Systematic review of evidence on the clinical effectiveness of Feldenkrais

Technical report prepared by Cochrane Australia

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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), citations for studies included in the evidence synthesis (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, citations for studies reported on the evidence inventory, studies awaiting classification, ongoing studies (1 file) |
| Appendix D. Citations for studies included in the evidence synthesis |
| Appendix E. Characteristics of studies included in the evidence synthesis (2 files) |
| Appendix F. Risk of bias assessments for studies contributing to meta-analyses (1 file) |
| Appendix G. Differences between the protocol and the review and methods not used |
| Appendix H. Response to methodological review |
| Appendix I. Abbreviations and list of measures |

# 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 the NHMRC, NTWC and NTREAP in order to confirm populations and outcomes for inclusion in the evidence synthesis.

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| Appendix A1. Review questions and criteria for considering studies for this review |
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| 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, prospectively registered on the International prospective register of systematic reviews (PROSPERO ID [CRD42023467191](https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=467191)). 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 Feldenkrais 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 Feldenkrais 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?

## Secondary objectives related to the following questions

1. What is the effect of *Feldenkrais* compared to evidence-based treatments (active comparators) on outcomes for each underlying condition, pre-condition, injury or risk factor?
2. What evidence exists examining the effects of *Feldenkrais* compared to other active comparators? (for inclusion in evidence inventory only, not the synthesis)

There are no results contributing to objective two, as pre-specified criteria for synthesis were not met (i.e. no two studies at low risk of bias evaluated the same evidence-based treatment). All studies with active comparators are listed in an inventory (Appendix E3).



**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 Feldenkrais is commonly sought or prescribed, including a scoping search of studies evaluating Feldenkrais, the wider literature on Feldenkrais, 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 [CRD42023467191](https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=467191)) [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 Feldenkrais (or the control) would be allocated to individuals in most studies, although clustering was likely in these studies given the way in which Feldenkrais lessons are delivered (i.e. the same teacher may deliver the intervention to multiple participants) [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 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.

For trials in which Feldenkrais was used for primary or secondary prevention, participants must have had a clearly-identified factor that put them at heightened risk of the condition or injury that the intervention is intended to prevent compared to the population at large. Where possible, decisions about whether a population was at risk was informed by evidence from a systematic review of risk factors.

We operationalised the criteria for risk as follows:

* The risk factor(s) for the condition that Feldenkrais was used to prevent was part of the eligibility criteria for the trial or reported in the baseline data (e.g. older age in a trial aimed at preventing falls; work that involves demanding posture or repetitive movement in a trial aiming to prevent workplace-related musculoskeletal conditions), and
* There was a direct link between the risk factor and the trial outcomes (i.e. an outcome that demonstrates progression to a diagnosable condition or pre-condition; musculoskeletal pain or injury in a trial that aims to prevent injury)

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 Feldenkrais is commonly sought or prescribed. Decisions about 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 as per guidance in the Cochrane handbook [8]. No such studies were included.

### A1.1.3 Types of interventions

For the purposes of this review, Feldenkrais was defined as a method that “… develops a functional awareness of the self in the environment…expands their repertoire of movements, enhances awareness, improves function and enables people to express themselves more fully” [9]. Because of the potential challenge of distinguishing components of Feldenkrais from related modalities, and the likelihood of identifying studies in which the defining techniques and principles of Feldenkrais are incompletely reported, studies were included if the therapy was described as Feldenkrais (including the Feldenkrais Method, Awareness Through Movement® or Functional Integration®). Studies that failed to mention or describe the intervention as Feldenkrais (or other synonyms) were excluded.

Feldenkrais treatments were eligible irrespective of the training or qualifications of the practitioner, the setting in which Feldenkrais was used, and the dose and duration of treatment. More details about each of these intervention features is provided under data extraction (see B1).

#### Comparisons

1. Feldenkrais *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. Feldenkrais *versus* evidence-based gold standard treatment(s) (see below for selection method)
3. Feldenkrais *versus* other active comparators (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). Where 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).

Comparisons 1 and 2 were to be addressed in separate syntheses (meta-analyses). Where a study included multiple arms, with at least one eligible comparator (e.g. a placebo control arm), we included the eligible comparison(s).

For comparison 2, there were no studies suitable for conducting a synthesis. Different active comparators were examined in each study, so the pre-specified criteria for synthesis were not met (i.e. at least two studies at low risk of bias with comparable PICO criteria). Characteristics of studies involving active comparators are briefly described in the evidence inventory of available evidence (Appendix E3).

