Australian Government
National Health and Medical Research Council

NHMRC

2019-2024 Review of the Australian Government Rebate on Private Health Insurance for Natural Therapies: NHMRC Process Report

JANUARY 2025

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Contents

About this report

This process report refers to the development of documents that assessed the evidence on the clinical effectiveness of 16 natural therapies: Alexander technique, aromatherapy, Bowen therapy, Buteyko, Feldenkrais, homeopathy, iridology, kinesiology, naturopathy, Pilates, reflexology, Rolfing, shiatsu, tai chi, western herbal medicine and yoga. The documents developed for each therapy included:

- Research protocols
- Evidence evaluation reports.

Background

In 2019, the Australian Government commissioned the review of the clinical effectiveness of 16 natural therapies excluded from private health insurance rebates. The excluded therapies under review were:

> *Alexander Technique, Aromatherapy, Bowen Therapy, Buteyko, Feldenkrais, Homeopathy, Iridology, Kinesiology, Naturopathy, Pilates, Reflexology, Rolfing, Shiatsu, Tai Chi, Western Herbal Medicine and Yoga.*

The Department of Health and Aged Care (the Department) engaged the National Health and Medical Research Council (NHMRC) to assist in its review. Between 2019 and 2024, NHMRC commissioned a series of evidence evaluation reports to assess published scientific evidence on each excluded therapy.

The evidence evaluations were designed to inform the Australian Government on whether certain natural therapies were underpinned by a credible evidence base that demonstrated their clinical effectiveness and re-eligibility for subsidy through private health insurance rebates. The evidence evaluations considered the Australian context when assessing the effectiveness of the therapies.

The evidence evaluations were not designed to assess all studies published for a particular therapy, nor were they intended to inform decisions about whether an individual or practitioner should use or practice a particular therapy. Assessments of cost effectiveness were not included, so any interpretations of the economic value or costs cannot be inferred from these evidence evaluations. Studies of healthy populations were not included and therefore no assessments can be made on the effectiveness of the natural therapies on this group. Assessments of safety were not included, so conclusions about how safe the therapies are cannot be inferred from these reviews.

Finalised research protocols were made publicly available on the International prospective register of systematic reviews (PROSPERO) at www.crd.york.ac.uk/prospero.

NHMRC's role in the Natural Therapies Review ended with submission of the final evidence evaluation to the Department on 7 January 2025. The Department is responsible for making recommendations about whether any of the natural therapies should be re-eligible for private health insurance rebates. The Department is also responsible for decision making about publication of the evidence evaluations and stakeholder engagement. The final decision about re-including private health insurance rebates for any of the natural therapies assessed as part of this Review is to be made by the Minister for Health and Aged Care.

Contributors

NHMRC Project Team

The evidence evaluation process was managed by a small project team within the Public Health Guidelines Section, Research Quality and Advice (formerly Research Translation) Branch at NHMRC. The NHMRC project team provided secretariat and project support throughout the review process to the contracted evidence and methodological reviewers and the NHMRC's Natural Therapies Working Committee (NTWC).

Department of Health and Aged Care Secretariat

The Department secretariat provided support to the Department's Natural Therapies Review Expert Advisory Panel (NTREAP) and managed public consultation and stakeholder engagement throughout the review process. More information about the Department's role in the Review of Natural Therapies can be found on the Department's website at www.health.gov.au.

Contractors

Evidence reviewers

NHMRC commissioned evidence reviewers to conduct the 17 evidence evaluations for the 16 natural therapies under the Review (including two separate evidence evaluations for Naturopathy due to the complexity and volume of evidence; this included Review A on *whole of practice* and Review B on *tools of the trade*). Evidence reviewers were commissioned by NHMRC via a procurement process consistent with Commonwealth Procurement Rules. The following contractors were commissioned to conduct the following evidence evaluations (PROSPERO numbers can be used to access each of the publicly available research protocols[1]):

Cochrane Australia, Monash University

• Systematic review of evidence on the clinical effectiveness of **Alexander Technique**	PROSPERO CRD42023409494
• Effectiveness of **aromatherapy** for prevention or treatment of disease, medical or preclinical conditions, and injury: a systematic review	PROSPERO CRD42021268244
• Systematic review of evidence on the clinical effectiveness of **Bowen therapy**	PROSPERO CRD42023467144
• Systematic review of evidence on the clinical effectiveness of **Buteyko**	PROSPERO CRD42023466774

[1] All evidence evaluations were endorsed as final by the NTWC by 20 November 2024 and submitted to the Department by 7 January 2025. PROSPERO pages are managed and updated by the contracted evidence reviewers for each review. NHMRC and/or the Department are not able to manage or update PROSPERO pages. As such, some PROSPERO pages have not been updated by the contracted evidence reviewers since initial upload and some evidence evaluations are listed as *ongoing* despite being complete..

