was not provided in the study reports. We could not confirm whether the “sham” content/protocol was sufficiently inactive to be combined with the wait list control group as per objective 1, or would be more appropriately categorised as an active intervention. Since this was the only study in this review, we considered it more informative to present the results separately for specialised kinesiology compared to either a “sham” intervention or wait list control. We used the terms reported by the trialists when describing comparator groups.

Active comparators were eligible for the review if pre-specified criteria for synthesis were met, (i.e. at least two studies with comparable PICO criteria and at low risk of bias), however we did not identify any studies with active comparators.

***Excluded comparisons***. In line with the main review objective, which is to examine the effects of specialised kinesiology rather than the comparative effects of different kinesiology treatments, we excluded head-to-head comparisons of specialised kinesiology. For example, comparisons of specialised kinesiology administered by people with different qualifications or specialisations (e.g. kinesiology practitioner vs. other health professional), or comparisons of different treatment schedules.

### A1.1.4 Types of outcomes

We considered for inclusion in the review any outcome that aligned with the reasons why specialised kinesiology is sought by patients and prescribed by practitioners. In principle, this could include any patient-important outcome that helps elucidate the effects of specialised kinesiology on an underlying condition or its symptoms, recovery, rehabilitation, or prevention of disease among people with specific risk factors or pre-conditions. Example outcome domains were shown in the initial analytic framework to illustrate the breadth of outcomes likely to be relevant across a wide range of conditions (Figure A1.1). The outcome domains were based on ICD11 codes and the COMET outcome taxonomy [2, 3]. These systems provide a widely agreed and understood structure for categorising different outcomes.

Studies were included in the review irrespective of the outcome(s) measured, but the summary and synthesis were limited to outcomes considered to be critical or important for each population group. Outcomes for inclusion in the synthesis were determined through the prioritisation process described in Appendix A5.

The outcome domains determined to be critical or important for the synthesis were as follows (see Appendix A6 and Figure A6.1 for details).

* pain
* physical function
* sleep quality
* fatigue
* health-related quality of life
* emotional functioning and mental health
* overall symptoms

From each study, we selected only one outcome per outcome domain for data extraction (results), risk of bias assessment and inclusion in the synthesis. In selecting outcomes for synthesis, we considered the outcome measure, timing of outcome measurement and data reported as follows.

***Outcome measures.***For each of these outcome domains, we considered for inclusion any measure of the outcome. Where studies reported multiple outcomes within an outcome domain, we used a population-specific hierarchy of outcomes measures to select the most relevant and valid outcome. The hierarchy of measures was proposed by the review team and agreed through the prioritisation process.

***Outcome timing.*** Where trials reported outcomes measured at multiple timepoints, we selected the first measurement taken after the end of the specialised kinesiology intervention period (i.e. if kinesiology was administered three times over a week, we took the first measure after the third administration).

***Data reported.*** We had planned to select results for final values when authors reported results for both change scores (change from baseline) and post-intervention (final) values. However, given there was only a single included study that reported effect estimates, we reported these estimates (mean difference) exactly as reported by the triallists.

***Excluded outcomes.*** Experience of care (e.g. satisfaction), safety, quality, and economic outcomes.

# Appendix A2. Search methods for identification of studies

### A2.1 Electronic searches

Studies were sought from the following databases: Cochrane Central Register of Controlled Trials (Cochrane Library, Issue 2, 2024), MEDLINE (Ovid), Embase (Ovid), Emcare (Ovid), AMED (Ovid), CINAHL (EBSCOhost) and Europe PMC. In addition, we searched two clinical trial registers for reports of ongoing or unpublished studies (ClinicalTrials.gov and WHO International Clinical Trials Registry Platform).

Although all the databases have a subject heading for kinesiology, the term was not included in the search strategy since the definition covers a form of kinesiology (applied kinesiology, muscle testing) that is different to the specialised or energy kinesiology that is in scope for this review.

For textwords we explored related concepts, such as "manual muscle testing" and kinesiotherapy, but both are more commonly used in settings and by health professionals distinct from kinesiology as a natural therapy. We therefore limited retrieval of irrelevant records (e.g. kinesio taping studies, kinesiotherapy) by restricting the textword search accordingly.

The term kinesiology was combined with a very broad study design filter, based partly on a validated filter for non-randomised studies by Waffenschmidt et al [36] but with fewer restrictions and additional textwords, plus the floating subheading 'therapy' in the MEDLINE and Embase search.

Searches were run on 15 February 2024 and were not limited by language, year of publication or publication status (see Appendix A4).

### A2.2 Searching other resources

The 2015 overview of kinesiology identified one systematic review that included studies of kinesiology (categorised by the authors as applied kinesiology, energy or specialised kinesiology, and one study of unknown kinesiology type) [15].

We examined the reference list of the included study to identify additional trials (i.e. backward citation searching), and conducted forward citation searching (i.e. looking for studies that have cited the included study) using citationchaser (<https://estech.shinyapps.io/citationchaser/>).

Finally, we checked PubMed for any retraction notice, expression of concern or published errata, as well as the Retraction Watch database (<http://retractiondatabase.org/>).

### A2.3 Public submissions

Citations provided by the public and key stakeholders (via the Department), NTREAP and NTWC were deduplicated against the records retrieved by the search and screened for eligibility. We examined the reference lists of any relevant systematic reviews.

# Appendix A3. Methods for selecting studies

### A3.1 Selection of studies

Records from the database searches were imported into EndNote and duplicates removed. All remaining records were imported into Covidence for screening.

Two reviewers piloted guidance for title and abstract screening on a sample of 179 records (10%) to ensure the review eligibility criteria were applied consistently (100% agreement was achieved). Remaining records were then screened at title and abstract by a single reviewer. Reports were screened independently by two reviewers at full-text review stage with disagreements resolved by consensus among members of the review team.

While screening full-text study reports in Covidence, we extracted the trial register and registry record number (if reported) into notes in Covidence. On completion of study report screening, we matched any registry record details in the included study notes (e.g. registry record number) with the registry records search results.