***Excluded comparisons***. In line with the main review objective, which is to examine the effects of Feldenkrais rather than the comparative effects of different Feldenkrais treatments, we excluded head-to-head comparisons of Feldenkrais. For example, comparisons of Feldenkrais administered by people with different qualifications or specialisations (e.g. Feldenkrais 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 Feldenkrais is sought by patients and prescribed by practitioners. In principle, this could include any patient-important outcome that helps elucidate the effects of Feldenkrais 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
* falls (rate of falls; risk of falling)
* physical function
* health-related quality of life
* overall disease status (e.g. motor and non-motor symptom of Parkinson disease)
* emotional functioning and mental health

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 Feldenkrais intervention period (i.e. if Feldenkrais was administered three times over a week, we took the first measure after the third administration).

***Data reported***

* When authors reported results for both change scores (change from baseline) and post-intervention (final) values, we selected results for final values.
* If data for the preferred measure was incompletely reported or uninterpretable, we selected another measure.

***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 10, 2023), 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).

The search strategy comprised the text word Feldenkrais or "awareness through movement" or "sensory awareness training" and, where available, the relevant subject heading term. No study design filter was applied. Searches were run on 6 October 2023 and were not limited by language, year of publication or publication status (see Appendix A4).

### A2.2 Searching other resources

We reviewed the studies included in the 2015 evidence evaluation for Feldenkrais and examined the reference lists of included studies and any other relevant systematic reviews (published from 2015 onwards).

We searched the first 10 pages (100 entries) of Google Scholar using the phrases Feldenkrais or "awareness through movement" or "sensory awareness training" appearing in the title. We also checked references to research articles in a database maintained by the International Feldenkrais Federation Research Network (https://www.zotero.org/groups/4149568/iffrg/library) and searched the online archive of the Feldenkrais Research Journal (feldenkraisresearchjournal.org). Both sources were searched with the words randomis(z)ed, trial, group(s) and control.

Finally, we searched PubMed for retracted publications, expressions of concern and published errata, as well as the Retraction Watch database.

### A2.3 Public submissions

No citations were received through the Department’s public call for submissions.

# Appendix A3. Methods for selecting studies

### A3.1 Selection of studies

Records from CENTRAL, PubMed, AMED and Emcare were imported into EndNote and duplicates removed. All remaining records were imported into Covidence for screening.

Two reviewers (MM, SM) piloted guidance for title and abstract screening on a sample of 50 records to ensure the eligibility criteria were applied consistently. All records were reviewed independently by two reviewers at both the title and abstract screening and full-text review stages in Covidence. Disagreements at either stage were resolved by consensus among members of the review team. Advice from NTWC regarding inclusion was not required.

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).

Published protocols for studies confirmed as meeting the eligibility criteria, but for which results were not available in a published report, were checked against potentially eligible trials identified from registry records and included in the list of ‘ongoing studies’ (Appendix C4). These were also considered in the 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’ (Appendix C3), 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 [10]).

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 [11, 12]. 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.

#### Dealing with multiple study IDs

If multiple study reports resulted in the same study ID (Author Surname, Year) and were reporting the same study, the study ID for index report was given the suffix ‘.1’ after the Year (e.g. Ziyaeifard 2017.1), and the study ID for the secondary report was given the suffix ‘.2.’ (e.g. Ziyaeifard 2017.2).

If multiple study reports resulted in the same study ID (Author Surname, Year) and were reporting different studies, the study IDs for each study were given the suffix ‘a’, ‘b’, etc after the Year (e.g. Ebrahimi 2021a, Ebrahimi 2021b) to differentiate them.

# Appendix A4. Results of the search

**Bibliographic databases**

The search of bibliographic databases retrieved 886 records. After removing duplicates in EndNote and Covidence, 408 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.

**Trial register records**

The search of ClinicalTrials.gov and WHO ICTRP retrieved 32 records, of which 2 were duplicates. Of the 30 unique records screened, 23 were ineligible and 7 eligible. Four (4) of the eligible records are linked to the studies included in the review and 3 are unpublished (see Appendix C4). One of the 3 unpublished studies was registered in 2022 and judged likely to be ongoing. The other 2 studies had enrolment start dates in 2016 and 2017 respectively and were assessed as missing studies.

**2015 evidence evaluation for Feldenkrais**

The 2015 overview of Feldenkrais identified 10 systematic reviews that included three randomised trials. All three trials were retrieved by our search.

