



Australian Government

Department of Health

Review of the Australian Government Rebate on Natural Therapies for Private Health Insurance

Professor Chris Baggoley AO

Chair, Natural Therapies Review Advisory Committee, Department of Health

Australian Government Department of Health

Review of the Australian Government Rebate
on Natural Therapies for Private Health Insurance

Australian Government Department of Health

Review of the Australian Government Rebate on Natural Therapies for Private Health Insurance

Online ISBN: 978-1-76007-171-4

Publications approval number: 11045

Copyright Statement:

Internet sites

© Commonwealth of Australia 2015

This work is copyright. You may download, display, print and reproduce the whole or part of this work in unaltered form for your own personal use or, if you are part of an organisation, for internal use within your organisation, but only if you or your organisation do not use the reproduction for any commercial purpose and retain this copyright notice and all disclaimer notices as part of that reproduction. Apart from rights to use as permitted by the *Copyright Act 1968* or allowed by this copyright notice, all other rights are reserved and you are not allowed to reproduce the whole or any part of this work in any way (electronic or otherwise) without first being given the specific written permission from the Commonwealth to do so.

Requests and inquiries concerning reproduction and rights are to be sent to the Communication Branch, Department of Health, GPO Box 9848, Canberra ACT 2601, or via e-mail to copyright@health.gov.au.

Contents

Foreword and acknowledgments	1
Executive summary.....	3
Quality of included reviews	5
Overview results	7
Effectiveness.....	11
Safety and cost-effectiveness	12
The role of the Advisory Committee	12
Background.....	13
Definition of a natural therapy	13
Hypnotherapy, biochemistry, nutrition and psychotherapy	14
Ayurveda.....	14
Department of Veterans' Affairs review.....	16
National Health and Medical Research Council (NHMRC).....	16
Evidence review process.....	17
Language restrictions	20
Limit on publication date	21
Quality.....	22
Submissions to the Review	25
NHMRC homeopathy review	25
Summary of evidence reports	28
Alexander technique overview report.....	29
Objective.....	29

Definition	29
Methods.....	30
Discussion.....	30
Conclusions.....	33
Submissions received on Alexander technique.....	34
Aromatherapy overview report.....	36
Objective.....	36
Definition	36
Methods.....	36
Discussion.....	37
Conclusions.....	42
Submissions received on aromatherapy.....	42
Bowen therapy overview report.....	44
Objective.....	44
Definition	44
Methods.....	44
Discussion.....	45
Conclusions.....	48
Submissions received on Bowen therapy	48
Buteyko therapy overview report.....	50
Objective.....	50
Definition	50
Methods.....	50

Discussion	51
Conclusions	54
Submissions received on Buteyko	55
Feldenkrais overview report	56
Objective	56
Definition	56
Methods	56
Discussion	58
Conclusions	61
Submissions received on Feldenkrais	62
Herbalism overview report	64
Objective	64
Definition	64
Methods	64
Discussion	65
Conclusions	66
Submissions received on herbalism	67
Homeopathy overview report	69
Objective	69
Background	69
NHMRC’s homeopathy review	70
Definition	70
Methods	70

Results of the Review	72
Plain language summary	72
Research gaps.....	72
Submissions received on homeopathy	73
Iridology overview report	76
Objective	76
Definition	76
Methods.....	76
Discussion	76
Submissions received on iridology	78
Kinesiology overview report.....	79
Objective	79
Definition	79
Methods.....	79
Discussion	80
Conclusions.....	83
Submissions received on kinesiology	84
Massage therapy overview report	85
Objective	85
Definition	85
Methods.....	86
Discussion	90
Conclusions.....	96

Submissions received for massage therapy.....	99
Naturopathy overview report	102
Objective.....	102
Definition	102
Methods.....	103
Discussion.....	103
Safety	106
Cost-effectiveness	106
Conclusions.....	107
Submissions received for naturopathy	108
Pilates overview report	110
Objective.....	110
Definition	110
Methods.....	111
Discussion.....	111
Safety outcomes	114
Conclusions.....	117
Submissions received on Pilates	118
Reflexology overview report	119
Objective.....	119
Definition	119
Methods.....	119
Discussion.....	120

Adverse events/safety	122
Conclusions.....	123
Submissions received for reflexology.....	123
Rolfing overview report.....	125
Objective.....	125
Definition	125
Methods.....	125
Discussion.....	126
Conclusions.....	126
Submissions received for rolfing	127
Shiatsu overview report	129
Objective.....	129
Definition	129
Methods.....	130
Discussion.....	130
Conclusions.....	131
Submissions received for shiatsu	132
Tai chi overview report.....	133
Objective.....	133
Definition	133
Methods.....	134
Discussion.....	134
Conclusions.....	137

Safety	139
Submissions received for tai chi	139
Yoga overview report	141
Objective	141
Definition	141
Methods.....	142
Discussion.....	142
Conclusions.....	155
Submissions received for yoga	157
Glossary	158
Acronyms and abbreviations.....	161
Attachment A	163
Natural Therapies Review Advisory Committee: Membership.....	163
Attachment B	164
Private health insurance	164
REFERENCES	168

Foreword and acknowledgments

This report has been produced by the Australian Government Department of Health (the Department). Drafts of the report were reviewed by the Natural Therapies Review Advisory Committee (NTRAC) chaired by the Chief Medical Officer (CMO), Professor Chris Baggoley AO.

The Office of the National Health and Medical Research Council (ONHMRC), as part of the Review, conducted a comprehensive literature review of natural therapies and assessed evidence provided by stakeholders. Evidence was assessed in the context of the National Health and Medical Research Council's 'NHMRC additional levels of evidence and grades for recommendations for developers of guidelines' (NHMRC Evidence Guidelines).¹

The Department acknowledges the contribution of the following groups:

Natural Therapies Review Advisory Committee (NTRAC)

The Department thanks the Advisory Committee members for their time, cooperation, engagement and technical contributions to this important work and overall the method of professionalism and transparency that they have shown throughout the review process.

Office of National Health and Medical Research Council (ONHMRC)

The Department acknowledges the shared goals and collaborative approach of the ONHMRC in relation to the examination of the available evidence, and the principles under which they worked together with us in the pursuit of the final goal.

The ONHMRC contributed a final consolidated process report to the Department on 28 July 2014. This report was intended as a guide to assist in interpreting the systematic reviews (SRs) that were done for each therapy and as a summary of the findings of the evidence reviews for the selected in-scope natural therapies.

¹ http://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/developers/nhmrc_levels_grades_evidence_120423.pdf

Reviewers

The Department also thanks the authors of the literature reviews, from which material in this report is drawn, and recognises their substantial contribution to the project.

Natural therapy associations and individuals

The Department acknowledges the 46 organisations and individuals who made a submission in relation to the Review and presented their work to the Advisory Committee. Without their contributions the Review would not have been as well informed.

Secretariat

We also acknowledge the work by the Secretariat in the preparation of this report and the administration of the Review.

Executive summary

The Review of the Australian Government Rebate on Private Health Insurance (the Rebate) for natural therapies (the Review) was announced in the 2012–13 Budget to ensure private health insurance covers clinically proven treatments. The Department would review ‘natural therapies’ to identify services that are not underpinned by a robust evidence base and for which the private health insurance rebate should be withdrawn.

The purpose of the Review was to ensure that natural therapies are underpinned by a credible evidence base that demonstrates their clinical efficacy, cost-effectiveness and safety and quality. The Rebate will be paid for insurance products that cover natural therapy services as described in the previous Government’s media release:

The Private Health Insurance Rebate will be paid for insurance products that cover natural therapy services only where the Chief Medical Officer finds there is clear evidence they are clinically effective.²

Such clear evidence has not been found.