Unmatched registry records were then screened to identify potentially eligible trials for which there was no published report to include in a list of ‘ongoing studies and unpublished studies’ (Appendix C4) and for assessment of bias due to missing results (B1.6).

The following categories of studies were to be included in a list of ‘studies awaiting classification’, if identified:

* Studies that were only published as abstracts or for which a full report was not available (i.e. we did not seek further information from study authors to confirm eligibility).
* Studies for which a full report was available but the report was incomplete or ambiguous such that eligibility based on one or more PICO criteria or study design could not be confirmed.
* Studies confirmed as likely to be eligible, but for which no English language translation of the full-text publication was available.
* Studies for which eligibility could not be confirmed following translation of the title and abstract using Google translate (Figure A3.1.1)
* Studies for which there were concerns about data that could not be resolved from full report(s) (e.g. where there were important discrepancies in study characteristics or data reported across multiple publications from the same study).

Translate title + abstract

Is the study likely to be eligible?

Study unlikely to be eligible

Exclude

Unclear. translation provides insufficient information

List in 'Characteristics of studies awaiting classification'

Study likely (or very likely) to be eligible

List in 'Characteristics of studies awaiting classification'

**Fig. A3.1.1 |** Flowchart showing handling of studies in languages other than English (reproduced from NHMRC framework for natural therapies systematic reviews [16]).

Studies that did not meet the eligibility criteria were excluded and the reason for exclusion was recorded at full-text screening. These studies are included in a list of excluded studies in which the reason for exclusion is reported (Appendix C1).

The search and study selection steps are summarised in the PRISMA flow diagram in Appendix A7.

#### Dealing with duplicate and companion publications

Multiple publications to the same study (e.g. protocols, trial registry entries, trial reports) were identified and linked at the study selection stage in Covidence. Identification and linking of multiple reports were also checked at data extraction in REDCap [17, 18]. Each study was given a unique identifier and all linked records are cited in the final report. Records were matched using trial registry numbers. Where these were not available we considered author names, trial name, trial location(s) and number of participants.

# Appendix A4. Results of the search

### Bibliographic databases

The search of bibliographic databases retrieved 3139 records. After removing duplicates in EndNote and Covidence, 1785 records were screened at title/abstract. The search strategies for each database are given below. The PRISMA flow diagram in Appendix A7 summarises inclusion decisions following title/abstract screening.

### Ongoing and unpublished studies

The search of trial registry entries from CENTRAL, ClinicalTrials.gov and WHO ICTRP retrieved 133 unique records, of which only one appeared eligible for the review. This record was for the completed study included in the review [19].

### 2015 evidence evaluation for kinesiology

The 2015 overview of kinesiology identified one systematic review published in 2008. The Hall 2008 review included 22 studies, none of which were eligible for this review (healthy population, intervention was applied kinesiology or diagnostic test accuracy studies) [15].

### Public submissions

Ninety-five (95) citations were received via the Department’s public call for evidence. Of these, 8 were retrieved by our search: one citation (Eardley 2013) was included in the review, and the other 7 citations were excluded at title and abstract screening. The remaining 87 citations were screened, and none were eligible. Citations and eligibility decisions for the 95 public submissions are reported in Appendix C2.

### Retractions and published errata

No retraction notices or errata were identified in PubMed or Retraction Watch in relation to the included study.

### Other searches

We did not identify any relevant systematic reviews published after 2015. The forward citation search using citationchaser did not identify any eligible studies. Nor did we identify any additional studies from checking the reference list of Eardley 2013.

### Search strategies

**Cochrane Central Register of Controlled Trials (Issue 2, 2024)**

|  |  |  |
| --- | --- | --- |
| **#** | **Search strategy** | **Results** |
| 1 | ((kinesiology or kinesiologist or kinesiologic\*) not (kinesio\* tap\* or kinesiotap\* or kinesio therapy or kinesiotherapy or kinesiologists or "kinesiology students")):ti,ab,kw | 264 [in Trials] |

**MEDLINE via Ovid**

Ovid MEDLINE(R) ALL 1946 to February 13, 2024

|  |  |  |
| --- | --- | --- |
| **#** | **Search strategy** | **Results** |
| 1 | ((kinesiology or kinesiologist or kinesiologic\*) not (kinesio\* tap\* or kinesiotap\* or kinesio therapy or kinesiotherapy or kinesiologists or kinesiology students)).ti,ab,kf. | 1081 |
| 2 | (Clinical Study or Comparative Study or Evaluation Study).pt. or exp Epidemiologic Studies/ or (trial or study or cohort or control or experimental or group\* or systematic review).ti,ab,kf. or th.fs. | 17383328 |
| 3 | 1 and 2 | 693 |

**Embase via Ovid**

 Embase Classic+Embase 1947 to 2024 February 13

|  |  |  |
| --- | --- | --- |
| **#** | **Search strategy** | **Results** |
| 1 | ((kinesiology or kinesiologist or kinesiologic\*) not (kinesio\* tap\* or kinesiotap\* or kinesio therapy or kinesiotherapy or kinesiologists or kinesiology students)).ti,ab,kf. | 1843 |
| 2 | exp Controlled Study/ or (trial or study or cohort or control or experimental or group\* or systematic review).ti,ab,kf. or th.fs. | 23530433 |
| 3 | 1 and 2 | 1238 |

**AMED via Ovid**

AMED (Allied and Complementary Medicine) 1985 to October 2023

|  |  |  |
| --- | --- | --- |
| **#** | **Search strategy** | **Results** |
| 1 | ((kinesiology or kinesiologist or kinesiologic\*) not (kinesio\* tap\* or kinesiotap\* or kinesio therapy or kinesiotherapy or kinesiologists or kinesiology students)).tw. | 411 |
| 2 | exp Research Design/ or exp Epidemiologic Methods/ or (trial or study or cohort or control or experimental or group\* or systematic review).tw. | 163408 |
| 3 | 1 and 2 | 182 |