• Systematic review of evidence on the clinical effectiveness of **Feldenkrais**	PROSPERO CRD42023467191
• Systematic review of evidence on the clinical effectiveness of **kinesiology**	PROSPERO CRD42024528900
• Effectiveness of **reflexology** for prevention or treatment of disease, medical or preclinical conditions, and injury: a systematic review	PROSPERO CRD42023394291

Health Technology Analysts Pty Ltd

• **Pilates** for preventing and treating health conditions: a protocol for an evidence evaluation	PROSPERO CRD42020191918
• **Shiatsu** for preventing and treating health conditions: a protocol for an evidence evaluation	PROSPERO CRD42021243311
• **Tai chi** for preventing and treating health conditions: a protocol for an evidence evaluation	PROSPERO CRD42020200130
• **Western herbal medicines** for preventing and treating health conditions: a protocol for an evidence evaluation	PROSPERO CRD42021243337
• **Yoga** for preventing and treating health conditions: a protocol for an evidence evaluation	PROSPERO CRD42020200084
• **Homeopathy** for preventing and treating health conditions: a protocol for an evidence evaluation	PROSPERO CRD42022346433

Bond University

• **Rolfing** for any indication in humans: a systematic review	PROSPERO CRD42020191251

HealthConsult Pty Ltd

• Whole system, multi-modal or single modal interventions delivered in the context of **naturopathic practice**, for preventing and treating health conditions: systematic review protocol	PROSPERO CRD42021266381

Griffith University

• Evidence Evaluation for the Diagnostic Accuracy of **Iridology**: Systematic Review Research Protocol	PROSPERO CRD42022323024
• Evidence on the clinical effectiveness of selected **nutritional supplements** prescribed in the context of naturopathic practice for preventing and/or treating injury, disease, medical conditions, or pre-clinical conditions: Overview of Reviews	PROSPERO CRD42023410906

All contracted evidence reviewers completed a declaration of interest process before being engaged by NHMRC. Declarations were checked and updated throughout the Review where required.

Independent methodological reviewers

As part of NHMRC's quality assurance process, methodological reviews were conducted on draft research protocols and draft evidence evaluation reports by independent methodological reviewers (i.e. by a different contractor group to the evidence reviewers). Methodological reviewers were commissioned by NHMRC via a procurement process consistent with Commonwealth Procurement Rules. The following groups were contracted to conduct the following methodological reviews:

Cochrane Australia, Monash University

- Homeopathy
- Naturopathy A
- Naturopathy B
- Pilates
- Rolfing
- Shiatsu
- Tai chi
- Yoga

Health Technology Analysts Pty Ltd

- Alexander Technique
- Aromatherapy
- Bowen Therapy
- Buteyko
- Feldenkrais
- Iridology
- Kinesiology
- Reflexology

Closed Loop Design, trading as Hereco

- Western Herbal Medicine

All methodological reviewers completed a declaration of interest process before being appointed by NHMRC. Declarations were checked and updated throughout the Review where required.

Independent Expert feedback

Where required, independent experts were contacted by NHMRC to provide advice or feedback on specific queries. The experts were:

- Dr Robbert van Haselen – advised on the draft research protocol for homeopathy. Dr van Haselen was also asked for input on the population prioritisation phase of the evidence evaluations, however decided not to be involved in this step.
- Dr Amie Steele – provided data collected through the Practitioner Research and Collaboration Initiative (PRACI) database which contributed to the evidence evaluations for aromatherapy, homeopathy, kinesiology, naturopathy and reflexology, and also to the population prioritisation process for aromatherapy, homeopathy and reflexology.
- Torrens University – provided information on nutritional supplements and western herbal medicines taught in their Bachelor of Health Science (Western Herbal Medicine) & Bachelor of Health Science (Naturopathy) curriculums.
- Endeavour College of Natural Health – provided information on nutritional supplements and western herbal medicines taught in their Bachelor of Health Science (Naturopathy) curriculums.

To ensure that each evidence evaluation described the way the therapies are practised in Australia, NTREAP and NTWC members liaised with experts in the field, where required, to provide general advice or clarify specific queries raised by members on the description or background of the therapies. NHMRC did not contact these experts.

Governance

The Department commissioned NHMRC to assess the evidence for the clinical effectiveness of 16 natural therapies. The Department contributed funding for expenses relating to the evidence evaluation reports, methodological reviews, committee costs and part of the NHMRC's Public Health team staffing costs. NHMRC contributed funding for some staffing costs.

All draft research protocols and evidence evaluation reports were considered and advised on by NHMRC's Natural Therapies Working Committee and the Department's Natural Therapies Review Expert Advisory Panel in line with their Terms of Reference (outlined below).

Natural Therapies Working Committee

The Natural Therapies Working Committee (NTWC) was established by NHMRC on 31 August 2019. Members of NTWC were appointed for their expertise in research methodology, synthesis methods (including epidemiology, statistics and biostatistics) and experience in conducting and designing research typical of the field of natural therapies. Some members were also practicing in the field of integrative medicine. NTWC's roles and functions were guided by its Terms of Reference.

Membership

The following members comprised NTWC across the 5 terms between 2019 and 2024:

MEMBER	POSITION	Term 1: 31 Aug 2019 to 31 Aug 2020	Term 2: 31 Aug 2020 to 31 Dec 2021	Term 3: 1 Jan 2022 to 30 Jun 2023	Term 4: 1 Jul 2023 to 31 Jul 2024	Term 5: 1 Aug 2024 to 31 Dec 2024
Professor Adele Green	Chair	-	✓	✓	✓	✓
Associate Professor Jennifer Hunter	Chair	✓	-	-	-	-
Professor Jon Wardle	Deputy Chair	✓	✓	✓	✓	✓
Professor Catherine Bennett	Member	✓	✓	✓	✓	✓
Professor Alan Bensoussan	Member	✓	✓	✓	✓	✓
Professor Rachelle Buchbinder	Member	-	✓	✓	✓	✓
Professor Susan Hillier	Member	-	✓	✓	✓	✓
Professor Philippa Middleton	Member	-	✓	✓	✓	✓
Professor Stephen Myers	Member	✓	✓	✓	✓	-
Dr Kylie Porritt	Member	✓	✓	✓	✓	✓
Professor Jerome Sarris	Member	-	✓	-	-	-
Professor Caroline Smith	Member	✓	-	-	-	-
Professor Tony Zhang	Member	✓	✓	✓	✓	✓

Terms of Reference

Terms of Reference for the initial term (Term 1) of NTWC were as follows:

> The National Health and Medical Research Council (NHMRC) is establishing a Natural Therapies Working Committee (the Committee) to oversee evidence evaluations on the clinical effectiveness of 16 natural therapies excluded from health insurance on 1 April 2019 (excluded natural therapies). These therapies are *Alexander technique, aromatherapy, Bowen therapy, Buteyko, Feldenkrais, western herbalism, homeopathy, iridology, kinesiology, naturopathy, Pilates, reflexology, Rolfing, shiatsu, tai chi, and yoga*.