The ONHMRC assisted the Department with the review by conducting comprehensive literature reviews of in-scope natural therapies and assessing evidence provided by stakeholders.

As with any methodology, this evidence review has limitations that are outlined below and discussed further within the body of the report. These should be taken into account when considering the evidence. In summary, these limitations are:

1. Literature searches were restricted to systematic reviews (SRs) published within the last 5 years (see page 21).
2. The searches were limited to SRs published in the English language databases, although these SRs may have included primary studies published in other languages. For some disciplines there is potentially a body of literature published in languages other than English, which may have reduced sources of evidence from being considered (see page 20).

² Media release ‘Government investing in frontline health services’ – Minister Plibersek, 8 May 2012 – [http://www.health.gov.au/internet/budget/publishing.nsf/Content/1CB1844163789BECCA257CA0003FF547/\\$File/healthmedia01.pdf](http://www.health.gov.au/internet/budget/publishing.nsf/Content/1CB1844163789BECCA257CA0003FF547/$File/healthmedia01.pdf)

3. There was considerable variation in the therapies that were reviewed and this necessitated some variation in the methodological approach. An alternative and more feasible approach in some circumstances was to consider the 'health service' delivered by the therapist, particularly for herbalism (see page 64), naturopathy (see page 102) and myotherapy (see page 85).

For a few modalities (Alexander technique, Buteyko, massage therapy, tai chi, yoga), there was evidence, which was graded as low to moderate quality, that these natural therapies may improve certain health outcomes for a limited number of clinical conditions. However, in most cases the quality of the overall body of evidence was not sufficient to enable definite conclusions to be drawn about the clinical effectiveness of the therapies. Very little literature exists in the area of health service delivery for most of the health-care disciplines evaluated in this report and this particularly affected consideration of herbalism, naturopathy and myotherapy.

Overall, there was not reliable, high-quality evidence available to allow assessment of the clinical effectiveness of any of the natural therapies for any health conditions. Component treatment modalities in herbalism (see page 64) and naturopathy (see page 102) were not considered.

The absence of evidence does not in itself mean that the therapies evaluated do or do not work. Natural therapies emerged in an environment where there was not a premium on rigorous evidence base. Where there is limited evidence in some modalities, there is value in conducting more research. It is also possible that there is a lack of evidence because the therapies are not effective, but it is also possible that further research may identify clinical conditions for which particular therapies are effective. This would appear more likely for those therapies that have some supporting evidence and scientific plausibility (for example, massage therapy) than for those that do not (for example, homeopathy). It is important to be mindful of the need to base conclusions on the entire body of evidence (that is, properly conducted SRs that have retrieved and evaluated the full body of evidence as a whole) rather than emphasising selected individual studies that may support a particular hypothesis. With the research gaps that have been identified, there are numerous opportunities for future research in this field as there is a clear lack of high-quality research available. Future research should focus on rigorous, well-designed,

randomised controlled trials that assess the effectiveness of the method in improving health outcomes in specific patient populations.

Quality of included reviews

A systematic review attempts to identify, appraise and synthesise all the empirical evidence that meets pre-specified eligibility criteria to answer a given research question. Researchers conducting SRs use explicit methods aimed at minimising bias to produce more reliable findings that can be used to inform decision-making (Cochrane Collaboration, 2011).

All SRs identified for inclusion in the overview were critically appraised and evaluated using the AMSTAR measurement tool (Shea, et al., 2007). The tool is an 11-item questionnaire that can be used to assess the methodological quality of SRs by assessing the presence of the criteria as presented in **Table 1**.

Each SR was assigned an AMSTAR score (maximum of 11 out of 11). SRs with an AMSTAR score of 9 to 11 were rated high-quality; those with an AMSTAR score between 6 and 8 were rated as moderate quality, and SRs with an AMSTAR score of 5 or less were rated as low quality.

The quality of the body of evidence was assessed using the GRADE³ approach to grading the quality of evidence and strength of recommendations. In rating the quality of the body of evidence, 5 domains are assessed: study design; inconsistency; indirectness; imprecision; and publication bias. The body of evidence for each outcome domain is assigned a quality rating on a scale ranging from very low to high, according to the level to which the body of evidence had been downgraded across the 5 GRADE domains. The GRADE process informs the recommendation and the strength of that recommendation. The definition of each quality rating is outlined in **Table 2**.

3 GRADE – Grading of Recommendations Assessment Development and Evaluation

Table 1. AMSTAR quality criteria for systematic reviews

Study type	Quality criteria
Systematic reviews	<p>Was an 'a priori' design provided?</p> <p>Was there duplicate study selection and data extraction?</p> <p>Was a comprehensive literature search performed?</p> <p>Was the status of publication (i.e. grey literature) used as an inclusion criterion?</p> <p>Was a list of studies (included and excluded) provided?</p> <p>Were the characteristics of the included studies provided?</p> <p>Was the scientific quality of the included studies assessed and documented?</p> <p>Was the scientific quality of the included studies used appropriately in formulating conclusions?</p> <p>Were the methods used to combine the findings of studies appropriate?</p> <p>Was the likelihood of publication bias assessed?</p> <p>Was conflict of interest stated?</p>

Table 2. Quality ratings and definitions

Quality rating	GRADE description	Interpretation
High	Further research is very unlikely to change our confidence in the estimate of effect	Body of evidence can be trusted to guide practice
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate	Body of evidence can be trusted to guide practice in most situations
Low	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	Body of evidence provides some support for recommendations but care should be taken in its application
Very low	Any estimate of effect is very uncertain	Body of evidence is weak and must be applied with caution

Overview results

The ONHMRC was tasked with identifying the available published overviews of systematic reviews⁴ on the effectiveness (and, where available, the safety, quality and cost-effectiveness) of the in-scope therapies. The ONHMRC commissioned a series of third-party reviewers to undertake overviews (a SR of existing SRs) and provide findings of the overviews in a series of individual reports to the Department.

There is considerable variation in the types of therapies that were reviewed. This has necessitated some variation in methodological approach, with regard to how the interventions have been assessed. In some cases, the practitioner performs the intervention, as with massage therapy. In other cases, the therapist instructs the individual, as with yoga or Pilates; or the practitioner may prescribe a product or regimen, as is the case with naturopathy and herbalism. Where it has been practical to do so, the evidence for the specific therapy has been reviewed. For example, for aromatherapy, the types of essential oils and types of application were considered.

An alternative, more feasible approach in some circumstances was to consider the ‘health service’ delivered by the therapist. For example, in the case of herbalism, this means that evidence was sought to show the efficacy of a consultation with a herbalist but not the herbal remedy. Given the very many herbal remedies available, it was not practical to consider evidence for all of them. Rebates, where applicable, are for the herbalist consultation, not the herbal remedies.

Overall, there was a paucity of reliable evidence identified for the 17 in-scope natural therapies. For 2 therapies (herbalism, iridology) no SRs at all were identified that met the overview inclusion criteria. For a further 4 therapies (Bowen therapy, kinesiology, rolfing, shiatsu), although SRs were identified, none included any in-scope randomised controlled trials (RCTs) and hence these SRs did not meet the overview inclusion criteria.

⁴ NHMRC defines a systematic review as ‘A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies.’ (<http://www.cochrane.org/glossary/5>). Systematic reviews should aim to identify all studies addressing the question, regardless of whether they have been published.