**Emcare via Ovid**

Ovid Emcare 1995 to 2024 Week 06

|  |  |  |
| --- | --- | --- |
| **#** | **Search strategy** | **Results** |
| 1 | ((kinesiology or kinesiologist or kinesiologic\*) not (kinesio\* tap\* or kinesiotap\* or kinesio therapy or kinesiotherapy or kinesiologists or kinesiology students)).ti,ab,kf. | 799 |
| 2 | exp Controlled Study/ or (trial or study or cohort or control or experimental or group\* or systematic review).ti,ab,kf. | 4654461 |
| 3 | 1 and 2 | 535 |

**CINAHL Complete**

|  |  |  |
| --- | --- | --- |
| **#** | **Search strategy** | **Results** |
| 1 | TI ( ((kinesiology or kinesiologist or kinesiologic\*)) not (kinesio\* tap\* or kinesiotap\* or kinesio therapy or kinesiotherapy or kinesiologists) ) OR AB ( ((kinesiology or kinesiologist or kinesiologic\*)) not (kinesio\* tap\* or kinesiotap\* or kinesio therapy or kinesiotherapy or kinesiologists))  | 605 |
| 2 | TX trial or study or cohort or control or experimental or group\* or systematic review | 4,270,296 |
| 3 | S1 OR S2 | 323 |

**Europe PMC (preprints only)**

|  |  |  |
| --- | --- | --- |
| **#** | **Search strategy** | **Results** |
| 1 | ((TITLE:"kinesiology") OR (ABSTRACT:"kinesiology")) AND (SRC:"PPR") | 10 |

**ClinicalTrials.gov and WHO ICTRP**
ClinicalTrials.gov (Intervention/treatment field): kinesiology NOT (kinesiology taping OR kinesiology tape) = 30

WHO ICTRP (Intervention field): kinesiology = 18

# Appendix A5. Prioritisation process: methods used to refine the questions addressed in the synthesis

The final synthesis questions, and criteria for including studies in each synthesis, were decided through the pre-specified prioritisation process (Figure A). The process was designed to minimise bias in the selection of results for inclusion in the synthesis and ensure coverage of populations and outcomes relevant to the Australian context. All information provided to NTREAP, NTWC and NHMRC was de-identified and presented in aggregate form so that it was not possible to identify the studies (no bibliographic information, titles etc). No information was provided about the number of studies, number of participants, methodological quality of studies or results.

### Prioritisation of populations and grouping of conditions for the summary and synthesis

There was no need to limit populations in this review, so the provision in the protocol to prioritise populations (conditions) for inclusion in the synthesis was not implemented. NTWC endorsed the proposal to structure the synthesis by the population groups outlined in the analytic framework.

### Prioritisation and selection of outcomes for the synthesis

We collated information about the outcomes addressed in the single eligible study. The purpose was twofold: (1) to enable prioritisation of the most important **outcome domains** for the population (irrespective of whether the study measured these domains), and (2) to facilitate selection of the **most relevant results** from the study.

***Prioritisation of outcome domains***

* All outcomes and outcome measures were listed under an **outcome domain** from the initial analytic framework for the review (Figure A1.1). All outcomes were covered by the initial framework, so there was no need to specify any additional outcome domains.
* For the single included condition, NTWC, with input from NTREAP, rated **outcome domains** as critical, important or of limited importance for understanding the effects of specialised kinesiology on the population. The intent was to identify up to seven outcome domains for which results would be reported.
* Only critical and important outcome domains were considered in the summary.

***Outcome selection.*** We selected one result per outcome domain from the study for data extraction, risk of bias assessment and reporting of results in the summary. Selecting one result per study for inclusion in each analysis ensures that individual studies do not receive too much weight. In addition, we aimed to ensure that all studies that should contribute to each synthesis were included.

Overall, the approach deals with multiplicity of results that arises when

1. the outcomes and measures of outcome domain vary across studies;
2. individual studies report results for multiple outcomes, measures and timepoints within an outcome domain (e.g. for HR-QoL, reporting an overall score and subscale scores for specific domains of HR-QoL).

To determine which results to select the following was done.

* For each outcome domain, we presented an initial ranking of all outcomes and measures. Where available, the ranking was informed by recommendations in core outcome sets, outcome hierarchies in published Cochrane reviews, and systematic reviews of outcome measures (i.e. to establish relevance, validity, and reliability).
* The NTWC considered the ranking and either confirmed or reranked the outcomes and measures.
* The highest ranked outcome/measure was selected from the study for each outcome domain.
* If data for the highest ranked outcome/measure could not be included in the analysis (e.g. due to incomplete reporting of data), this was reported and the next highest ranked outcome was selected (and so forth).
* Where an outcome measure was potentially eligible for more than one outcome domain, we selected the measure that enabled us to include a study in the largest number of syntheses (e.g. if a study reported scores for the psychological and physical domains of a HR-QoL measure, but no measure of emotional functioning and mental health (EFMH), we chose the physical domain for HR-QoL and the psychological domain for EFMH).

# Appendix A6. Final framework for summary and synthesis

Figure A6.1, panel A shows the final analytic framework for the evidence summary and synthesis. The framework provides a guide to the structure of the synthesis and reporting of results (see caption for details). We included all eligible studies in the summary and synthesis (i.e. no limitations by population or condition).

### Prioritised outcomes and comparisons

The outcome domains specified in the initial analytic framework were endorsed. For outcomes measured at multiple timepoints, we selected the first measurement after the end of the intervention period (i.e. if specialised kinesiology was given three times over a week, we took the first measure after the third administration).



**Fig A6.1** | Final analytic framework for the review as agreed through the prioritisation process (Appendix A5).
Panel A, columns 1 to 3 show the populations, comparisons and outcome domains eligible for the evidence synthesis. Column 4 shows the populations *(conditions)* and outcome domains for which studies were available for each comparison. Results are reported for each population in the section indicated in column 1. Study-level data and results are presented for each comparison in the Summary of Findings table indicated in column 4. Panel B shows outcome domain rated as of limited importance. \* Outcome domain prioritised as critical for decision-making.

# Appendix A7. Summary of inclusion decisions based on the final framework

The flow of studies through the review is summarised in Figure A7.1, the PRISMA flowchart. Inclusions for each synthesis are reported in Figure A6.1 and described in the main report.