The evidence evaluations will update the evidence underpinning the *2015 Review of the Australian Government Rebate on Private Health Insurance for Natural Therapies* (2015 Review) and support the Australian Government [Deputy] Chief Medical Officer to provide advice to Government on whether any of the excluded therapies should be re-included as eligible for private health insurance rebates.

The role of the Committee is to oversee the evidence evaluations commissioned by NHMRC by advising on:

- their research protocol, including:
  - the scope, clinical questions and methods to identify and evaluate relevant studies
  - appropriate inclusion and exclusion criteria.
- evidence provided by the Department of Health's Natural Therapies Expert Advisory Panel (the Panel), including its eligibility and how to incorporate this into the evidence evaluations
- the draft and final evidence evaluation reports provided by the contractors for each of the 16 natural therapies
- the evidence statements in the above reports
- any other matter requested by the NHMRC Chief Executive Officer on this project.

The evaluations will be done in two tranches[2]:

- Tranche one therapies: Naturopathy, western herbal medicine, yoga, tai chi, Pilates and shiatsu.
- Tranche two therapies: Alexander technique, aromatherapy, Bowen therapy, Buteyko, Feldenkrais, homeopathy, iridology, kinesiology, reflexology and Rolfing.

The Committee will be effective for the period 1 August 2019 to 31 August 2020, with a possibility of extension and will report to the Chief Executive Officer of NHMRC.

Appointments were extended four times throughout the project: from 31 August 2020 to 31 December 2021, from 1 January 2022 to 30 June 2023, from 1 July 2023 until 31 July 2024 and from 1 August 2024 to 31 December 2024. The role of the Committee remained the same across all terms. The Committee's Terms of Reference throughout the project are available on NHMRC's website at: www.nhmrc.gov.au.

Declaration of interest process

Committee members were required to declare their interests in writing prior to appointment, in accordance with *NHMRC's Policy on the Disclosure of Interests Requirements for Prospective and Appointed NHMRC Committee Members*.

Throughout the project and at each Committee meeting, members were reminded of their obligation to consider any interest that may have risen since the last meeting or with any agenda items. In 2021, NHMRC project team developed a *Framework for the Natural Therapies Working Committee on Disclosing Interests* (DOI Framework) at Attachment A.

The DOI framework was developed to support NTWC members in disclosing and managing interests relevant to the Natural Therapies Review. The framework provides advice about what

[2] Text relating to tranches were removed from the Terms of Reference after Term 1, as each therapy was progressing at differing rates and use of tranches were no longer suitable.

constitutes a relevant interest in the context of the Natural Therapies Review and provides information on:

- types of interests relevant to the work of NTWC
- the level of detail expected for each interest
- processes NTWC members follow when a new interest is disclosed
- assessing the significance of an interest
- options for management strategies, including a risk matrix.

A record of declared interests was managed by NHMRC and updates made to the NHMRC website as required.

Following review by NHMRC, interests declared by two members were deemed to require a management strategy:

Declared Interest:

Activities, Grants, relationships, employment, publications and board membership related to Naturopathy.

Management strategy:

For discussions about Naturopathy, the member can be in the room (or videoconference) and participate in discussions but cannot be involved in decision making. The member will not be included in out-of-session correspondence relating to naturopathy unless their expertise is specifically sought.

Declared Interest:

Activities, Grants, relationships, employment, publications and board membership related to Feldenkrais.

Management strategy:

For discussions about Feldenkrais, the member can be in the room (or videoconference) and participate in discussions but cannot be involved in decision making. The member will not be included in out-of-session correspondence relating to Feldenkrais unless their expertise is specifically sought.

No other declared interests required a management strategy or precluded any member from Committee deliberations. All discussion and decisions about declared interests were recorded in Committee meeting minutes, via email and/or on NHMRC's Committee Centre.

Full Committee meetings

The full committee met 20 times via videoconference between 2019 and 2024, with a final in-person meeting (Meeting 21) in November 2024. These meetings included discussion of the scope of the evidence evaluations, development and endorsement of research protocols, development of population and outcome prioritisation processes and feedback on the draft and final evidence evaluation reports.

Working group meetings

Working groups were established in August 2020 (NTWC term 2) and included 2-4 members per therapy. Working groups were established to streamline the progress of each evidence evaluation and to ensure the workload of the full committee was manageable. The role of each working group was to provide advice on initial draft research protocols, draft population and outcome prioritisation worksheets and draft evidence evaluations. The full NTWC was responsible for all recommendations on the final research protocols and final evidence evaluations.

Working groups continued until July 2024 (NTWC term 4), but were not used in term 5. This decision was made in consultation with the Chair to streamline committee consideration of several smaller (and more similarly structured) evaluations.

The composition or working group membership comprised a balance of content expertise (where available and where this did not coincide with any declared interests) and methodological or research expertise. If a member had declared an interest related to a particular therapy, membership of that working group was comprised of members with no declared interest. Where agreed by the working group or full NTWC, members with a declared interest could be called upon to provide advice or answer queries relating to that therapy but were not involved in any decision making. The intent was to mitigate any potential or perceived conflict of interest or undue influence on decision making. NTWC sought advice from members with an interest for the description of intervention and background sections for Feldenkrais and Naturopathy.