**Published systematic reviews**

We identified two studies from published systematic reviews retrieved in search. Both of these studies compared Feldenkrais to an active comparator only and are reported on the evidence inventory (see Appendix E3).

**Google Scholar**

Scanning the references of the first 10 pages yielded one study for which the full text was reviewed. This study was included in the evidence synthesis.

**International Feldenkrais Federation Research Network (IFFRN) database**

One study with two citations was identified from the IFFRN database and was excluded following full-text review (see Appendix C1).

**Retractions and published errata**

No records were retrieved from PubMed or the Retraction Watch database.

**Search strategies**

**Cochrane Central Register of Controlled Trials (Issue 10, 2023)**

|  |  |  |
| --- | --- | --- |
| **#** | **Search strategy** | **Records** |
| 1 | (feldenkrais or "awareness through movement" or "sensory awareness training"):ti,ab,kw. | 44 |

**MEDLINE ALL (Ovid) 1946 to October 4**

|  |  |  |
| --- | --- | --- |
| **#** | **Search strategy** | **Records** |
| 1 | (feldenkrais or awareness through movement or sensory awareness training).af. [af=all fields] | 98 |

**Embase Classic+Embase (Ovid) 1947 to October 4**

|  |  |  |
| --- | --- | --- |
| **#** | **Search strategy** | **Records** |
| 1 | Feldenkrais Method/ or (feldenkrais or awareness through movement or sensory awareness training).af. | 205 |

**Emcare (Ovid) 1995 to 2023 week 39**

|  |  |  |
| --- | --- | --- |
| **#** | **Search strategy** | **Records** |
| 1 | Feldenkrais Method/ or (feldenkrais or awareness through movement or sensory awareness training).af. | 131 |

**AMED (Ovid) 1985 to September 2023**

|  |  |  |
| --- | --- | --- |
| **#** | **Search strategy** | **Records** |
| 1 | Feldenkrais Technique/ or (feldenkrais or awareness through movement or sensory awareness training).af. | 95 |

**CINAHL Complete via EBSCOhost**

|  |  |  |
| --- | --- | --- |
| **#** | **Search strategy** | **Records** |
| 1 | SU Feldenkrais Method OR ( TI feldenkrais OR TI "awareness through movement" OR TI "sensory awareness training ) OR ( AB feldenkrais OR AB "awareness through movement" OR AB "sensory awareness training ) OR ( MW feldenkrais OR MW "awareness through movement" OR MW "sensory awareness training )  | 216 |

**Europe PMC**

|  |  |  |
| --- | --- | --- |
| **#** | **Search strategy** | **Records** |
| 1 | (TITLE:"feldenkrais" OR TITLE:"awareness through movement" OR TITLE:"sensory awareness training" OR ABSTRACT:"feldenkrais" OR ABSTRACT:"awareness through movement" OR ABSTRACT:"sensory awareness training") | 97 |

**ClinicalTrials.gov and WHO ICTRP**

feldenkrais or "awareness through movement" or “sensory awareness training” (limited to Intervention/treatment in ClinicalTrials.gov (n=25) and limited to Intervention in WHO ICTRP (n=7))

**Google Scholar**

Advanced search options (phrase in title): feldenkrais\*, "awareness through movement", "sensory awareness training". first 10 pages only (100 records)

# 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 the 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

For each population, we collated information about the outcomes addressed in all eligible studies. The purpose was twofold: (1) to enable prioritisation of the most important **outcome domains** for each population (irrespective of whether studies measured these domains), and (2) to facilitate selection of the **most relevant results** from each 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). For outcomes not covered by the initial framework, additional outcome domains were specified allowing categorisation of all outcomes and measures.
* For each condition, NTWC, with input from NTREAP, rated **outcome domains** as critical, important or of limited importance for understanding the effects of Feldenkrais on each population group. 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 and synthesis.

***Outcome selection.*** From each study, we selected one result per outcome domain for data extraction, risk of bias assessment and reporting of results in the summary and synthesis (using the standardised mean difference to combined effects measured on different scales see B1.2 and B2.1). 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 each 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. Where trials measured outcomes at multiple timepoints, we selected the first measurement after the end of the intervention period (i.e. if Feldenkrais was given three times over a week, we took the first measure after the third administration).