**Fig. A7.1** | PRISMA diagram showing the flow of studies through the review. Studies are the unit of interest in the review. Each study could have multiple reports. CoIS: characteristics of included studies.\*see results section ‘Public submissions’

# Appendix B. Data collection, analysis and interpretation of findings

## B1 Data extraction and management

Study data were collected and managed using REDCap electronic data capture tools hosted at Monash University [17, 18]. The form for extracting results data was developed by the review biostatistician (JM). The form was developed for use by our team for the natural therapies reviews and had been applied to over 200 trials in the first review we conducted. Revisions to the data extraction form were made as required to maximise the quality and consistency of data collection.

For the included study one review author (MM) coded the population group, outcome domains and comparisons, and allocated the study to analyses according to the analytic framework for the review. We listed all outcomes measured and selected the outcomes for inclusion according to our pre-specified decision rules. During triage, study eligibility was confirmed and basic checks of methodology were done (e.g. confirming that a trial met the minimum requirements for randomisation). Questions about coding, allocation to analyses and outcome selection were referred to a senior author (SB).

For the included study, one review author (MM) then extracted study characteristics and quantitative data using the data extraction and coding form. A second author (SB) independently verified the coding, allocation to analyses, outcome selection and data extraction. Discrepancies were resolved through discussion if agreement could not be reached or for more complex scenarios.

Where available, we extracted information relating to the characteristics of the included study and results as follows.

1. Study identifiers and characteristics of the study design
* Study references (multiple publications arising from the same study were matched to an index reference; code as index paper, protocol, registry entry, results paper 1, 2, …)
* Study name, location (country), enrolment dates (not reported by most studies), and trial registration number
* Study design (categorised as ‘individually randomised’, ‘cluster randomised’, ‘crossover’, or ‘NRSI’); whether clustering was likely to arise because of the way specialised kinesiology was delivered (e.g. at a regular clinic such as for chemotherapy; this information was used to determine which risk of bias tool to use for assessment).
* Funding sources and funder involvement in study, financial and non-financial interests declared by investigators, potential conflicts (reviewer judgment), ethics approval.
1. Characteristics of each intervention group (including comparator groups)
* Characteristics of the intervention covering domains of the Template for Intervention Description and Replication (TIDieR) checklist [20]
* Specialised kinesiology intervention goal (coded, for example: relieve symptoms of a condition, prevent a condition among people with risk factors)
* Coding of comparators (e.g. inactive – sham, inactive – no intervention, active - massage)
* Number of participants: randomised to each group, at follow up for selected outcome, and included in analysis and reasons for loss to follow-up
1. Characteristics of participants
* Participant eligibility criteria (verbatim; precis of key criteria to characterise population)
* Participant characteristics: age (e.g. mean, median, range), sex
* Population group: coded using categories specified in the final analytic framework for the review (e.g. chronic musculoskeletal pain, headache or migraine, other chronic conditions)
* Condition: specific underlying condition as described in study (e.g. cervical spine pain; chronic primary pain), including information about severity (if relevant) and closest ICD-11 code.
* Treatment/procedure: applied to studies in which specialised kinesiology was administered for the relief of symptoms or side effects of a treatment or procedure for an underlying condition (e.g. chemotherapy). Could include pharmacological treatment (e.g. chemotherapy), surgical, diagnostic or other procedures (as described in study).
* Other characteristics of importance within the context of the study
1. Outcomes assessed and results
* Outcomes measured (list of all outcomes categorised as ‘eligible’ or ‘ineligible’ and categorised according to the final analytic framework; measures used for each)
* For outcomes selected for inclusion in the summary and synthesis of results:
	+ Outcome domain: categorised according to the outcome domains specified in the final analytic framework for the review (e.g. pain, physical function, health-related quality of life, emotional functioning and mental health)
	+ Outcome as described in the included study (verbatim or precis)
	+ Measurement method (e.g. WOMAC; overall score and pain, function and stiffness subscales), information required to interpret the measure (scale range and direction, minimally important difference) and timing of outcome measurement (exact timing; described in relation to timing of specialised kinesiology (e.g. immediately after end of kinesiology intervention period)
	+ Results including: summary statistics by group (means and standard deviations, or number of events for outcomes that have been dichotomised, and sample size), estimates of intervention effect (e.g. mean differences (or adjusted mean differences), confidence intervals, t-values, p-values, or risk ratios/odds ratios for binary outcomes).
	+ Data required to support risk of bias judgements (see Assessment of risk of bias of included studies) [21]

### B1.1 Assessment of risk of bias of included studies

#### B1.1.1 Assessment of risk of bias in RCTs

We assessed the risk of bias in the included study using the revised Cochrane ‘Risk of Bias’ tool (RoB 2) for randomised trials [4, 21] for each outcome included in the synthesis.

RoB 2 addresses five domains:

* bias arising from the randomisation process;
* bias due to deviations from intended interventions;
* bias due to missing outcome data;
* bias in measurement of the outcome;
* bias in selection of the reported result.

We applied review-specific guidance developed for the suite of natural therapies reviews to ensure consistency across reviewers. This guidance had been used by the author team to assess over 200 natural therapies studies prior to application in the current review. One review author (MM) then applied the tool to the selected results from each study following the RoB 2 guidance [4], and a second author (SM) checked assessments. Areas of uncertainty and frequently asked questions were shared with extractors to promote concordance. Advice was sought from the lead reviewer (SB) where there was uncertainty. Supporting information and justifications for judgements for each domain (low, some concerns, high risk of bias) was recorded. We derived an overall summary of the risk of bias from each assessment, following the algorithm in the RoB 2 guidance as implemented in the Excel assessment tool [4].

When multiple effects of the intervention using different approaches were presented in the trial report, we selected one effect for inclusion in the meta-analysis and for risk of bias assessment. The selected effect was chosen according to the following hierarchy, which orders the approaches from (likely) least to most biased for estimating the *effect of assignment to the intervention*: 1. the effect that corresponds to a full intention-to-treat analysis, where missing data have been multiply imputed, or a model-based approach has been used (e.g. likelihood-based analysis, inverse-probability weighting); 2. the effect corresponding to an analysis that adheres to intention-to-treat principles except that the missing outcome data are excluded; 3. the effect that corresponds to a full intention-to-treat analysis, where missing data have been imputed using methods that treat the imputed data as if they were observed (e.g. last observation carried forward, mean imputation, regression imputation, stochastic imputation); or 4. the effect that corresponds to an 'as-treated' or 'per-protocol' analysis, or an analysis from which eligible trial participants were excluded [4, 21]. The effect used in the assessment was recorded in the data extraction form.