SRs that included in-scope RCTs were identified for the remaining 11 therapies. For 4 of these therapies, the included SRs identified less than 10 RCTs for each therapy (Alexander technique: 3 RCTs in 763 patients; Buteyko: 7 RCTs in 988 patients; Feldenkrais: 3 RCTs in 178 patients; and naturopathy as a health service: 6 RCTs in 692 patients).

Although a larger number of RCTs were identified for the remaining 7 therapies (aromatherapy, homeopathy, massage therapy, Pilates, reflexology, tai chi, yoga), the studies identified typically spanned a larger number of clinical conditions, and so the body of evidence identified for each clinical condition remained small and hence difficult to assess conclusively. A summary of the body of evidence identified by the natural therapies overviews is presented at **Table 3**.

For those natural therapies where few, or no, relevant SRs published since 2008 were identified within the overviews, the OHNMRC supplemented the overviews by undertaking an environmental scan of the literature for this report. This included searching a bibliographic database (PubMed) for SRs published before 2008, and any RCTs.

These searches were limited to 1 database, and do not constitute an exhaustive review of the evidence.

Table 3. Body of evidence identified from overviews

Alexander technique	2 clinical conditions (9 SRs; 3 RCTs and 1 EE⁵; 763 participants)
The Alexander technique may improve short-term pain and disability in people with low back pain, but the longer-term effects remain uncertain. For all other clinical conditions, the effectiveness of Alexander technique was deemed to be uncertain, due to insufficient evidence.	
Aromatherapy	8 clinical conditions (20 SRs; 45 RCTs; 27,595 participants⁶)
Despite promising evidence that aromatherapy may have beneficial effects on anxiety and pain in particular populations, the effect of aromatherapy on health outcomes in people with various clinical conditions remains uncertain.	
Bowen therapy	0 clinical conditions (2 SRs; 0 RCTs)
There is insufficient evidence from SRs to reach any conclusion regarding the effectiveness, safety, quality or cost-effectiveness of Bowen therapy.	
Buteyko	1 clinical condition (2 SRs; 7 RCTs; 988 participants)
There is insufficient evidence to support the clinical use of the Buteyko breathing technique for the management of asthma. For conditions other than asthma, conclusions about the effectiveness of Buteyko could not be drawn due to a paucity of evidence.	
Feldenkrais	3 clinical conditions (10 SRs; 3 RCTs; 178 participants)
The effectiveness of Feldenkrais for the improvement of health outcomes in people with any clinical condition is uncertain.	
Herbalism as a health service	0 clinical conditions (0 SRs; 0 RCTs)
As no SRs of the effects of herbalism as a health-care practice were identified, no conclusions can be drawn about the effectiveness of herbalism as a health service.	
Homeopathy	68 clinical conditions (57 SRs; 176 primary studies⁷; ~18,319 participants)
The available evidence failed to demonstrate that homeopathy is an effective treatment for any of the clinical conditions for which it has been examined.	
Iridology	0 clinical conditions (0 SRs; 0 RCTs)
As the review did not identify any SRs conducted in the last 5 years that assessed the efficacy of iridology as a diagnostic technique for any clinical condition, no conclusions could be drawn.	

⁵ Economic evaluation.

⁶ Only 1 study had a large sample size (23,857 participants). Given the potential for this large study to influence the overview, the evidence reviewers checked the original report and found that this was not a concurrently controlled trial. Since no outcome data from this study contributed to the results, the overall findings of the overview were not affected.

⁷ NHMRC's homeopathy overview was provided to the Department to inform its natural therapies review. The homeopathy overview included any case-control studies (that is, it included level II evidence – RCTs – as well as level III-I and some level III-II studies).

Kinesiology	0 clinical conditions (1 SR; 0 RCTs)
There is insufficient evidence to reach a conclusion about the effectiveness of specialised kinesiology for any clinical condition.	
Massage therapy or myotherapy	46 clinical conditions (99 SRs; 158 RCTs; >8,884 participants)
Although a large number of SRs were identified in massage therapy, the quality of the RCTs included in those reviews was generally poor. As a result, the evidence evaluating the effectiveness of massage therapy remains uncertain for 43 of the 46 clinical conditions assessed in the overview. Compared with control, there is moderate-quality evidence to suggest that massage therapy may be effective in providing immediate-term relief in patients with chronic low back pain and for reducing the length of hospital stay in pre-term infants. However, massage therapy may be no more effective than control for long-term pain relief in people with chronic low back pain. There is also a small body of low-quality evidence that suggests massage therapy may be effective in providing immediate, short-term pain relief for patients with acute low back pain, and for promoting weight gain in pre-term infants, compared with control. There is low-quality evidence to suggest that massage therapy may be no more effective than other interventions (the spray and stretch technique, spinal manipulation, traditional bone setting, physiotherapy, traction) for relieving the intensity of pain in people with chronic, non-specific or mechanical neck pain. However, it was beyond the scope of this overview to assess the effectiveness of comparison interventions, and there is insufficient good-quality evidence to determine the effect of massage therapy compared with inactive control in people with chronic, non-specific or mechanical neck pain. As a result, the effectiveness of massage therapy within this population remains uncertain. No studies were identified that assessed the effect of myotherapy in people with a clinical condition, and the effectiveness of this therapy is therefore unknown.	
Naturopathy	6 clinical conditions (1 SR; 6 RCTs; 692 participants)
Further evidence is required to estimate the effectiveness of naturopathic practice, as practised in Australia, for particular chronic conditions and outcomes. One unpublished SR was identified (Oberg 2013). This SR limited inclusion to trials of whole-system naturopathic practice conducted in North America by licensed naturopathic doctors. It included 13 studies, 6 of which were RCTs. Four RCTs were conducted in a specific population (Canadian postal workers) and results may therefore have limited applicability to the broader population.	
Pilates	5 clinical conditions (13 SRs; 18 RCTs; 710 participants)
As the available evidence for the effectiveness of Pilates consisted of a small number of methodologically limited RCTs, the effectiveness of Pilates for the improvement of health outcomes in people with any clinical condition is uncertain.	
Reflexology	16 clinical conditions (18 SRs; 31 RCTs; 2,146 participants)
The effectiveness of reflexology is uncertain for all clinical conditions for which it has been assessed.	
Rolfing	0 clinical conditions (1 SR; 0 RCTs)
There is a lack of evidence about the effectiveness of rolfing and therefore no reliable conclusions can be drawn about the effectiveness of rolfing for any clinical condition.	
Shiatsu	0 clinical conditions (4 SRs; 0 RCTs)
There is a lack of evidence from SRs or RCTs published since 2008 about the effectiveness of shiatsu. Therefore no reliable conclusions about the effectiveness of shiatsu can be made for any clinical condition.	