Because there were few studies, we broadened criteria for inclusion of outcomes to include HR-QoL and physical function outcomes irrespective of population (i.e. not limited to chronic or longer-term conditions), duration of Feldenkrais (i.e. not limited to weeks or longer) and length of follow-up (not limited to time-frames likely to detect meaningful improvement).



**Fig A6.1** | Final analytic framework for the review as agreed through the prioritisation process (Appendix A5).
Panel A, columns 1 and 2 show the populations and outcome domains eligible for the evidence synthesis. Column 3 shows the populations *(conditions)* and outcome domains for which studies were available. Results are reported for each population group in the section indicated in column 1. Study-level data and meta-analyses are presented for the main comparison in the forest plot indicated in column 3. Panel B shows outcome domains rated as of limited importance. \* Outcome domain prioritised as critical for at least one population group.

# 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 (reproduced from main report Fig. 4.1.1). \*\*Studies are the unit of interest in the review. Each study could have multiple reports. CoIS: characteristics of included studies. \*see main report section 4.1 for flow of ongoing and unpublished studies

# 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 [11, 12]. 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. Two authors (MM and SB) pre-tested the data extraction and coding form on a pilot study. Both authors discussed the coding after one author (MM) had reviewed the extracted and coded data on study characteristics for completeness, accuracy and consistency. Revisions to the data extraction form were made as required to maximise the quality and consistency of data collection.

We implemented a two-step process for data extraction. In the first step, studies were triaged by a senior author (MM). For each study we coded population groups, 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 in the synthesis 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 each 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. All queries related to the quantitative data were referred to a biostatistician (ST). Discrepancies were resolved through discussion with a senior author (SB, JM) if agreement could not be reached or for more complex scenarios.

Where available, we extracted information relating to the characteristics of included studies 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 Feldenkrais 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 [13]
* Feldenkrais 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 Feldenkrais 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 each 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, emotional functioning and mental health, health-related quality of life, physical function)
	+ 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 Feldenkrais (e.g. immediately after end of Feldenkrais 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) [14]

### 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 included studies using the revised Cochrane ‘Risk of Bias’ tool (RoB 2) for randomised trials [4, 14] 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, 14]. 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 [15, 16] to assess risk of bias in NRSIs, however there were no NRSIs in the included studies.

### B1.2 Measures of treatment effect

We anticipated that many of the outcomes would be continuous (e.g. pain, anxiety), and that varying measurement instruments would be used to measure the same underlying construct across the studies. For this reason, we quantified the effects of Feldenkrais using the standardised mean difference (SMD) (implementing the Hedges’ adjusted *g* version). In trials where a continuous measure had been dichotomised (e.g. a continuous pain scale is dichotomised into improvement or no improvement) and analysed as binary outcomes, we re-expressed reported, or calculated, odds ratios as SMDs [17]. We did not report any of our meta-analysis results as dichotomous outcomes.

#### B1.2.1 Interpretation of treatment effects

Given the wide range of conditions, outcomes and measurement methods reported in the studies included in this review, it was not possible to specify thresholds for interpreting the size of the effect for each outcome measure. We planned to use Cohen’s guiding rules for interpreting SMDs where 0.2 represents a small effect, 0.5 a moderate effect, and 0.8 a large effect [18]. In practice, our interpretation was based on whether there was an important effect or not [19, 20], with an SMD of 0.2 standard units set as the threshold for an important difference. If the SMD fell within the pre-specified range of -0.2 to 0.2 (i.e. within both thresholds), the effect of Feldenkrais was considered to be no different from control. An SMD above 0.2 or below -0.2 was interpreted as an important effect. We opted to use the most intuitive interpretation of effect estimates for each outcome, so positive values indicate benefit for some outcomes (an increase in health-related quality of life) and harm for other outcomes (an increase in pain). 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).

### B1.3 Unit of analysis issues

There were no unit of analysis issues in studies included in this review (no studies with more than two eligible groups (arms) for a comparison, and no cluster or cross over trials).

### 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). However, we attempted to calculate statistics necessary for meta-analysis using algebraic manipulation of reported statistics (e.g. computing the standard error for the treatment effect from a reported p-value). Studies for which we calculated or imputed statistics are annotated in forest plots. We planned to explore the impact of these decisions in sensitivity analyses but there were too few studies to do so. Studies for which we could not calculate or impute the statistics required for inclusion in the meta-analysis are noted in the relevant results sections of the main report.

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 were too few trials included in the review [[1]](#footnote-2). Risk of bias ‘due to missing outcome data’ was considered within the overall bias judgement for each trial.