#### B1.1.2 Assessment of risk of bias in NRSIs

We had planned to use ROBINS-I [22, 23] to assess risk of bias in NRSIs, however there were no NRSIs in the included studies.

### B1.2 Measures of treatment effects

Given there was only a single eligible study included in the review, we reported the effect estimates (adjusted mean differences) exactly as reported by the triallists.

#### B1.2.1 Interpretation of treatment effects

Our interpretation was based on whether there was an important effect or not, using a minimal important difference (MID) for each outcome as the threshold for an important difference. The MIDs used were identified from primary studies validating MIDs or from systematic reviews of these validation studies. Where possible, we used sources that had been used in other natural therapies reviews for consistency of interpretation. If the effect estimate fell between the specified thresholds for important harm and important benefit (e.g. a mean difference of 0.5 points, where the threshold for an important effect was 1 point), the effect of specialised kinesiology was considered to be no different from the comparator. A mean difference above or below the threshold (e.g. >1 point or < -1 points) was interpreted as an important effect. We used the interpretation for each outcome as reported in the study, so positive values indicate benefit for some outcomes (an increase in health-related quality of life or emotional functioning and mental health) and harm for other outcomes (an increase in pain or disability).

### B1.3 Unit of analysis issues

There were no unit of analysis issues in the study included in this review (i.e. not more than two eligible groups (arms) for a comparison, and not a cluster or cross over trial).

### B1.4 Dealing with missing data

As planned in the protocol, we did not contact trial authors to obtain missing information (e.g. study characteristics, description of conduct of the trial) or aggregate level statistics (e.g. missing standard deviations). As we reported the effect estimates exactly as reported by the triallists from the single included study, we did not need to use any algebraic manipulation to calculate statistics necessary for meta-analysis or explore the impact of these decisions in sensitivity analyses.

We planned to deal with missing outcome data within the primary trials through sensitivity analyses, where trials judged to be at a high risk of bias or some concerns would be excluded; however, this was not possible because there was only a single trial included in the review [[2]](#footnote-3). Risk of bias ‘due to missing outcome data’ was considered within the overall bias judgement for the included study.

### B1.5 Assessment of heterogeneity

Given there was only a single eligible study included in the review, there was no need to undertake these analyses.

### B1.6 Assessment of biases due to missing results

We used a framework for assessing risk of bias due to missing results in which an assessment is made for each meta-analysis regarding the risk and potential impact of missing results from studies in which we knew an outcome was measured but not reported (termed ‘known-unknowns’) and the risk of other missing studies or results (termed ‘unknown-unknowns’) [29]. The assessment of ‘known-unknowns’ involved assessment of whether trials meeting the inclusion criteria for a particular summary have missing results through examination of the publication’s methods section, trial registry entry (if available), and trial protocol (if available). We did not need to examine the potential impact of studies for which data could not be included in the meta-analysis (see A1.1.1 Types of studies; A3.1 Selection of studies). We made an assessment as to whether the missing result was potentially due to the result itself (e.g. ‘not statistically significant’), and whether inclusion of the result could lead to a notable change in the meta-analysis (e.g. if the missing result is from a large trial). These assessments are reported in the results section and considered in the GRADE assessment of publication bias.

We also planned to consider whether there was evidence of selective non-reporting of results from the assessment of ‘unknown-unknowns’. In assessing ‘unknown-unknowns’, we planned to judge whether the trials not identified were likely to have results eligible for inclusion (i.e. for the outcome domain ‘pain’, is it likely that missing studies would have been eligible for inclusion in the overall analysis or for particular conditions). We were unable to use contour enhanced funnel plots to examine whether there was evidence of small study effects [30]. As we did not use meta-analytic methods due to the inclusion of a single study, we were also unable to undertake sensitivity analyses to compare the combined effect estimated from the random-effects model (primary analysis) with that estimated from a fixed (common) effect model (together these analyses would inform a decision to downgrade for ‘suspected’ reporting (publication) bias). In the absence of these analyses, we considered evidence of selective non-reporting in the natural therapies’ literature more generally.

## B2 Data synthesis

### B2.1 Meta-analysis

Given there was only a single eligible study included in the review, there was no need to undertake these analyses.

### B2.2 Summary and synthesis when meta-analysis is not possible

Separate comparisons were set up for each comparator group and outcome domains agreed in the final framework. We presented the effect estimates (adjusted mean differences) of the single eligible study as reported by the triallists in summary of findings tables. We did not present these results in forest plots.

### B2.3 Subgroup analysis and investigation of heterogeneity

For chronic and episodic pain conditions, we had planned to undertake a subgroup analysis to examine whether population group explained any observed statistical heterogeneity in the intervention effects, using the pre-defined groups specified in the final framework (see Figure A6.1). Given there was only a single eligible study included in the review, there was no need to undertake this analysis.

### B2.4 Sensitivity analyses

Given there was only a single eligible study included in the review, there was no need to undertake these analyses.

### B2.5 Summary of findings tables and assessment of certainty of the body of evidence

We prepared GRADE summary of findings tables for each of the inactive comparisons in the included study (C1 treatment described as a sham intervention and C2 wait list control), reporting results for critical and important outcome domains (up to seven). For each result, one author (MM) used the GRADE approach to assess our confidence in where the effect lies relative to our threshold of an important effect (or not) (the certainty of evidence) (see Measures of treatment effect). In accordance with detailed GRADE guidance [27, 32, 33], an overall GRADE of high, moderate, low or very low certainty is reported for each result based on whether there are serious, very serious or no concerns in relation to each of the following domains [26].