Kinesiology	0 clinical conditions (1 SR; 0 RCTs)
Tai chi	16 clinical conditions (43 SRs; 117 RCTs; 8,852 participants)
<p>There is very-low-quality evidence to suggest that tai chi may have some beneficial health effects when compared to control in a limited number of populations for a limited number of outcomes including older people (muscle strength) or people with heart disease (quality of life), hypertension (systolic and diastolic blood pressure) or osteoarthritis (physical function). There is also very-low-quality evidence that tai chi may have beneficial effects on selected outcomes in people with osteoarthritis (pain, physical function) relative to active comparators.</p> <p>Very-low-quality evidence suggests that there may be no difference between tai chi and another active comparator in a limited number of conditions and for a limited number of outcomes including hypertension (systolic and diastolic blood pressure), osteoporosis (bone mineral density) and type 2 diabetes (glycated haemoglobin, fasting blood glucose, total cholesterol). There is also low- to very-low-quality evidence that tai chi may have no effect on selected outcomes in older people (falls) and people with heart disease (heart rate variability, exercise capacity) compared to control.</p> <p>The magnitude and clinical significance of any potential health benefits are uncertain. For many outcomes, the health effects of tai chi are uncertain. The overall poor quality of the included SRs and the implied poor quality of the RCTs they included prevents more definite conclusions to be drawn and does not enable confidence in effect estimates.</p>	
Yoga	31 clinical conditions (67 SRs; 111 RCTs; >6,562 participants)
<p>There is weak evidence yoga improves symptoms in people with depression compared with control. For all other clinical conditions in which yoga was assessed there was insufficient evidence to draw any conclusions about the effect of yoga on outcomes.</p>	

Effectiveness

Clinical efficacy measures how well a treatment works in clinical trials or laboratory studies. For the purposes of the evidence review, ONHMRC considered the effectiveness of the in-scope natural therapy; where effectiveness means accuracy or success of a diagnostic or therapeutic technique when carried out in an average clinical environment, that is, the extent to which a treatment achieves its intended purpose.

Overall effectiveness could not be proven in any in-scope therapy. In several therapies positive effects were reported. However, overall effectiveness was inconclusive.

The reviewers were limited in drawing definite conclusions not only due to a lack of studies for some clinical conditions, but also due to the lack of information reported in the reviews and potentially in the primary studies.

The absence of SRs on a specific therapy should not be taken to infer that the specific therapy is not effective. There may be other published evidence on a specific therapy that was not captured.

Also, the work undertaken by the ONHMRC for the Department was an examination of existing SRs, rather than the commissioning of the synthesis of new evidence. Some evidence was only considered where it was provided as part of the Department's call for submissions.

Non-specific health outcomes such as wellbeing, self-esteem and anxiety may not be useful in determining the effectiveness of a therapy for a specific condition, unless they have been measured against a validated tool.

Safety and cost-effectiveness

SRs were searched for on the basis of the intervention in relation to a specific condition. Where those SRs also reported on safety or cost-effectiveness, that information was included in the overview. However, there were no search terms that specifically looked for safety or cost-effectiveness solely in respect of an intervention.

The role of the Advisory Committee

The NTRAC was established on 14 February 2013 and has met on 8 occasions to discuss the evidence reports and finalise advice to Government. The list of representatives, the organisation represented and their role on the Committee is described at **Attachment A**.

The role of the NTRAC as described in the Advisory Committee Terms of Reference was to undertake consultation with consumers, natural therapy and health insurance organisations represented by members and to provide advice to the Australian Government about the natural therapies that should continue to attract the Rebate. The Advisory Committee is advisory and consultative and does not have a decision-making role.

Background

Definition of a natural therapy

In-scope therapies are referred to as ‘natural’, ‘alternative’ and/or ‘complementary’ and are offered through General Treatment cover under complying health insurance policies by private health insurance (PHI) that are not eligible to be subsidised directly under Medicare and are not provided by a health professional registered under the National Registration and Accreditation Scheme (NRAS).⁸

For the purposes of the review, a natural therapy is one which is being offered by a private health insurer, and is defined as a treatment that meets the definition of general treatment under section 121-10 of the *Private Health Insurance Act 2007* (the Act):

121-10 Meaning of general treatment.

- 1) **General Treatment** is treatment (including the provision of goods and services) that:
 - a) is intended to manage or prevent a disease, injury or condition; and
 - b) is not hospital treatment.
- 2) Without limiting subsection (1), **general treatment** includes any other treatment, or treatment included in a class of treatments, specified in the *Private Health Insurance (Health Insurance Business) Rules* for the purposes of this subsection.

The types of services that can be directly subsidised under the Medical Benefits Schedule (MBS) and health professionals regulated under the NRAS by a corresponding National Board were not affected by the proposal (see **Table 4**).

The Review began on 1 July 2012 with Rebate changes originally to be

List of in-scope therapies

• • •

Alexander technique
Aromatherapy
Ayurveda
Bowen therapy
Buteyko
Feldenkrais
Herbalism/western herbalism
Homeopathy
Iridology
Kinesiology
Massage therapy
Naturopathy
Pilates
Reflexology
Rolwing
Shiatsu
Tai chi
Yoga

⁸ Information on the definition of a natural therapy was driven by the classifications used in the Rules Application Processing System (RAPS) as provided by insurers.

implemented from 1 January 2014. The Australian Government agreed to delay the implementation date of the Review until 1 April 2015. The revised date allowed the Department, in consultation with the ONHMRC, to complete a full evidence-based review process in consultation with industry.

Hypnotherapy, biochemistry, nutrition and psychotherapy

In January 2014, NTRAC decided not to proceed with the review of some natural therapies originally considered in scope (hypnotherapy, biochemistry, nutrition and psychotherapy) as there remained some ambiguity around which aspects of the modalities are considered to be natural therapies.

There was also an argument that the 4 therapies were out of scope of the Review because of their connection with the Australian Health Practitioner Regulation Agency (AHPRA) and the MBS. For example, biochemistry is considered as a diagnostic procedure under the MBS. Hypnotherapy and psychotherapy can be provided by psychologists and psychiatrists, who are registered under AHPRA. There are also group and family psychotherapy session benefits available under the MBS and items for dietitians under the MBS.

Ayurveda

The ONHMRC has been unable to finalise the evidence review for Ayurveda within the current timeframes. Ayurveda, a traditional Indian therapy, is an extensive system of therapies. Consequently, the evidence review for Ayurveda is more complex than other in-scope therapies, requiring extra research, translation of SRs into English and consultation with the Indian Ministry. Advice was sought from the Indian Council of Medical Research to identify appropriate research. Despite follow-up, at the time of this report, a response has not been received.

Table 4. AHPRA registered National Boards and Health Practitioners⁹

National Board	Profession	Division
Aboriginal and Torres Strait Islander Health Practice Board of Australia	Aboriginal and Torres Strait Islander health practitioner	
Chinese Medicine Board of Australia	Chinese medicine practitioner	Acupuncturist Chinese herbal medicine practitioner Chinese herbal dispenser
Chiropractic Board of Australia	Chiropractor	
Dental Board of Australia	Dental practitioner	Dentist Dental therapist Dental hygienist Dental prosthetist Oral health therapist
Medical Board of Australia	Medical practitioner	
Medical Radiation Practice Board of Australia	Medical radiation practitioner	Diagnostic radiographer Nuclear medicine technologists Radiation therapist
Nursing and Midwifery Board of Australia	Nurse	Registered nurse (Division 1) Enrolled nurse (Division 2)
Nursing and Midwifery Board of Australia	Midwife	
Occupational Therapy Board of Australia	Occupational therapist	
Optometry Board of Australia	Optometrist	
Osteopathy Board of Australia	Osteopath	
Pharmacy Board of Australia	Pharmacist	
Physiotherapy Board of Australia	Physiotherapist	
Podiatry Board of Australia	Podiatrist	
Psychology Board of Australia	Psychologist	

Further information about private health insurance for natural therapies is provided at **Attachment B**.

⁹ AHPRA registered health practitioners at Australian Health Practitioner Regulation Agency

Department of Veterans' Affairs review

In 2010, the Department of Veterans' Affairs (DVA) undertook a review of alternative therapies to determine if benefits for these services could be offered under Gold and White Card arrangements. The alternative therapies reviewed included: acupuncture and acupressure, aromatherapy, homeopathy, hypnotherapy and hypnosis, massage therapy or therapeutic touch, meditation, music therapy, reflexology and relation therapy, reiki, tai chi and yoga.