### B1.5 Assessment of heterogeneity

We assessed statistical heterogeneity of the intervention effects visually by inspecting the overlap of confidence intervals on the forest plots. While we report formal tests for heterogeneity using the χ 2 test (using a significance level of α=0.1), and quantified heterogeneity using the I2 statistic [21], these statistics are unlikely to be informative with so few studies. When there was evidence of heterogeneity, we judged its importance by considering where the point estimates for studies lay in relation to the threshold for an important difference (all on one side, indicating similar interpretations across the studies, or not).

### 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’) [22]. The assessment of ‘known-unknowns’ involved assessment of whether trials meeting the inclusion criteria for a particular meta-analysis have missing results through examination of the publication’s methods section, trial registry entry (if available), and trial protocol (if available). We also examined 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 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 [23]. 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) as there were too few studies for these analyses. In the absence of these analyses, we considered whether there was concern about selective non-reporting arising from small study effects (multiple small studies reporting large effects) and evidence of selective non-reporting in the natural therapies literature more generally.

## B2 Data synthesis

### B2.1 Meta-analysis

Separate comparisons were set up for each population group and outcome domains agreed in the final framework (see Figure 3.5.1). Some comparisons were stratified by more specific conditions (with an overall estimate and estimate for each condition presented) (see Figure A6.1 Appendix A6). Subgroup analysis by population group was used to examine whether these population groups explained any observed statistical heterogeneity in the intervention effects (see Subgroup analysis).

We combined the effects using a random effects meta-analysis model, since we expected and found there to be clinical and methodological diversity across the trials that may contribute to statistical heterogeneity. These analyses used the restricted maximum likelihood estimator (REML) of between trial heterogeneity variance and the Hartung-Knapp-Sidik-Jonkman confidence interval method. Analyses were conducted in Stata Statistical Software [24]

Forest plots were used to visually depict the intervention effect estimates and their confidence intervals. Forest plots are stratified by condition and risk of bias (within population group). For completeness, results for all studies for which an effect estimate (SMD) could be calculated are presented on the forest plot, including where a single study contributed to the comparison. Studies that had missing or uninterpretable results, or for which an effect estimate (SMD) could not be calculated, are not depicted on the plot.

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

Studies that were eligible for the evidence synthesis but could not be included in meta-analyses, are included in the characteristics of included studies table (Appendix E1). These studies are counted as ‘missing results’ rather than included in a summary or other synthesis (i.e. the result was judged to be uninterpretable or there were major concerns about the integrity of the data). We report available data from these analyses in forest plots and summary of findings tables, except where the authors report a result that is uninterpretable. We did not assess risk of bias because bias (under- or over-estimating the effect) is only relevant if results are included in a meta-analysis or reported. The reasons why these studies were not included in the analysis do not relate to bias (i.e. incomplete reporting of effects and their variances, errors in reporting or analysis of data, no information to interpret), so a risk of bias assessment would not characterise the problems with these studies.

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

For mobility and falls prevention, we undertook a subgroup analysis to examine whether population group explains any observed statistical heterogeneity in the intervention effects, using the pre-defined groups specified in the final framework (see Figure A6.1 for population groups in each meta-analysis). However, these analyses provide limited additional information due to the small number of studies.

### B2.4 Sensitivity analyses

We planned to undertake and report sensitivity analyses examining if the meta-analysis estimates were robust to the meta-analysis mode, assumptions made to enable inclusion of results in the meta-analysis, and the impact of excluding studies at risk of bias. However, there were too few studies for 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 main comparisons, 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 for a small effect (the certainty of evidence) (see Measures of treatment effect). In accordance with detailed GRADE guidance [20, 25, 26], 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 [19].