1. **Risk of bias**. We assessed the overall risk of bias of the included study contributing to each result. There were too few studies to perform sensitivity analyses to examine whether removing studies at high risk of bias or some concerns changed the direction or size of effect estimate importantly (a reduction in benefit or an increase in harm being most concerning) (see Sensitivity analyses) [[3]](#footnote-4). Where the result assessed was at high risk of bias, we rated down for very serious concerns.
2. **Imprecision**. We judged imprecision by examining where the 95% confidence interval for each effect estimate lay in relation to our threshold for an important effect (an MID specified for each outcome; see Measures of treatment effect). Where the confidence interval crossed a threshold leading to different interpretations (e.g. interpretation of the upper bound of the interval was ‘an important effect’ and the lower bound ‘little or no effect’), we considered rating down for imprecision. If the extent to which the confidence interval crossed the threshold was modest, and the interpretation was consistent with the point estimate, we did not rate down (e.g. if the upper bound of the confidence interval was an MD of -0.90 points and the point estimate -1.50 points, where the threshold for an important effect was 1 point). We rated down for serious imprecision if the confidence interval crossed one threshold (important benefit or important harm) and the interpretation of either the upper or lower bound of the interval was different from the point estimate (e.g. if the upper bound of the confidence interval was an MD of 1.40 points indicating an important increase in pain, and the point estimate was -0.15 points indicating an unimportant reduction in pain, where the threshold for an important effect was 1 point). We rated down for very serious imprecision if the confidence interval crossed two thresholds (important benefit and important harm). We rated down for extremely serious imprecision if the 95% confidence interval crossed both thresholds for an important effect (e.g. an MD of -1.0 or 1.0 points, where the threshold for an important effect was 1 point), but was too wide for the result to be interpretable. In line with GRADE guidance, we considered the likely impact of inconsistency when rating imprecision since inconsistency can contribute to imprecision [34, 35].
3. **Inconsistency**. We had planned to assess whether there was important, unexplained inconsistency in results across studies considering the overlap of confidence intervals (non-overlap indicating potentially important differences in direction or size of effect). Inconsistency was not assessed in this review, as only one study contributed results to each summary.
4. **Indirectness.** We assessed whether there are important differences between the characteristics of the study included in each synthesis and the question we were seeking to address, such that the effects observed may not apply to our question (i.e. the applicability of the evidence). For example, differences between the interventions delivered and specialised kinesiology practice in Australia that are likely to influence the size of effect. The results came from a single small study that addressed only part of the population of interest (i.e. the only form of chronic or episodic pain was chronic low back pain), so we rated down for indirectness, specified the population from which the data came when interpreting results and indicated uncertainty for the population group more generally.
5. **Publication bias**. Our judgement of publication bias was based on assessment of bias due to missing results, primarily from previous evidence documenting the presence of reporting bias in trials of natural therapies, such that selective non-reporting is strongly suspected (see Assessment of biases due to missing results).
6. **Upgrading domains** (large effect size, dose response gradient, opposing plausible residual confounding). While, in principle, these domains apply to randomised trials, there is no precedent for rating up the evidence from randomised trials, and we did not have reason to apply them in this review.

Using GRADE decision rules, we derived an overall GRADE for the certainty of evidence for each result included in the summary of findings table [33]. A result from a body of evidence comprised of randomised trials begins as ‘high’ certainty evidence (score=4), and can be rated down (-1 or -2) for serious or very concerns on any GRADE domain that reduces confidence that specialised kinesiology has an important effect (as determined by the pre-specified thresholds) [32, 33, 37]. As indicated in point 2, we applied the most recent GRADE guidance which has provision for rating down (-3) for extremely serious imprecision.

Summary of findings tables were prepared using the GRADEpro GDT software [27]. The tables include:

* estimates of the effects of specialised kinesiology reported as adjusted mean differences (as reported by the triallists)
* the overall GRADE (rating of certainty) and an explanation of the reason(s) for rating down (or borderline decisions) [38].
* the study design(s), number of studies and number of participants contributing data
* a plain language statement interpreting the evidence for each comparison and outcome, following GRADE guidance for writing informative statements (see B2.6 interpretation of findings) [39].

We present the certainty of evidence in summary of findings tables using one of four levels with the following symbols and interpretations.

|  |  |  |
| --- | --- | --- |
| **Certainty** | **GRADE interpretation** | **Implications** |
| High (⊕⊕⊕⊕) | we are very confident that the true effect lies close to that of the estimate of the effect | further research is very unlikely to change the confidence in the estimate of effect |
| Moderate (⊕⊕⊕⊝) | 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. | further research is likely to have an important impact in the confidence in the estimate of effect |
| Low (⊕⊕⊝⊝) | our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect. | further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate |
| Very low (⊕⊝⊝⊝) | we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect. | any estimate of effect is very uncertain |

### B2.6 Interpretation of findings (evidence statements)

When interpreting results, we followed GRADE guidance for writing informative statements [39]. All interpretations are based on where the point estimate lies in relation to the pre-specified thresholds for an important effect (an important effect or not) and the direction of effect (beneficial or harmful). The certainty of evidence is communicated by qualifying the interpretation of effect (e.g. ‘probably’ improves for moderate certainty). For low certainty evidence the interpretation is qualified with the word ‘may’. For example, ‘specialised kinesiology may improve health-related quality of life’ indicates that the point estimate lies above the threshold for important benefit (e.g. a MD >1) and that the evidence is of low certainty.

For very low certainty evidence, we do not provide an interpretation of the result except to state ‘The evidence is very uncertain about the effect of specialised kinesiology on [outcome]’. This is one of two options that GRADE provides for interpreting findings based on very low certainty of evidence: “one option gives the direction of the effect, the other does not” [39]. The decision not to interpret very low certainty results was made independently by the NTWC to ensure a consistent and clear interpretation of findings across Natural Therapy Review reports (see Appendix G).

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# Appendix C. Lists of studies considered for review

## Overview of Appendix C – separate file

Appendix C is comprised of three parts in a single file (below).

These Appendices report the studies excluded at full text review with reason for exclusion, the public submissions and eligibility decision for each, and the studies awaiting classification with reason for awaiting classification.

|  |
| --- |
| Appendix C1. Citation details of studies from search results excluded |
| Appendix C2. Citation details of public submissions |
| Appendix C3. Citation details of studies awaiting classification |

Note – no ongoing studies were found.