Working groups generally met one to three times for each deliverable per therapy. For research protocols, members met for the first few therapies and thereafter generally provided feedback and endorsed protocols as ready to send for full NTWC comment out of session. This also occurred for some of the smaller evidence evaluations, where members feedback was minimal, and a full meeting was not required. The protocols for Bowen, Buteyko and Feldenkrais were ready at the same time and were similar to the protocol for Alexander Therapy, so were considered by the full NTWC at a meeting. Outcome prioritisation was also completed by the full NTWC for Bowen, Buteyko, Feldenkrais and Kinesiology. The full NTWC also considered the draft evidence evaluations for Alexander Technique, Bowen, Buteyko, Feldenkrais, Kinesiology and Reflexology in one meeting as they were mostly similar in structure and ready for review at the same time.

Composition of working groups

- **Alexander Technique:** Professor Bennett and Professor Hillier
- **Aromatherapy:** Professor Bennett, Professor Wardle and Professor Middleton
- **Bowen Therapy^:** Professor Myers and Professor Hillier
- **Buteyko^:** Professor Myers and Dr Porritt
- **Feldenkrais^:** Professor Wardle and Professor Buchbinder
- **Homeopathy:** all Committee members (including Chair)
- **Iridology:** Professor Wardle and Professor Middleton
- **Kinesiology:** Professor Buchbinder and Professor Hillier
- **Naturopathy (A):** Professor Bennett, Professor Buchbinder, Professor Myers and Professor Zhang

- **Naturopathy (B):** Professor Bensoussan, Professor Bennett, Professor Middleton, Professor Myers and Professor Sarris (2020-21)
- **Pilates:** Professor Bensoussan, Professor Wardle and Professor Hillier
- **Reflexology:** Professor Bensoussan, Professor Wardle and Dr Porritt
- **Rolfing:** Dr Porritt and Professor Hillier
- **Shiatsu:** Dr Porritt and Professor Zhang
- **Tai Chi:** Professor Bensoussan, Professor Middleton and Professor Zhang
- **Western Herbal Medicine:** Professor Middleton, Professor Zhang, Dr Porritt and Professor Sarris (2020-21)
- **Yoga:** Professor Buchbinder, Professor Myers, Professor Hillier and Professor Zhang

^ working group did not meet, discussed by full NTWC.

Decision making

Throughout the Review, working group advice and decisions were provided to the full committee who were then required to reach a quorum to make a final decision and progress the evaluations to their next stage. Quorum was considered a minimum of five to six members, depending on the overall number of NTWC members (including periods of leave).

Final endorsement of the evidence evaluations was considered by the full committee (and not working groups). Quorum was required and upon final endorsement, the evaluations progressed through NHMRC Executive clearance for approval for submission to the Department.

Natural Therapies Review Expert Advisory Panel

The Natural Therapies Review Expert Advisory Panel (NTREAP) was established by the Department of Health and Aged Care in 2019. NTREAP was tasked with providing advice to the Chair, Professor Michael Kidd (Deputy Chief Medical Officer until June 2023 and then external Chair) about the 16 excluded natural therapies on:

- additional evidence of clinical effectiveness published since the 2014–15 review
- high-quality evidence not included in the 2014–15 review
- the draft evidence evaluation reports for each therapy.

In addition to the NTREAP Terms of Reference, NHMRC sought NTREAP input on the draft research protocols, population prioritisation (where applicable, as not all therapies required this step) and the outcome prioritisation process.

More information about NTREAP is available on the Department of Health and Aged Care's website at www.health.gov.au.

Evidence evaluation development

Scoping

NHMRC sought initial scoping reports (or 'horizon scans') which purposed to:

- provide a brief overview of the number of studies, study types and population, intervention, comparator, outcome (known as 'PICO') likely to be identified in the systematic literature search
- provide a rationale on the selection of a study design (see **below** for descriptions of study designs) for the evidence evaluation
- provide recommended search terms, databases and detailed inclusion/exclusion criteria to optimise search results
- develop a thorough, well-informed description of the therapy
- develop a summary of how the therapy might work without pre-empting the evidence (including in-vitro studies, explanatory studies on healthy adults etc.)
- thoroughly scope the literature and relevant practitioner websites (e.g. contact experts in the field) in Australia and abroad, to ensure a well-informed and accurate description of each therapy as practiced in Australia.

Horizon scan reports were initially contracted as a separate deliverable to the research protocol in the first tranche of therapies. However, for most of the second tranche of therapies this step was incorporated into drafting the research protocol to expedite timing.

Study selection and data extraction

Evidence evaluations were initially intended to be systematic reviews of systematic reviews (overviews – see *Framework for selecting study designs* for more information) of evidence that was published since the 2014-15 review of the Australian Government Rebate on Natural Therapies for Private Health Insurance. Early in the process, NTWC and NTREAP raised that for some therapies in the Natural Therapies Review, overviews may not be appropriate. Based on NTWC/NTREAP advice and horizon scanning results, NHMRC and the Department agreed that it would be more appropriate to conduct a systematic review of primary evidence (e.g. randomised control trials) for most therapies in the Review. The exceptions to this were for Western Herbal Medicine, Naturopathy Review B (selected nutritional supplements) and the Acupressure supplement within the Shiatsu report, for which systematic review level evidence was evaluated under an overview[3] approach (i.e. systematic review of systematic reviews).