1. **Risk of bias**. We assessed the overall risk of bias across all studies contributing to each synthesised 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) [[2]](#footnote-3). We therefore considered the weight that studies at risk of bias contributed to each result. Where the majority of studies were 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 pooled effect estimate lay in relation to our threshold for an important effect (an SMD of -0.2 or 0.2; 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 SMD of -0.15 and the point estimate -0.50). 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 SMD of 0.40 indicating an important increase in pain, and the point estimate was -0.15 indicating an unimportant reduction in pain). We rated down for very serious imprecision if the confidence interval crossed two thresholds (important benefit and important harm) and for extremely serious imprecision where the confidence interval was so wide that the result was considered uninterpretable. In line with GRADE guidance, we considered the likely impact of inconsistency when rating imprecision since inconsistency can contribute to imprecision [27, 28].
3. **Inconsistency**. We assessed 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). Where there was concerns about inconsistency based on non-overlapping confidence intervals, we considered where the point estimates lie in relation to the threshold for an important effect (if all to one side of a threshold, we were less concerned). While we calculated statistical measures to quantify and test for heterogeneity (I2 statistic, χ2 test), there were too few studies for these statistics to be informative. To enhance our interpretation of whether inconsistency is important, we planned to calculate and examine the prediction interval, considering whether it included values that lead to a different conclusion than an assessment based on the confidence interval [29]. However, this is only informative with more than 10 studies, so the method could not be used. Due to the small number of studies, we were unable to used results of subgroup analyses to explain the inconsistency (see Assessment of heterogeneity; specifically, the population subgroups). Where inconsistency was not explained, we rated down. Where a result was based on a single study, inconsistency was not rated [27].
4. **Indirectness.** We assessed whether there are important differences between the characteristics of studies 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 Feldenkrais practice in Australia that are likely to influence the size of effect. Where results came from a single small study, we were concerned that similar effects might not be observed in the population of interest more generally, and rated down for serious indirectness. Where the included studies addressed only part of the population of interest (e.g. the only form of chronic musculoskeletal pain was chronic low back pain), we also rated down for indirectness, specified the population from which 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 interpretation of ‘known unknowns’ (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 GRADE for the certainty of evidence for each result included in the summary of findings table [26]. 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 serious concerns on any GRADE domain that reduces confidence that Feldenkrais has an important effect (as determined by the pre-specified thresholds) [25, 26, 30]. As indicated above, we applied the most recent GRADE guidance which makes provision for rating down (-3) for extremely serious imprecision.

Summary of findings tables were prepared using the GRADEpro GDT software [20]. The tables include:

* estimates of the effects of Feldenkrais reported as standardised mean differences
* the overall GRADE (rating of certainty) and an explanation of the reason(s) for rating down (or borderline decisions) [31].
* 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) [32].

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 [32]. 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, ‘Feldenkrais may improve pain’ indicates that the point estimate lies above the threshold for important benefit (an SMD >0.2) 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 Feldenkrais 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” [32]. 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 four parts (below).

These Appendices report the studies excluded at full text review with reason for exclusion, the citations for studies reported on the evidence inventory, the studies awaiting classification, and ongoing and unpublished studies.

|  |
| --- |
| Appendix C1. Citation details of studies from search results excluded |
| Appendix C2. Citation details of studies reported on the evidence inventory |
| Appendix C3. Citation details of studies awaiting classification |
| Appendix C4. Characteristics of ongoing and unpublished studies |