# Appendix D. Citation for included study

|  |  |
| --- | --- |
| **Eardley 2013** | Eardley, S.; Brien, S.; Little, P.; Prescott, P.; Lewith, G. Professional kinesiology practice for chronic low back pain: single-blind, randomised controlled pilot study. Forschende Komplementarmedizin. 2013; 20(3) 180-8. [Full-text](../Full-text) retrievable via [ResearchGate](https://www.researchgate.net/publication/249965702_Professional_Kinesiology_Practice_for_Chronic_Low_Back_Pain_Single-Blind_Randomised_Controlled_Pilot_Study). |

# Appendix E. Characteristics of studies included in the review

## Overview of Appendix E – separate file

Appendix E is comprised of two parts, in a single file.

**Appendix E1** provides information about the characteristics of the included study.

* study ID, location, setting, and study design
* the population eligibility criteria, number of participants randomised, participant characteristics, and ICD codes
* the specialised kinesiology treatment goal, and details about the specialised kinesiology intervention(s) and comparator(s)
* a list of all reported outcome(s) categorised according to whether they were eligible or ineligible for the synthesis, the measurement method for each eligible outcome, the timing of outcome measurement, and the outcome(s) selected for inclusion in the synthesis for each outcome domain

**Appendix E2** provides information about funding, declaration of interest and ethics approval for the included study.

|  |
| --- |
| E1. Characteristics of the study included in the evidence synthesis |
| E2. Funding sources, potential conflicts of interest and ethics approval for the study included in the evidence synthesis |

# Appendix F. Risk of bias assessments

## Overview of Appendix F – separate file

Appendix F is a single file containing the full risk of bias assessments for the included study.

The Appendix

* begins with information to orient the reader to the content, and
* provides the signalling questions for the risk of bias tool.

|  |
| --- |
| F. Risk of bias assessments for the included study |

# Appendix G. Differences between the protocol and the review

Changes from the protocol and methods not implemented.

|  | **Section** | **Planned method** | **Change** | **Details (text, rationale or both)** |
| --- | --- | --- | --- | --- |
|  | A1. Objectives | In our protocol, we planned an overall synthesis across any condition for each outcome domain. | Could not be done | This review only included a single study in one condition. |
|  | A1. Objectives | We planned to examine the effects of specialised kinesiology compared to “evidence-based” treatments, in the exceptional circumstance that there were studies at low risk of bias that could be combined in a synthesis.  | Could not be done | We did not identify any studies comparing specialised kinesiology to “evidence-based” treatments. |
|  | A1.1.3 Types of interventions | We listed five excluded therapies/ systems in the protocol:* applied kinesiology
* kinesiology as used to refer to human movement science
* kinesiology taping
* kinesiotherapy
* other systems that use kinesiology muscle testing
 | Addition of an excluded therapy | We added educational kinesiology (Edu-K) to the list of excluded therapies when developing the screening guidance. Educational kinesiology is an educational movement-based program using core Brain Gym® activities that proponents claim to improve brain functioning and learning [12]. Brain Gym® activities are “physical activities done in a specific sequence to improve focus, concentration, eye-hand coordination and brain integration” [13].  |
|  | A2.2 Searching other resources | We included an excerpt in error from another natural therapies review in the protocol, section 3.3.3 Searching other resources. “The 2015 overview of kinesiology identified three systematic reviews that included studies of kinesiology. The three RCTs and 10 non-randomised studies from these reviews will be added to the records we screen.” | Correction to text copied in error | **Revised text:** “The 2015 overview of kinesiology identified one systematic review that included studies of kinesiology…” |
|  | A3.1 Selection of studies | We had planned to pilot title and abstract screening by three reviewers. | Change in process | We piloted title and abstract screening by two reviewers. |
|  | A3.1 Selection of studies | We had planned to screen at title and abstract by two reviewers. | Change in process | **Revised text:** Following pilot title and abstract screening by two reviewers (10% sample), we screened the remaining records at title and abstract using a single reviewer.**Rationale:** One reviewer (who developed the protocol and determined the intervention eligibility criteria in consultation with another senior reviewer) scanned the 1785 unique search results and determined that the vast majority were easily identified as excluded interventions not related to energy or specialised kinesiology (e.g. human movement science, kinesiotherapy, kinesiology taping)Following pilot ti/ab screening by two reviewers on a 10% sample to ensure eligibility criteria were being applied consistently (particularly in relation to the intervention), it was agreed that double screening the remaining titles and abstracts would not be worthwhile. Of the 1785 records screened at ti/ab, 1760 (99%) were excluded. |
|  | B1.2 Measure of treatment effects | We planned to use Cohen’s guiding rules for SMDs where 0.2 represents a small effect, 0.5 a moderate effect, and 0.8 a large effect. | We used a single threshold for an important effect based on an MID specified for each outcome (not SMD).  | **Revised text (and rationale).** “… given there was only a single eligible study included in the review, we reported the effect estimates (adjusted mean differences) exactly as reported by the triallists. Our interpretation was based on whether there was an important effect or not, using a minimal important difference (MID) for each outcome as the threshold for an important difference.” (Because we were concerned that bias may be leading to exaggerated effect sizes, we chose not to describe the size of effect (i.e. we did not interpret effects as small, moderate or large) because this is likely to be misleading) **Implications.** This has no implications for the certainty of evidence because our a priori plan was to assess certainty in relation to whether there was an important effect or not (i.e. in relation to a threshold for an important difference of an SMD of 0.2), not our certainty in the magnitude of effect (trivial, small, moderate or large).  |
|  | B1.5 Assessment of heterogeneity | We planned to undertake subgroup analysis to examine whether population group explained any observed statistical heterogeneity in the intervention effects. | Could not be done | **Revised text.** Given there was only a single eligible study included in the review, there was no need to undertake these analyses. |
|  | B2 Synthesis | We had planned to undertake a meta-analysis and associated analyses (see right-hand column). | Could not be done | **Revised text.** Given there was only a single eligible study included in the review, there was no need to undertake these analyses.B2.1 Meta-analysisB2.3 Subgroup analysis and investigation of heterogeneityB2.4 Sensitivity analyses |
|  | B2.5 GRADE assessments – risk of bias | As per B2.4 we did not use the term ‘some concerns’ when describing our approach to rating down for risk of bias | Terminology corrected (not a change to protocol) | The use of ‘some concerns’ is consistent with the RoB2 tool. Our approach to GRADE is consistent with that for sensitivity analyses where downgrades of -1 are considered where the majority of studies are rated as ‘some concerns’ or studies with the majority of weight in the analysis are rated as ‘high risk of bias’. Downgrades of -2 are made where most or all studies are at high risk of bias. Decisions not to rate down in these circumstances would be warranted if sensitivity analyses showed removal of studies at risk of bias did not materially alter the effect estimate.  |
|  | B2.5 GRADE assessments – inconsistency | We had planned to assess whether there was important, unexplained inconsistency in results across studies considering the overlap of confidence intervals, etc. | Could not be done | **Revised text:** Inconsistency was not assessed in this review, as only one study contributed results to each summary. |
|  | B2.6 Interpretation of findings | Our endorsed protocol stated that we would report “a plain language statement interpreting the evidence for each comparison and outcome, following GRADE guidance for writing informative statements”. We did not specify which option would be used for very low certainty evidence (i.e. give the direction of the effect, or limit to a statement that the ‘evidence is very uncertain’). | NTWC advised not to include direction of effect for very low certainty evidence.  | The decision not to interpret very low certainty results was made independently by the NTWC to ensure a consistent and clear interpretation of findings across Natural Therapy Review reports. |