[3] The overview method (systematic review of systematic reviews) compiles evidence from multiple systematic reviews to examine the effectiveness of specific interventions (e.g. the clinical effectiveness of western herbal medicine on specific populations/conditions) and generally is limited to recent/up to date systematic reviews (e.g. published in the last 5 years). This method is often used when the research question is broad in scope (i.e. what is the clinical effectiveness of western herbal medicine) and where there are many eligible studies, resource and timing constraints. Overviews utilise a clearly formulated question and use systematic and explicit methods to identify, select, and critically appraise relevant systematic reviews, and to collect and analyse data from included systematic reviews. Overviews usually take one of two forms: (1) using systematic reviews to find primary studies with risk of bias (etc.) information and then synthesising the relevant primary study results or (2) choosing the "best" systematic review to fit the Population, Intervention, Comparison, and Outcome (PICO) and presenting results from that without reanalysis. Two evaluations in the Natural Therapies Review are overviews: Western Herbal Medicine and Naturopathy Review B. The supplementary report on Acupressure (within the Shiatsu evaluation) is also an overview. Western Herbal Medicine and Acupressure use overview form 1 and Naturopathy Review B uses overview form 2.

Framework for selecting study designs

Study designs

- A **systematic review of randomised controlled trials and non-randomised studies of interventions (SR of RCTs and NRSI)** was selected when a therapy was unlikely to have a large evidence base of RCTs alone. To be eligible, NRSIs needed include minimum design features which are outlined in each research protocol, where relevant.
- A **systematic review of randomised controlled trials (SR of RCTs)** was selected when a therapy was likely to have a substantial RCT evidence base. For this study design, NRSI were only eligible for inclusion for certain populations, settings or outcomes where an NRSI was considered more appropriate or feasible, for example, in children, pregnant people, long-term or rare outcomes.
- A **systematic review of systematic reviews or overview (SR of SRs)** was selected for therapies that assessed a component of a therapy or 'tool of the trade' for example, western herbal medicines and nutritional supplements that can be used independent of a delivery by a practitioner, such as a naturopath or herbalist.
- **Primary studies measuring diagnostic accuracy** were selected for therapies that were considered diagnostic tools rather than interventions (this was applied to the evidence evaluation for iridology).

Study design for each therapy

THERAPY	STUDY DESIGN
Alexander technique	SR of RCTs and NRSI
Aromatherapy	SR of RCTs
Bowen therapy	SR of RCTs and NRSI
Buteyko	SR of RCTs and NRSI
Feldenkrais	SR of RCTs and NRSI
Homeopathy	SR of RCTs
Iridology	Diagnostic accuracy studies (e.g. Case control studies)
Kinesiology	SR of RCTs and NRSI
Naturopathy: • Review A - whole system, multi-component or single component interventions delivered in the context of naturopathic practice. • Review B – selected nutritional supplements (as a tool of naturopaths).	SR of RCTs and NRSI SR of SRs (Overview)
Pilates	SR of RCTs and NRSI
Reflexology	SR of RCTs
Rolfing	SR of RCTs and NRSI
Shiatsu	SR of RCTs and NRSI

THERAPY	STUDY DESIGN
Acupressure (as a tool of shiatsu)	SR of SR's (Overview)
Tai chi	SR of RCTs
Western herbal medicines (as a tool of naturopaths and herbalists)	SR of SRs (Overview)
Yoga	SR of RCTs

RCT = Randomised Controlled Trials

NRSI = Non-Randomised Studies of Interventions

More information on the study design features selected for each individual therapy is available in finalised research protocols linked on NHMRC's website at www.nhmrc.gov.au or on PROSPERO.

Principles for populations and prioritisation

'At risk' populations

To address one of the criticisms of the 2015 Review, the inclusion criteria were expanded to include prevention of 'at risk' populations (the 2015 Review limited eligibility to people with a diagnosed clinical condition). To be considered, NTWC agreed:

- that 'at risk' be limited to studies that provide appropriate evidence that an individual study participant, not a population in general, has met a minimum threshold for being 'at risk' - i.e. presenting with symptoms, or being assessed for symptoms of a condition, or a history of previous condition, etc.
- for studies where there is uncertainty about whether the minimum threshold has been met, working groups were to review the aim of the study and decide whether the study was eligible or not.

Population prioritisation

While the evidence evaluations aimed to assess the full breadth of eligible studies, in some cases, the number of published studies was too great to support synthesis and analysis of all eligible studies within the time and resource limits provided to the evidence reviewers. In these cases, NTWC decided to focus analysis and synthesis on those populations most relevant to the Australian context. To do so, NTWC followed a population prioritisation process broadly consistent across all therapies where required[4].

To select priority populations, the NTWC considered a blinded list of all eligible populations/conditions that were identified following screening against the inclusion/exclusion criteria for each therapy as detailed in the protocol. Where possible, populations and conditions were selected based on objective data about practice in the Australian context (e.g. practitioner or patient surveys that reported reasons for use in Australia). NTREAP input was sought to inform development of a final list of priority populations. Studies which included populations and

[4] For aromatherapy and reflexology a unique process was developed due to the mechanism of action (i.e. that these therapies treat symptoms rather than the underlying conditions) This process is outlined within the final research protocols (linked at www.nhmrc.gov.au or see PROSPERO).

conditions not prioritised for synthesis were listed in an evidence inventory in each evidence evaluation report, to ensure that all eligible evidence was catalogued.

Population prioritisation was conducted for the following therapies:

- Aromatherapy[4]
- Homeopathy
- Naturopathy Review B (selected nutritional supplements)
- Pilates
- Reflexology[4]
- Tai Chi
- Western Herbal Medicine, and
- Yoga.