# Appendix D. Citations for studies included in the evidence synthesis

If multiple reports, the first citation is the index paper

|  |  |
| --- | --- |
| **Johnson 1999** | Johnson, S. K.; Frederick, J.; Kaufman, M.; Mountjoy, B. A controlled investigation of bodywork in multiple sclerosis. 1999. Journal of alternative and complementary medicine (New York, N.Y.); 5(3) 237-243. doi: 10.1089/acm.1999.5.237 |
| **Lundblad 1999** | Lundblad, I.; Elert, J.; Gerdle, B. Randomized controlled trial of physiotherapy and Feldenkrais interventions in female workers with neck-shoulder complaints. 1999. Journal of occupational rehabilitation; 9(3) 179-194. doi: 10.1023/A:1021301801292 |
| **Lundqvist 2014** | Lundqvist, Lars-Olov; Zetterlund, Christina; Richter, Hans O. Effects of Feldenkrais method on chronic neck/scapular pain in people with visual impairment: a randomized controlled trial with one-year follow-up. 2014. Archives of physical medicine and rehabilitation; 95(9) 1656-1661. doi: 10.1016/j.apmr.2014.05.013 |
| **Mohan 2020** | Mohan, V.; Paungmali, A.; Sitilertpisan, P.; Joseph, L.; Ramlan, A.; Ramlan, S. A. Improved respiratory characteristics in non-specific low back pain: Comparison of Feldenkrais method versus routine physiotherapy. 2020. Physiotherapy Practice and Research; 41(2) 99-107. doi: 10.3233/PPR-190382 |
| **Palmer 2017** | Palmer, Carolyn F. Feldenkrais Movement Lessons Improve Older Adults' Awareness, Comfort, and Function. 2017. Gerontology & geriatric medicine; 3() . doi: 10.1177/2333721417724014 |
| **Smith 2001** | Smith, A. L.; Kolt, G. S.; McConville, J. C. The effect of the Feldenkrais Method on pain and anxiety in people experiencing chronic low back pain. 2001. New Zealand Journal of Physiotherapy; 29(1) 6-14.  |
| **Stephens 2001** | Stephens, J.; DuShuttle, D.; Hatcher, C.; Shmunes, J.; Slaninka, C. Use of awareness through movement improves balance and balance confidence in people with multiple sclerosis: a randomized controlled study. 2001. Neurology report; 25(2) 39-49. doi: 10.1097/01253086-200125020-00002 |
| **Stephens 2005** | Stephens, James; Pendergast, Christopher; Roller, Beth Ann; Weiskittel, Robert Scott Learning to improve mobility and quality of life in a well elderly population: the benefits of awareness through movement. 2005. Feldenkrais Research Journal; 2(2005).  |
| **Torres-Unda 2017** | Torres-Unda, J.; Polo, V.; Dunabeitia, I.; Bidaurrazaga-Lentona, I.; Garcia-Gil, M.; Rodriguez-Larrad, A.; Irazusta, J. The Feldenkrais Method improves functioning and body balance in people with intellectual disability in supported employment: A randomized clinical trial. 2017. Research in developmental disabilities; 70() 104-112. doi: 10.1016/j.ridd.2017.08.012 |
| **Ullmann 2010** | Ullmann, Gerhild; Williams, Harriet G.; Hussey, James; Durstine, J. Larry; McClenaghan, Bruce A. Effects of Feldenkrais exercises on balance, mobility, balance confidence, and gait performance in community-dwelling adults age 65 and older. 2010. Journal of alternative and complementary medicine (New York, N.Y.); 16(1) 97-105. doi: 10.1089/acm.2008.0612Ullmann, Gerhild; Williams, Harriet G. Can Feldenkrais exercises ameliorate subclinical depressive symptoms in older adults? A pilot study. Journal of the South Carolina Medical Association (1975) 2011;107 Suppl():7-10Ullmann G. The Efficacy of Feldenkrais in Improving Balance, Mobility, and Health Related Factors in an Older Adult Population (Doctoral dissertation, University of South Carolina). [not retrieved] |
| **Vrantsidis 2009** | Vrantsidis, Freda; Hill, Keith D.; Moore, Kirsten; Webb, Robert; Hunt, Susan; Dowson, Leslie Getting Grounded Gracefully: effectiveness and acceptability of Feldenkrais in improving balance. 2009. Journal of aging and physical activity; 17(1) 57-76. doi: 10.1123/japa.17.1.57 |

# Appendix E. Characteristics of studies included in the review

## Overview of Appendix E – separate file

Appendix E is comprised of three parts in a combined file.

**Appendix E1** provides information about the characteristics of each of the studies eligible for the evidence synthesis.

* study ID, location, setting, and study design
* the population eligibility criteria, number of participants randomised, participant characteristics, and ICD codes
* the Feldenkrais treatment goal, and details about the Feldenkrais 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 each study.

Studies were included in E1 and E2 irrespective of whether they provided data that could be included in the meta-analysis.

**Appendix E3** provides details of the characteristics of each of the studies included in the evidence inventory. These studies were eligible for the review, but were excluded from the synthesis. The reasons why each study was excluded from the synthesis is reported in this file.

Appendices are as follows

|  |
| --- |
| E1. Characteristics of studies included in the evidence synthesis |
| E2. Funding sources, potential conflicts of interest and ethics approval for studies included in the evidence synthesis |
| E3. Characteristics of studies included in the evidence inventory (ineligible for 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 assessment for each study that contributed data for meta-analysis.