The review found that there is emerging evidence (at different levels of quality and strength) about some therapies for some conditions. However, there was often only limited information available on the evidence for the effects of an alternative therapy; the methodological quality of known reviews and trials tended to be low; and there was often not enough evidence to make a recommendation about safety or efficacy of a particular therapy.

As a result of the review, the DVA found that they could not be confident that funding alternative therapies by alternative therapy providers under Gold and White Card arrangements would have significant benefits for patients, be cost-effective or be practical to implement and decided that they would continue to not cover alternative therapies provided by alternative therapy providers.

National Health and Medical Research Council (NHMRC)

The National Health and Medical Research Council (NHMRC) Strategic Plan 2010–2012 identified 'examining alternative therapy claims' as a major health issue for consideration by the organisation, including the provision of research funding.

In addition to research funding, the NHMRC undertook 2 separate but related complementary and alternative medicines (CAM) projects. It developed under the auspice of NHMRC's Health Care Committee a complementary and alternative medicine guidance document for health professionals.

The NHMRC also finished a review of the evidence on the effectiveness of homeopathy. The outcomes of this report have informed the development of an NHMRC information paper.

The ONHMRC was asked to assist with the Department's natural therapies review. The ONHMRC was tasked with examining the available evidence on clinical efficacy,¹⁰ safety, quality and cost-effectiveness¹¹ of a number of in-scope and prioritised natural therapies. The work conducted aligns with the *National Health and Medical Research Act 1992*¹² to 'inquire into' matters relating to health and the NHMRC 2010–12 Strategic Plan identified major health issue 'examining alternative therapy claims'.

The Department entered into a Memorandum of Understanding (MoU) with the ONHMRC, which has conducted an evidence review relating to in-scope therapies. Based on their findings, the ONHMRC has provided advice to the NTRAC.

Evidence review process

The ONHMRC engaged third-party contractors to assess the evidence on the effectiveness, cost-effectiveness and safety of the in-scope natural therapies identified. The outcomes of the evidence reviews on the prioritised in-scope natural therapies were provided to the Department as a series of stand-alone reports.

The evidence for the in-scope natural therapies was categorised using the evidence hierarchy from the NHMRC Evidence Guidelines.

The third-party reviewers were commissioned to undertake the independent evaluation of the evidence of the effectiveness of the in-scope natural therapies.

The evidence reviews included:

- a systematic review¹³ of SRs (overview) that have considered the effectiveness (and safety, quality and cost-effectiveness, where this has been included) of the therapy

10 Clinical efficacy measures how well a treatment works in clinical trials or laboratory studies. For the purposes of the evidence review, NHMRC has considered the effectiveness of the in-scope natural therapy; where effectiveness means the accuracy or success of a diagnostic or therapeutic technique when carried out in an average clinical environment; that is, the extent to which a treatment achieves its intended purpose.

11 Cost-effectiveness means where an in-scope natural therapy has evidence supporting effectiveness to the extent to which the Department and its Advisory Committee considers the benefit to the consumer in receiving this therapy does not outweigh the cost to the Commonwealth in subsidising it. For the purposes of the evidence review, NHMRC has considered effectiveness of the in-scope natural therapy and cost-effectiveness where evidence is available.

12 *National Health and Medical Research Act 1992*, http://www.austlii.edu.au/legis/cth/consol_act/nhamrca1992342/

13 NHMRC defines a systematic review as 'A review of a clearly formulated question that uses systematic and explicit methods to identify, select and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies' ([Cochrane Community \(beta\)](#)). Systematic reviews should aim to identify all studies addressing the question, regardless as to

- a summary of any additional level 1 and 2 evidence identified from evidence provided by stakeholders during the Department’s call for submissions.

The process agreed in the Review project plan is outlined below.

Contracting of external reviewers

The ONHMRC contracted external reviewers to undertake a SR of SRs (overview) to identify those reviews that addressed the effectiveness of the natural therapy for improving any health outcome for any clinical condition or health problem. Overviews compile evidence from multiple SRs into a single accessible and usable document, and are used by the OHNMRC when the scope of a project is very broad, and/or the timeframes for the project are relatively short.

As part of its review of natural therapies, the Department also invited key organisations to make submissions. Submissions were required to give evidence that demonstrated the clinical efficacy, cost-effectiveness, safety and quality of the natural therapies under consideration. Submissions from non-invited organisations were also accepted. The external reviewers were required to review submissions that met the above requirements.

In undertaking the task, the external reviewers were required to:

- use the methodology outlined in Chapter 22, ‘Overviews of reviews’ of the *Cochrane handbook for systematic reviews of interventions* (Higgins 2011)
- produce an overview protocol for each natural therapy, outlining the methodology to be used to evaluate the effectiveness of the therapy in treating a clinical condition¹⁴
- search for and retrieve relevant literature
- consider and report on additional evidence provided through the Department’s call for submissions from stakeholders, including evaluating submitted literature that was considered in scope and tabulating any submission literature considered out of scope
- develop an evidence table summarising the systematic assessment and critical appraisal of all studies that met the inclusion criteria
- summarise the findings in an evidence report.

whether or not it has been published. As a minimum unpublished literature should include trials registered on clinical trial databases.

¹⁴ Iridology is a diagnostic technique so in this instance the external evidence reviewers were required to evaluate the effectiveness of the therapy for diagnosing (rather than treating) clinical conditions.

Out-of-scope submitted literature included the following:

- literature that did not address the natural therapy for the treatment¹⁴ of a clinical condition
- studies assessed as level III evidence or below, using the NHMRC levels of evidence hierarchy
- literature that could not be assigned a level of evidence (for example, opinion pieces, textbooks, website items); and where a natural therapy was used in combination therapy, yielding confounded comparisons
- level 1 SRs that had been considered in the overview and level II studies that had been considered in a SR within the overview report
- literature with a publication date before 1 January 2008.

The external reviewers were required to appraise all SRs conducted since 2008 that contained RCTs describing the effectiveness of the natural therapy as an intervention for any clinical condition. Safety, quality and cost-effectiveness were not considered except where these outcomes were included within a SR that assessed the effectiveness of an in-scope therapy. The overview searched for SRs of in-scope therapies in adults and children of any age, gender or sociodemographic characteristics with a described clinical condition or health problem. All settings – hospital, other health care or non-health care – were considered, as were all types of practitioners (that is, trained, untrained, or where the level of training was unclear), except where the intervention was delivered by an ‘out of scope’ practitioner (for example, practitioners whose profession is eligible for AHPRA registration in Australia, such as physiotherapists or traditional Chinese medicine practitioners). Where SRs were identified that included both RCTs and other study designs, further consideration was limited to the subset of RCTs¹⁵ included in the systematic review. Publications in languages other than English were also considered only where a full-text translation into English was available.

¹⁵ As iridology is a diagnostic technique rather than an intervention, the iridology review was not limited to systematic reviews that included RCTs. RCTs are not always needed, or indeed feasible, in the evaluation of a diagnostic test (Lord et al., 2006). Instead, the iridology overview included systematic reviews that included other study types; and systematic reviews that searched for, but did not identify, studies of iridology.

Where the natural therapy was used in combination with other therapies, so that the contribution of the component of the therapy under review was unable to be assessed separate to other therapies, studies were considered outside the scope of the review.

Language restrictions

In line with the parameters of the Review, exclusion criteria were applied to the literature submitted to the Department. Where the external reviewers identified publications in languages other than English, they were only considered where a full-text translation into English was available.

This was primarily because the ONHMRC does not have the capacity to assess the quality of reviews and studies not published in English, even though it may be possible to understand parts of these papers (such as data tables).