Principles for outcome prioritisation

In general, it is considered good methodological practice to specify outcomes of interest at the protocol stage. The purpose of pre-specifying outcomes to be prioritised in a review is to:

- reduce the risk of bias, by pre-specifying which outcomes will be prioritised for data synthesis (and hence ensuring there is no selective reporting of outcomes)
- aid transparency and reproducibility in systematic reviews
- ensure that the outcomes considered by the review are most relevant to decision-making
- make the best use of limited review resources by focusing on the evidence that is most relevant to decision-making.

For the Natural Therapies Review, NTREAP was initially asked to identify key outcomes they would like to see assessed for each population included in the evidence evaluations. Given the complexity of specifying outcomes at the protocol stage for an unknown range of populations, in consultation with NTWC, the project team developed a blinded outcome prioritisation process that NTWC and NTREAP applied to each therapy. This process took place after population prioritisation but without knowledge of study results.

For each population identified for inclusion in an evidence evaluation (see population prioritisation process above), the evidence reviewers developed a spreadsheet which included the population/condition, outcome domains from eligible studies, “core outcome sets” for each population/condition if available (e.g. *Core outcome measures in effectiveness trials* (COMET) database) and/or primary and secondary outcomes in Cochrane reviews relevant to the condition/population. The inclusion of outcomes from both the published studies and from core outcome sets and relevant Cochrane reviews was to ensure that the outcomes selected covered those important for decision-making, not only those measured in studies or for which evidence is available.

In deciding which outcomes should be included in evidence evaluations, NTWC considered what was most relevant and meaningful to the intended users and recipients of the reviewed evidence and the importance to decision making, using the GRADE (Grading of Recommendations,

Assessment, Development and Evaluation)[5] rating scale (critical, 7-9; important but not critical, 4-6, of limited importance, 1-3).

Critical outcomes were considered essential for decision making and form the basis of a 'Summary of findings' table in each review, with the aim being to include up to 7 outcome domains consistent with Cochrane Guidance (1). In some cases, NTWC decided that there were not 7 relevant outcomes so fewer than 7 outcomes were included. In some cases, outcomes were split at later stages and so the number of outcomes was not always 7. Results data were extracted for studies that include outcomes prioritised (as critical or important) in the evidence evaluation. If evidence was lacking for an outcome considered critical or important for a population, this was acknowledged as a gap in the evidence base, rather than being omitted as an outcome in the evidence evaluation. Studies that did not report data for any outcomes prioritised for data extraction were generally listed in the 'Characteristics of included studies' tables, which included details about which outcomes the study did measure and report.

Key steps for each Evidence Evaluation

The milestones for each of the 16 evidence evaluations are outlined below. These include the general process for each evidence evaluation. The key steps outlined below were applied across reports. Some minor differences (such as to order of the key steps) required to expedite the process or align with contractor and committee timeframes and workloads may not be explicitly outlined below.

Major milestones per therapy	Key Step	Who
Research Protocol	**Submission of draft research protocol**	Evidence reviewer
	Check and review draft protocol for inconsistencies before progressing to methodological review	NHMRC project team
	Draft protocol sent to independent methodological reviewer and NTREAP for review	NHMRC project team
	Submission of draft methodological review report	Methodological reviewer
	Submission of NTREAP input into draft protocol	NTREAP
	For homeopathy only: input from external homeopathy researcher	*Dr Van Haselen*
	Collate feedback from NTREAP and methodological review for NTWC consideration	NHMRC project team
	Review draft protocol, consider methodological review and NTREAP input and provide feedback	NTWC working group or full NTWC (depending on therapy)

[5] GRADE is an internationally recognised framework and tool. The Cochrane Handbook recommends that GRADE be adopted to assess the certainty (or quality or strength) of an evidence base as part of a systematic review.

	Provide evidence reviewers with feedback from NTWC/working group (inclusive of decisions made about methodological review feedback and NTREAP input)	NHMRC project team
	Submission of revised research protocol from evidence reviewer	Evidence reviewer
	Endorsement of protocol	Full NTWC
	Feedback (if any) provided to evidence reviewer	NHMRC project team
	Submission of final protocol and upload to PROSPERO	Evidence reviewer
	Final protocol circulated to NTWC and NTREAP for noting	NHMRC project team
Population Prioritisation (where applicable)	Develop population prioritisation spreadsheet including list of populations from eligible studies, Australian or equivalent survey data and/or PRACI data (where available)	Evidence reviewer and NHMRC project team
	Population prioritisation spreadsheet circulated to self-nominated NTREAP members for input into priority populations (may include input from external experts at the discretion of NTREAP)	NTREAP (specific members)
	Submission of NTREAP input into population prioritisation	Department of Health and Aged Care
	Population prioritisation circulated to NTWC working group for initial input/prioritisation	NHMRC project team
	Meet to discuss priority populations and groupings	NTWC working groups and NHMRC project team
	Formal endorsement of final population prioritisation	Full NTWC
	Final list of populations circulated to evidence reviewer	NHMRC project team
Outcome Prioritisation	Submission of blinded outcome prioritisation spreadsheet (including populations and conditions from eligible studies, Core Outcome sets and relevant Cochrane reviews)	Evidence reviewer
	Outcome spreadsheet circulated to self-nominated NTREAP members for input into priority outcomes (may include input from external experts at the discretion of NTREAP)	NTREAP (specific members)