# Appendix H. Response to comments from the Methodological review

Methodological review (or peer review) was conducted to appraise the methodological quality and assess the appropriateness of reporting for this systematic review (including appendices).

For reporting, the methodological review assessed the systematic review against the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) Checklist (2020) and where applicable, the MECIR (Methodological Expectations of Cochrane Intervention Reviews) manual to ensure the systematic review was designed and conducted in accordance with:

* NHMRC’s Developing your Guideline module in NHMRC’s Guidelines for Guidelines Handbook
* Cochrane Handbook for Systematic Reviews of Interventions (updated 2022)
* GRADE guidance and GRADE working group criteria for determining whether the GRADE approach was used (GRADE handbook).

Assessment included the application of criteria for considering studies for the review and synthesis, search methods, data extraction and analysis, assessment of risk of bias of studies, assessment of the certainty of evidence using GRADE, and the interpretation and summary of findings.

The systematic review (including appendices) has been updated to reflect the amendments suggested by methodological review and NHMRC’s Natural Therapies Working Committee, where appropriate. In summary, updates included additional information and/ or clarification of the Plain Language Summary, Executive Summary, Results sections and Appendices, including:

* Rewording and additional explanatory text in various parts of the report to improve clarity.

A detailed record of responses to all comments indicating changes that were made was provided to NHMRC together with the amended Report and Appendices documents.

# Appendix I. Abbreviations

Below is a list of abbreviations used in the report. Abbreviations for outcome measures are in a table following the list.

**AIK:** Australian Institute of Kinesiologists

**AKA:** Australian Kinesiology Association

**AMED:** Allied and Complementary Medicine Database

**CAM:** complementary and alternative medicine

**CENTRAL:** Cochrane Central Register of Controlled Trials

**CINAHL:** Cumulative Index of Nursing and Allied Health Literature

**CI:** confidence interval

**CM:** Complementary Medicine

**COMET:** Core Outcome Measures in Effectiveness Trials

**DEFF:** design effect

**EUROPE PMC:** Europe PubMed Central

**GRADE:** Grading of Recommendations, Assessment, Development and Evaluation

**HR-QoL:** health-related quality of life

**ICC:** intra-cluster correlation

**ICD-11:** International Classification of Diseases 11th Revision

**ICTRP:** International Clinical Trials Registry Platform

**MA:** Meta-analysis

**MeSH:** Medical Subject Headings

**MID:** minimal important difference

**NHMRC:** National Health and Medical Research Council

**NRSI:** non-randomised study of interventions

**NTREAP:** Natural Therapies Review Expert Advisory Panel

**NTWC:** Natural Therapies Working Committee

**PICO:** population, intervention, comparator, outcome

**PKP:** Professional Kinesiology Practice

**PRACI:** Practitioner Research and Collaboration Initiative

**PRISMA:** Preferred Reporting Items for Systematic review and Meta-Analyses

**PRISMA-P:** Preferred Reporting Items for Systematic review and Meta-Analyses Protocols

**PROSPERO:** International prospective register of systematic reviews

**RCT:** randomised controlled trial

**REML:** restricted maximum likelihood estimator

**ROB:** risk of bias

**RR:** risk ratios

**SMD:** standardised mean difference

**TIDieR:** Template for Intervention Description and Replication

**TGA:** Therapeutic Goods Administration

**Abbreviations for measures reported in this review**

| **Abbreviation** | **Measure** |
| --- | --- |
| VAS | Visual analogue scale  |
| SF-36 | Short Form Health Survey  |
| RMDQ | Roland-Morris Disability Questionnaire |

1. PAK is trademarked so that it can only be used by certified members of International College of Applied Kinesiology (ICAK) <https://www.icaka.org.au/Applied-Kinesiology-Certification> [↑](#footnote-ref-2)
2. In the protocol we reported that we would conduct sensitivity analyses excluding trials judged at high or unclear risk of bias. The terminology “Unclear risk of bias” has been replaced in ROB2 with “some concerns”. The approach described here is consistent with the protocol in that the sensitivity analyses were to be restricted to studies at low risk of bias. [↑](#footnote-ref-3)
3. In the protocol we reported that we would conduct sensitivity analyses excluding trials judged at high or unclear risk of bias. The terminology “Unclear risk of bias” has been replaced in ROB2 with “some concerns”. The approach described here is consistent with the protocol in that the sensitivity analyses were to be restricted to studies at low risk of bias. [↑](#footnote-ref-4)