If a non-English journal is indexed on a database such as PubMed, it will often at least have an abstract that is available in English, to enable a limited assessment of the publication's relevance to be made.

Where SRs otherwise appeared to meet the overview inclusion criteria, but were excluded due to language, this has been noted within each overview report. For 11 of the 17 therapies, 61 potentially relevant publications were excluded because a full-text English language translation was not available.

The number and language of publications excluded due to this limitation are listed in **Table 5**. Although it is unlikely that all of these articles would have met the inclusion criteria for the review, it was not possible to include or exclude them without examining a full-text, English language version of the publication.

Also, the evidence review only searched English language databases and so SRs published in languages other than English may not have been identified through these searches. Although the review did not consider SRs published in languages other than English, this did not prevent the inclusion of non-English primary studies where these were identified within English language SRs.

Table 5. Number and languages of publication of potentially relevant studies excluded due to language limitation

Therapy	Number of potentially relevant studies excluded (language/s)	
Aromatherapy	2	(Korean, Portuguese)
Bowen therapy	9 ¹⁶	(Spanish, German, Dutch)
Buteyko	1	(German)
Feldenkrais	5	(German, Russian, Italian, French, Polish)
Homeopathy	10	(German, French)
Massage therapy	20	(Spanish, German, Dutch, Russian, French, Lithuanian, Chinese)
Pilates	1	(Portuguese)
Reflexology	5	(Korean, German, Greek)
Shiatsu	2	(Korean, Farsi)
Tai chi	5	(Chinese, French, German, Spanish)
Yoga	1	(Chinese)

Limit on publication date

The reviewers were required to limit their searches for SRs of each natural therapy to those published in the last 5 years. Limiting searches to this time period ensured that the overview would capture the recent body of scientific evidence, as SRs published before this time would not capture primary evidence published within the last 5 years.

This approach is consistent with the Cochrane Collaboration, which requires its reviews to either be updated within 2 years of first publication, or to have a commentary added explaining why this has occurred less frequently.

Although the 5-year limitation was applied to the SRs included within the overviews, the majority of SRs searched for all potentially relevant primary studies, without date limitations. As a result, many of the SRs identified in the overviews included RCTs published before 2008. Also, the literature submitted by stakeholders identified only a minimal number of pre-2008 studies. These were typically of poor quality and did not impact on the independent reviewers' findings for those particular therapies.

¹⁶ There are similarities between specific massage therapeutic techniques and those used during Bowen therapy. Any non-English language systematic review of manual therapies, that may have included Bowen therapy, was included here, as it was not possible to retrieve the full-text, English-language version to verify whether the interventions included within the systematic review included Bowen therapy.

Quality

The key problem with the body of evidence evaluating the effectiveness of the various natural therapies is its poor quality. The main quality problems are:

1. The lack of randomised controlled trials
 - a. Even if a study included in a SR claimed to be an RCT it was often not possible to ascertain how the randomisation process was performed (allocation concealment and sequence generation) due to poor reporting. It was therefore not possible to verify if these studies really were RCTs.
2. Confounded comparisons
 - a. If a natural therapy is given in combination with another natural therapy then it may be possible to evaluate the effectiveness of the combination, but not of each separate therapy. For example, if a study compared a combination of massage therapy and counselling with a 'no treatment' control, and there was a significant effect detected for a particular outcome, then it would not possible to determine whether it was the massage therapy, or the counselling, or the combination of the 2 that was having an effect.
3. Underpowered studies
 - a. Most of the RCTs identified were very small and unlikely to be able to give enough information to be able to answer the questions being asked by the investigators.
4. Lack of masking (blinding) of the intervention
 - a. Most of the natural therapies evaluated in this body of work are of a type that makes it difficult to compare with a 'placebo' or sham therapy. In most RCTs it was therefore likely that the individuals giving and receiving the therapy were aware of the type of therapy being received. Awareness of the type of therapy may influence the outcome of the study; for example, if someone knows they received a massage rather than 'nothing' then they may be more likely to report 'positive' outcomes. One way to deal with this sort of bias is to be careful about the choice of outcomes. That is, the type of outcome (objective rather than subjective), how it is measured and who does the measuring.
 - b. Rather than compare a natural therapy with nothing, a sham or a placebo, the trial investigators may choose an 'active' control. That is, an alternative choice of therapy. The

problem is that it can sometimes be difficult to tell if a control is an ‘active’ or ‘inactive’ control. For example, if massage therapy is compared with a counselling session or an information leaflet, is this an active or inactive control? This can make it difficult to interpret the results of a study.

5. Different methods of assessing the quality of individual studies

a. The use of different quality-assessment tools across SRs was compounded by the lack of consistency in their application, with some reviews reporting conflicting assessments of the same RCT.

6. Heterogeneity

a. Differences across studies in relation to the populations in which the studies were conducted, the way therapies were delivered, the control groups and the outcomes evaluated means that it was either not possible or it was inappropriate to pool data from multiple studies so it could be statistically analysed.

b. As the data could not be pooled, it was often not possible to determine if there was a difference between the groups or what direction any difference might be in (that is, whether it favoured the natural therapy or the control group).

c. To give readers of the report some sense of the direction of any effect that might exist, external reviewers may have used a version of vote counting to summarise the results of studies. For example, they may have counted and reported on the number of RCTs or outcomes that favoured the intervention and the number that favoured the control group. This is a crude way of summarising information that may be of limited use.

7. Data dredging

a. In normal circumstances, an overview of SRs would start with a set of clearly defined questions where the population of interest, the intervention/s, the comparator/s and the outcomes are defined before the process begins. In addition, the outcomes would normally be prioritised and those of key interest (the primary outcomes) identified.

b. Specifying outcomes at the outset reduces the risk of bias posed by data dredging, whereby authors may (either intentionally or unintentionally) report a large number of outcomes and associations in a bid to identify any possible statistically significant results.¹⁷

c. The overviews of natural therapies were very broad in scope. Specifically, the outcomes were not defined up front. As a result, the outcomes included in each overview were driven by the outcomes that were reported in each included systematic review. As the choice of outcomes can be subjective (different people will place a different priority on different outcomes) it was not unusual for each SR to report on different outcomes, even those otherwise asking the same question.

d. To deal with this problem, external contractors attempted to identify primary outcomes (for example, as stated by the individual SRs). However, it was often not possible to do so.

Clearance processes and reporting

For this project, the ONHMRC enquired into the effectiveness of a number of in-scope therapies through a number of SRs of SRs (overviews). The outputs of this project did not provide recommendations or advice on the effectiveness of the natural therapies. The NHMRC Planning and Quality Committee provided input and clearance to project plans, statement of requirements for the evidence reviews, evidence review protocols and reports. The final report for this project was cleared through the Chief Executive Officer of NHMRC.

Once accepted by the NHMRC, draft evidence review reports were provided to external independent methodological reviewers. Methodological reviewers were required to assess the reviews' adherence to the approved protocols and whether the conclusions drawn accurately reflected the body of evidence. Feedback from methodological review was then considered by the evidence reviewers, in conjunction with NHMRC, for incorporation into the final report for each therapy. This final report for each therapy was then provided to the Department for consideration.

¹⁷ Conventionally, a result is said to be statistically significant when there is less than a 5% chance of the result occurring by random chance ($p < 0.05$). This means that in about 5% of cases, a statistically significant result may be observed due to chance alone, producing a 'false positive' result. Therefore, the greater the number of statistical tests that are performed, the greater the likelihood that one of the results will be a 'false positive' result that is statistically significant due to random chance alone.