	Submission of NTREAP input into outcome prioritisation	Department of Health and Aged Care
	Blinded outcome prioritisation spreadsheet (including input from NTREAP members) circulated to NTWC working group or full NTWC (depending on therapy)	NHMRC project team
	Submission of up to 7 outcomes per population/condition	NTWC working group members or full NTWC (depending on therapy)
	Meet to discuss priority outcomes	NTWC working groups or full NTWC (depending on therapy) and NHMRC project team
	Formal endorsement of final outcome prioritisation	Full NTWC
	Final list of outcomes submitted to evidence reviewer	NHMRC project team
Evidence evaluation and technical report	**Submission of draft evidence evaluation and technical reports**	Evidence reviewer
	Reports were checked for consistency with protocols, and for later reports, with NTWC preferences	NHMRC project team
	For the first two reports (Pilates and Rolfing) only: NTWC provided feedback on the draft evidence evaluation before methodological review and NTREAP. This focused largely on overall formatting to be used in these and subsequent reports	*NTWC*
	Submission of next draft evidence evaluation and technical report	Evidence reviewer
	Check and review draft evidence evaluation and technical report before progressing to methodological and NTREAP review	NHMRC project team
	Draft evidence evaluation and technical report sent to independent methodological reviewer and NTREAP for review/comment	NHMRC project team
	Submission of draft methodological review report	Methodological reviewer
	Submission of NTREAP input into evidence evaluation	Department of Health and Aged Care
	Collate feedback from NTREAP and methodological review for NTWC consideration	NHMRC project team

	Review and provide feedback on draft evidence evaluation and technical report and consider methodological review and NTREAP input	NTWC working group or full NTWC (depending on therapy)
	Provide evidence reviewer with feedback from NTWC (inclusive of decisions made about methodological review feedback and NTREAP input)	NHMRC project team
	Submission of **final draft evidence evaluation and technical report** incorporating feedback from methodological review, NTREAP and NTWC	Evidence reviewer
	Final draft report circulated to full NTWC for review and endorsement	NHMRC project team
	Review and endorsement of final draft report as the **final evidence evaluation report** with no changes or minor changes (as noted by NTWC)	Full NTWC
	Any final minor changes actioned (e.g. typos, formatting, consistency)	NHMRC project team
	Final report prepared for NHMRC Executive clearance	NHMRC project team
	Final report cleared by NHMRC Executive for submission to the Department of Health and Aged Care	NHMRC Executive
	Final report sent to Department of Health and Aged Care with a summary of NTWC discussion and responses to NTREAP feedback	NHMRC project team
	Final report and summary of NTWC discussion and responses to NTREAP feedback provided to NTREAP for noting	Department of Health and Aged Care
	Final report provided to NHMRC Council for noting	NHMRC Executive, Council and project team
	Final report submitted to (former) Chief Medical Officer	Department of Health and Aged Care
	Recommendations provided to the Minister for Health and Aged Care	(former) Chief Medical Officer

Additional checks by NTWC on evidence for Western Herbal Medicine

The overview of Western Herbal Medicine (WHM) used systematic reviews to find primary study information (such as risk of bias) and then synthesised the relevant primary study results. A total of 854 systematic reviews were identified as eligible for inclusion in this overview. Of these, 402 systematic reviews covering 16 conditions were considered in the evidence evaluation. For the synthesis, 270 RCTs covering 11 prioritised conditions compared WHMs with placebo and 5 RCTs covering 2 prioritised conditions compared WHMs with inactive control (no intervention, wait list or usual care) were considered.

Because of the overall large volume of evidence, it was not feasible to assess the evidence for 4 of the 16 prioritised conditions (these were diabetes, impaired glucose tolerance, metabolic syndrome, upper respiratory tract infections). Therefore, systematic reviews for these 4 conditions were not critically appraised or included in synthesis. The Natural Therapies Working Committee (NTWC) was not involved in selection of which prioritised conditions were completed versus not completed. Instead, this was a pragmatic decision made by the reviewer to allow them to finalise the report within the time and resource constraints.

When seeking final endorsement from NTWC, committee members expressed concern that some of the 4 conditions not examined in synthesis were important to the Australian public and may have a large evidence base. They felt this was particularly true of diabetes/impaired glucose tolerance and upper respiratory tract infections (URTI). The NHMRC project team advised that unless the evidence for these conditions was of high certainty, it would not change the overall conclusion that there was *low to moderate certainty evidence for effectiveness of Western herbal medicine for some conditions*.

NHMRC also sought advice from the Department on this matter, who advised that they considered this review complete, despite the reviewer having made a pragmatic decision to not provide results for 4 conditions. The Department asked for this to be detailed more explicitly within the report, particularly in the Limitations section and these changes were made by NHMRC.

To assist NTWC in ensuring they had enough information to endorse this report, the NHMRC project team proposed a check to confirm that no high-quality evidence had been missed for diabetes/impaired glucose tolerance and URTI (i.e. to check there was no evidence that would have changed the overall conclusion of the report). This proposal involved looking at the information already collected by the reviewers (i.e. that in the appendices) and selecting some reviews to be sent for ROBIS assessment (a tool for assessing risk of bias in systematic studies). ROBIS is an assessment of the overall bias of a review; that is, a way to check whether the results of the review should be trusted.

The appendices of the report contained information about which reviews the reviewers would have selected to be critically evaluated for these 4 conditions and the outcomes included in those reviews. For diabetes, the information in the appendices also included the number of participants in synthesis, how many of those matched the PICO (population, intervention, outcome and comparator) and risk of bias of included studies as reported in those reviews.

Overall, there were 23 reviews on diabetes and impaired glucose tolerance noted for critical appraisal by the WHM reviewer. Of these, 13 had outcomes prioritised as critical or important by NTWC. For URTI there were 7 reviewers noted for critical appraisal and data extraction.