The Appendix

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

Appendices are as follows

|  |
| --- |
| F. Risk of bias assessments for each study that contributed data for meta-analysis |

# Appendix G. Differences between the protocol and the review

Changes from the protocol and methods not implemented

| **No.** | **Section** | **Planned method** | **Change** | **Details (text, rationale or both)** |
| --- | --- | --- | --- | --- |
| 1 | A1. ObjectivesA1.1.3 | In our protocol, we planned an overall synthesis across any condition for each outcome domain. | Not done | The plan to synthesise across conditions was a contingency for reviews that included a large number of studies examining effects diverse conditions. This was not the case for this review. As such, at the prioritisation step, the NHMRC endorsed a proposal to structure and report the summary and synthesis by population group, without reporting an overall analysis across conditions.  |
| 2 | A1. ObjectivesA1.1.3 | We planned to examine the effects of Feldenkrais 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.  | Not possible | Not two studies in the same population had the same active comparator.  |
| 3 | 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. |
| 4 | 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 (0.2) and did not interpret effect size.  | **Revised text (and rationale).** 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).  |
| 5 | B1.2 Measure of treatment effect | Where a valid and reliable minimal important difference (MID) is available for a familiar measure of relevance to the population groups in the meta-analysis, we will re-express the SMD in units of the measure and interpret the effect in relation to the MID if feasible to do so.  | We did not re-express SMDs in units of a familiar measure | **Rationale**. We followed GRADE and Cochrane guidance which recommends use of SMD for interpreting continuous outcomes in the absence of well-established MIDs. In addition using SMDs provided a consistent basis for interpretation across all results.  |
| 6 | B2.4 Sensitivity analysis | Analysis to examine if the meta-analysis estimates were robust to the meta-analysis mode, assumptions made to enable inclusion of results in the meta-analysis, and the impact of excluding studies at risk of bias.  | Could not be done | **Revised text.** There were too few studies to undertake these analyses. |
| 7 | B2.4 Sensitivity analysis | Our stated method was to undertake and report sensitivity analyses in which we excluded “trials judged to be at an overall high or unclear risk of bias.” | Terminology corrected (not a change to protocol) | **“**Unclear risk of bias” is the terminology used in the original ROB tool. Updated ROB2 terminology replaces this wording with “some concerns”.  |
| 8 | 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.  |
| 9 | 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. This decision was made after endorsement of the protocol, and prior to preparation of the Feldenkrais review report.  |
| 10 | B2.2Summary and synthesis when meta-analysis is not possible | For a particular comparison, if we are unable to analyse most of the effect estimates (due to incomplete reporting of effects and their variances, variability in the effect measures across the studies), we will consider alternative synthesis method. | Other synthesis methods not used. We report available data if interpretable. | **Rationale.** Where possible, we report available data and present the studies on the meta-analyses. We do not include these studies in another synthesis because the data are incompletely reported and any interpretation thereof would be inconsistent with that for other results.  |

# 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:

* GRADE judgements clarified and confirmed where appropriate.
* Clarifications to the PRISMA diagram.
* 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.

**AFG:** Australian Feldenkrais Guild

**AMED:** Allied and Complementary Medicine Database

**ATM:** Awareness Through Movement

**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

**CTM:** connective tissue massage

**DEFF:** design effect

**EUROPE PMC:** Europe PubMed Central

**FI:** Functional Integration

**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

**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** |
| --- | --- |
| ABC | Activities-Specific Balance Confidence Scale |
| AQoL | Assessment of Quality of Life  |
| ASES | Arthritis Self-Efficacy Scale |
| BDI | Beck Depression Inventory |
| CDC HRQOL-4 | Center for Disease Control HRQOL-4 |
| CES-D | Center of Epidemiologic Studies-Depression Scale  |
| FAI | Frenchay Activity Index  |
| FES | Falls Efficacy Sale  |
| FEV1 | forced expiratory volume in 1 second |
| HADS | Hospital Anxiety and Depression Scale  |
| HAP | Human Activity Profile |
| HR-QOL-BREF | WHO Quality of life-BREF |
| MFES | Modified Falls Efficacy Scale  |
| MPI | Multidimensional Pain Inventory |
| MPQ | McGill Pain Questionnaire |
| MSSE | Multiple Sclerosis Self-Efficacy Scale  |
| none | [MS] Performance Scales |
| NRS | Numerical Rating Scale  |
| OWD | Oswestry Disability Index |
| SCL-90 | Symptom Checklist-90 |
| SF-36 | Short Form Health Survey  |
| SF-MPQ | Short-form McGill Pain Questionnaire  |
| SPPB | Short Physical Performance Battery  |
| STAI | State-Trait Anxiety Inventory  |
| TFBS | Total Faulty Breathing Scale [Mohan 2020]  |
| VAS | Visual analogue scale  |
| VMBC | Visual, Musculoskeletal, and Balance Complaints Questionnaire [Zetterlund 2009]  |

1. In the protocol we reported that we would conduct sensitivity analyses excluding trials judged at high or unclear risk of bias. “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-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)