Submissions to the Review

In addition to the commission of overviews of in-scope therapies by the OHNMRC, the Department called for submissions of potentially eligible research to inform the review from the stakeholders.

Key stakeholders were contacted and provided with information regarding the nature and scope of evidence that may be submitted. Submissions closed on 21 December 2012, with extensions granted until 31 January 2013 and further extensions granted until 8 February 2013. The Department granted an extra extension for homeopathy until 8 March 2013.

The Department received 46 submissions in relation to the Review; all lodged submissions were accepted and included in the process. A list of submissions is provided at **Table 6**. Non-confidential submissions have been published on the Department's website on the [Natural Therapies Review submissions page](#).

Only submitted level 1 or 2 evidence were considered in the evidence review. The reviewers assessed if the evidence had already been considered as a part of the overview process. Any additional identified level 1 studies were included in the overview. Any identified level 2 evidence not considered as a part of the overview was critically appraised and the outcomes were summarised by the reviewer.

Stakeholders who provided a submission to the Review were invited to present to the NTRAC on 1 May 2013 and 8 August 2013. Presentations were made by 12 stakeholders and focused on the evidence statements that were made in their submissions.

ONHMRC also provided the report for the NHMRC review on the effectiveness of homeopathy in treating clinical conditions to the Department. Any submissions made to the Department regarding homeopathy were considered and summarised separately to the NHMRC homeopathy review process.

NHMRC homeopathy review

Prior to the Department's request that NHMRC examine the effectiveness of the in-scope natural therapies, which included homeopathy, the NHMRC had independently begun a review of the scientific evidence for the effectiveness of homeopathy. The purpose of the NHMRC's

homeopathy review was to inform development of an information paper and position statement to help Australians make informed health-care choices as a part of NHMRC's activities under its Strategic Plan. Due to the requirements of the *National Health and Medical Research Council Act 1992* (the NHMRC Act), this review had a different process and purpose, and differed from the approach to the other natural therapies in the following respects:

- A Homeopathy Working Committee (HWC) comprised of experts in evidence-based medicine and complementary and alternative medicine was set up by the NHMRC to oversee the review.
- For the information paper to be useful to the public, it needed to provide an NHMRC position on the effectiveness of homeopathy, based on the evidence as well as the HWC's expert judgment. As the underlying principles of homeopathy lack scientific plausibility, the review used the null hypothesis that homeopathy has no effect as a treatment for a condition, unless there was sufficient reliable evidence to demonstrate otherwise. Evidence for each clinical condition was summarised and evidence statements were formulated after consultation and agreement with the HWC. In contrast, the evidence statements for the other in-scope natural therapies in this report state that the evidence is uncertain, unless there was sufficient evidence to demonstrate otherwise.
- The external reviewers for the homeopathy overview appraised all SRs published between January 1997 and 3 January 2013, whereas the other natural therapies overviews included all SRs done since 2008. In addition, the homeopathy overview included any prospectively designed and controlled studies included within SRs; that is, level III evidence, whereas for the other therapies, studies assessed as level III evidence or below were excluded.
- In line with NHMRC's requirements under the NHMRC Act, the draft information paper was open for public consultation from 9 April to 2 June 2014. Submissions received during public consultation, along with comments received from independent experts in evidence-based medicine and/or complementary medicine, are being considered by the HWC in finalising the information paper.

Table 6. List of submissions provided to the Department

Academy of Applied Hypnosis	Complementary Medicine Association
Association of Massage Therapists Ltd	Dietitians Association of Australia
Association of Remedial Masseurs	Endeavour College of Natural Health
Australasian Integrative Medicine Association	Friends of Science in Medicine
Australian Acupuncture and Chinese Medicine Association Ltd	Hypnotherapy Council of Australia
Australian Association of Ayurveda Inc.	Institute for Clinical Hypnotherapy and Psychotherapy (Australia)
Australian Association of Massage Therapists	Institute of Registered Myotherapists of Australia
Australian Feldenkrais Guild Inc.	International Aromatherapy and Aromatic Medicine Association
Australian Hypnotherapists' Association	International Institute of Psychosomatic Medicine
Australian Institute of Kinesiologists	International Yoga Teachers Association
Australian Kinesiology Association	Massage Association of Australia
Australian Natural Therapists Association Ltd	National Herbalists Association of Australia
Australian Naturopathic Practitioners Association	Mr Adam Hovav – Individual – remedial massage
Australian Pilates Association	National Institute of Complementary Medicine
Australian Register of Homeopaths	Nutrition Society of Australia
Australian Reiki Connection	Psychotherapy and Counselling Federation of Australia
Australian Society of Teachers of the Alexander Technique	Reflexology Association of Australia
Australian Traditional Medicine Society	Mr Bernard Scully – Individual – massage therapy
BB Benefits	Shiatsu Therapy Association of Australia Inc.
Mr Peter Berryman – Individual – remedial massage	Society of Natural Therapists and Researchers Inc.
Bowen Association of Australia	Tai Chi for Health Institute and Tai Chi Association of Australia
Bowen Therapists Federation of Australia Inc.	Dr Jon Wardle – Individual
Chinese Medicine Board of Australia	Ms Trixie Whitmore – Individual – homeopathy

Summary of evidence reports

The following pages contain extracts from the evidence reports as compiled by contractors on behalf of the NHMRC on each of the in-scope therapies. Only minor editorial changes were made to this section of the report.

Alexander technique overview report

Objective

The objective of this overview is to summarise the evidence from SRs that examined the effectiveness (and, where available, the safety, quality and cost-effectiveness) of Alexander technique for improving health outcomes for any clinical condition.

Definition

Alexander technique is a type of taught physical therapy that aims to improve movement and correct posture, with the goal of improving health and reducing pain (Beckner & Berman, 2003). Through a series of movements this technique aims ‘to bring the body into natural alignment’ (Dennis & Cates, 2012) and involves individualised assessment and lessons to help patients ‘recognise, understand, and avoid poor habits affecting postural tone and neuromuscular coordination’ (Little, et al., 2008). In particular, Alexander technique focuses on releasing unwanted tension in the head, neck and spine, with relief achieved through both verbally guided movements and hand contact (Little, et al., 2008). It can be applied while sitting, lying down, standing, walking, lifting and during other daily activities.

To become a practitioner in Alexander technique in Australia, the training course requires a minimum of 1,600 hours over at least 3 years, with 80% of contact hours to comprise practical instruction (Australian Society of Teachers of the Alexander Technique, 2014). Typical courses run for 35 weeks and consist of 15 class hours each week over 4 terms (ATI Teacher Training School, 2014; Sydney Alexander technique, 2014).

Alexander technique is either taught as private lessons, in classes or intensive workshops. It is usual for people to attend a series of

...

A
L
E
X
A
N
D
E
R
T
E
C
H
N
I
Q
U
E

lessons; however, on occasion a single session is enough to address a particular problem. Prices can range from about \$20 per hour in a group setting, to \$150 per hour as a private lesson, to over \$100 per workshop (School for F.M. Alexander Studies, 2014).

Methods

This overview used the methodology outlined in Chapter 22 of the *Cochrane handbook for systematic reviews of interventions*, which is designed to compile evidence from multiple SRs into a single document (Becker & Oxman, 2011). It does not aim to repeat the searches, assess the eligibility, or assess the risk of bias of the individual studies within included SRs.

The search was restricted to SRs published between 1 April 2008 and 5 September 2013. In addition, any relevant SRs identified through the Department's call for submissions were assessed for inclusion in this overview.