For each review with prioritised outcomes, the NHMRC project team collated the following information for NTWC's consideration:

- Review ID
- Year review was published
- Population
- Intervention (specific herbs included)
- Outcomes
- For diabetes we were also able to include number of studies and participants, Risk of Bias as listed by the original reviews, and any other relevant comments about outcomes etc.

NTWC were asked to use their methodological and clinical expertise to choose the 5 'best' systematic reviews to be sent for a ROBIS assessment by independent reviewing company, KSR Evidence. NTWC were not guided on criteria for choosing the 'best' systematic reviews but were instead asked to apply their individual knowledge and expertise to rank the reviews by principles they deemed important. This was noted by members to include how relevant the systematic review was to providing information on relevant populations, interventions and outcomes, the size of the study and any information available about Risk of Bias of included studies. Six (of 9) members provided feedback, which met quorum. For diabetes, 3 of the reviews were rated by 4 or more NTWC members, 1 review by 3 members and 4 reviews by 2 members. As such, all 8 reviews of these reviews for diabetes were sent for a ROBIS assessment. For URTI there were only 7 reviews, one of which did not specify the intervention (specific herbs used). As such, the 6 other reviews for URTI were sent for ROBIS assessment.

The ROBIS assessments for the each of the 8 reviews on diabetes and 6 on URTI (see Attachment B) were provided to NTWC (along with the evidence previously provided in the spreadsheet) ahead of their 20 November 2024 meeting. At this meeting, NTWC discussed this information and it was noted that:

- For diabetes/impaired glucose tolerance, 7 of 8 reviews had overall **high** risk of bias and the remaining one review was **unclear**.
- For URTI, 4 of 6 reviews had overall **high** risk of bias, one review was **unclear**, and one review had overall low risk of bias.

In total, only one of the reviews had overall low risk of bias: a review of Elderberry for URTI. For this single review, NTWC looked at the results as presented in the abstract, which concluded that there was low certainty evidence of effect on some outcomes. NTWC concluded that the results of this review would not change the overall conclusion of the WHM report. NTWC advised that inclusion within the main report or appendices of this ROBIS information would be inconsistent with the level of assessment currently contained in the Natural Therapies Review.

Based on this process, NTWC were confident that **no** high-quality evidence had been missed for important conditions in this review (i.e. the results for the single low ROBIS review would not change the overall conclusion of the WHM report and were considered to be consistent with the overall conclusion of the report that there is some *low to moderate certainty evidence of effectiveness of WHM*).

Assessment of Naturopathy as a Modality

NTWC considered that the available evidence for naturopathy as a whole-system treatment was probably limited and sought an additional review on 'tools of the trade' to aid in the Government's decision making. The two reviews specific to naturopathy are Review A (whole-system) and Review B (nutritional supplements as a 'tool of the trade'). In considering the evidence on the overall effectiveness of naturopathy as a modality, NTWC advised that the two evidence evaluations for Naturopathy, plus the review of Western Herbal Medicines (WHM), should be considered by the Department to assess the overall effectiveness of naturopathy as a modality, as relevant to the re-inclusion of Naturopathy for private health insurance rebates. NTWC advised that nutritional supplements and herbal medicine are considered core modalities (i.e. an individual must have qualifications in both modalities to be considered a naturopath) most used by naturopaths.

Other commonly prescribed 'tools of the trade' used by naturopaths, including lifestyle modifications, dietary modifications, exercise and meditation were not considered, as they were out of scope for the purposes of the Natural Therapies Review. Yoga, homeopathy and iridology are sometimes considered tools of the trade, but were assessed as separate therapies under the Review. NTWC advised that these are not considered core modalities of naturopathy (i.e. practicing these modalities is optional for naturopaths), nor core units in any Tertiary Education Quality and Standards Agency approved naturopathy curriculums.

A document titled *Guidance Overview for the Assessment of Naturopathy as part of the Natural Therapies Review* was developed by NHMRC for the Department of Health and Aged Care outlining the background and information relevant to assessing naturopathy as a modality using these three evidence evaluations (Naturopathy Review A, Review B and WHM).

Development of Evidence to Decision framework

NHMRC Project Team drafted two additional documents as resources for the Department to aid in their evidence to decision making process. The documents were designed to complement the final evidence evaluation reports. The documents include:

1. GRADE **Evidence to Decision framework** (Attachment C) for 'coverage decisions' – the document provides:
    - an overview of the GRADE Evidence to Decision frameworks used by NHMRC when considering and providing judgement on evidence-based decisions and recommendations
    - information about how evidence to decision frameworks can be adopted alongside evidence evaluation reports
    - an indication of what evidence evaluation reports do and do not answer under the evidence to decision framework.
2. Outline of how to assess **GRADE certainty of evidence** (Attachment D) - the document provides:
    - an overview of the GRADE approach to rating certainty and is intended to assist in translating the GRADE judgements and statements in the natural therapy evidence evaluations.

List of Attachments

Attachment A - Framework for the Natural Therapies Working Committee on Disclosing Interests (DOI Framework)

Attachment B – KSR ROBIS Assessments for Western Herbal Medicine

Attachment C - GRADE Evidence to Decision framework

Attachment D - GRADE certainty of evidence

References

1. Schünemann HJ, Higgins JPT, Vist GE, Glasziou P, Akl EA, Skoetz N, Guyatt GH. Chapter 14: Completing 'Summary of findings' tables and grading the certainty of the evidence [last updated August 2023]. In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA (editors). *Cochrane Handbook for Systematic Reviews of Interventions* version 6.5. Cochrane, 2024. Available from www.training.cochrane.org/handbook.