A single evidence reviewer conducted the literature search and reviewed the titles and abstracts of every record identified using pre-specified eligibility criteria. Articles considered to meet these criteria were then retrieved for further assessment. From each included systematic review, the methodological quality of the review was assessed. Each stage in this process was documented and quality checks were performed by a second evidence reviewer, with any disagreements resolved by a third reviewer.

Where SRs included RCTs of Alexander technique, they extracted outcome data on the effectiveness (and, where available, the safety, quality and cost-effectiveness) of Alexander technique. The evidence for each outcome identified was then summarised and the overall quality of the evidence rated using the GRADE system.

Discussion

Main results

Nine SRs were identified that met the criteria for inclusion within this overview. Three of the 9 reviews included evidence from 3 RCTs and 1 economic evaluation study, and reported on the effectiveness of Alexander technique for 2 clinical conditions: chronic low back pain and Parkinson disease. One RCT (Little, et al., 2008) identified was a factorial study (579 participants) that assessed the effectiveness of interventions (massage therapy, Alexander technique) with or without exercise in reducing pain and disability in participants with chronic

low back pain. The economic evaluation study (Hollinghurst, et al., 2008) was based on the findings of this RCT. The other RCT that assessed Alexander technique in people with chronic low back pain (Vickers, et al., 1999) was an unpublished report in fewer than 100 participants. The final RCT identified in this overview assessed Alexander technique in patients with Parkinson disease (Stallibrass, et al., 2002). Statistically significant improvements favouring Alexander technique were reported for improvements in pain (median number of days in pain, pain intensity, raw pain score), disability, or mood and behavioural outcomes in both populations examined when compared with usual care, self-help group sessions or an exercise prescription. Overall, the evidence was limited by the small number of participants in the intervention arms, wide confidence intervals or a lack of replication of results.

In people with low back pain, Alexander technique may be effective in improving pain and disability in the short term (up to 3 months) but the long-term effectiveness of Alexander technique on these outcomes is uncertain. For all other clinical conditions, the effectiveness of Alexander technique is uncertain because of insufficient evidence. Evidence for the safety of Alexander technique was lacking, with most trials not reporting on this outcome. Cost-effectiveness was not established in the 1 trial assessing Alexander technique in participants with chronic low back pain.

Overall completeness and applicability of evidence

The evidence base for the effectiveness of Alexander technique was limited to a small number of RCTs in 2 patient populations, which was insufficient to address the objectives of this overview. Although 9 SRs were identified from the literature search, only 3 contained evidence specific to Alexander technique. The remaining 6 reviews did not identify any RCTs of Alexander technique that met their inclusion criteria. Notably, those reviews evaluated the effect of interventions for conditions which proponents claim Alexander technique may benefit; including neck pain (non-specific, whiplash, or neck pain with radiculopathy), chronic musculoskeletal pain, asthma, post-traumatic stress disorder and generalised anxiety disorder. The lack of complete data reported by the SR or trial authors (for example, reporting of p-values only, reporting total number of participants rather than number included in analysis) made it difficult to analyse and interpret the evidence that was available. The data that were available were restricted to specific populations (people with chronic low back pain and people with Parkinson

disease) and may not be generalisable to people with other clinical conditions. The included SRs concluded that more research is needed to establish the effectiveness, safety and cost-effectiveness of Alexander technique.

Quality of evidence

The SRs included in this overview were considered to be of moderate to high quality (AMSTAR ratings between 6 and 10 out of 11). All reviews sufficiently critiqued and evaluated the available evidence; however, overall conclusions were limited by the paucity of available studies evaluating Alexander technique for a particular condition. Lists of excluded studies, discussions on heterogeneity, or assessments of publication bias were often not provided. Two of the 3 reviews that did report evidence for Alexander technique were rated high quality (Furlan et al., 2010; Savigny, et al., 2009) and 1 was assessed as moderate quality (Woodman & Moore, 2012). Support for Alexander technique relied largely on 1 moderate-sized factorial RCT (579 participants, including massage arms) with a low risk of bias (and a Jadad¹⁸ score of 4 out of 4) that assessed Alexander technique in participants with chronic low back pain (Little, 2008). A total of 288 participants received lessons (6 or 24) in Alexander technique, with almost half of these (142 participants) also receiving an exercise prescription. The other RCT assessing this condition was a smaller, unpublished report by Vickers and others (1999), which has a modified Jadad score of 3 out of 4. Evidence for Parkinson disease was limited to 1 RCT with an overall low risk of bias (Stallibrass, et al., 2002), and a modified Jadad score 3 out of 4. Only 1 economic evaluation study was identified (Hollinghurst, et al., 2008), but the results of the economic evaluation should be interpreted with caution, due to wide confidence intervals surrounding cost and outcome estimates.

Potential biases in the overview process

This overview was restricted to SRs published since April 2008, as a means to include the most recent evidence for Alexander technique. This meant that SRs published before 2008 were not considered, representing a potential source of bias for this overview. However, many of the identified SRs were broad in scope and did not limit their searches by date. This includes the

18 The Jadad Scale, sometimes known as Jadad scoring or the Oxford quality scoring system, is a procedure to independently assess the methodological quality of a clinical trial.

review by Woodman and Moore (2012), which specifically searched for all primary studies on Alexander technique for any health-related condition in multiple databases. It is therefore likely that the review by Woodman and Moore (2012) identified much of the evidence that might have been identified by reviews published before 1 April 2008.

Another potential source of bias in this overview is that the literature was derived exclusively from searches of online databases; therefore, informally published SRs (grey literature) may have been missed. Also, the reviewers did not conduct a systematic search for RCTs published since the search date of included SRs. However, it is likely that any such omitted SRs or RCTs would have been included in the stakeholder submissions; therefore, it is unlikely that these potential biases have impacted on the conclusions of this overview.

During the methodological review, it was also identified that searches did not include a specialist CAM bibliographic database; however, it is not believed that any primary studies were missed due to this omission. This is because several other major bibliographic databases were searched and no additional SRs were identified in the literature submitted to the Department.

Another potential source of bias relates to the issue of publication bias, where studies with significant positive findings are often published in journals, whereas negative or non-significant results remain unpublished. It is therefore possible that there remains a body of unpublished evidence regarding the effectiveness of the Alexander technique that may not be as favourable as that identified in this overview.

Finally, although checks were performed on a subset of records in this overview, the use of a single reviewer for screening records introduced another potential source of bias.

Conclusions

Authors' conclusions

In people with low back pain, Alexander technique may be effective in improving pain and disability in the short term (up to 3 months) but the long-term effectiveness of Alexander technique on these outcomes is uncertain. For all other clinical conditions, the effectiveness of Alexander technique is uncertain because of insufficient evidence. If conducted, future research should focus on rigorous, well-designed RCTs that evaluate the effectiveness of this intervention in a variety of targeted populations and settings.

Implications for practice

In people with low back pain, Alexander technique may be effective in improving pain and disability in the short term (up to 3 months) but the long-term effectiveness of Alexander technique on these outcomes is uncertain. For all other clinical conditions, the body of evidence is insufficient to allow conclusions to be drawn regarding the effectiveness of Alexander technique. The available research is restricted to people with chronic low back pain or people with Parkinson disease and is focused on outcomes of pain, disability and mood. The evidence is generalisable and applicable to the Australian context for these patient populations, but further data are required to establish the number of lessons that provides the most benefit and to determine the effectiveness of Alexander technique for other clinical conditions for which benefits are claimed. Little data have been reported on the safety or cost-effectiveness of Alexander technique, therefore the safety or cost-effectiveness of this intervention remains uncertain.

Implications for research

This overview highlights the lack of evidence and gaps in research in the field of Alexander technique, providing numerous opportunities for future research in this field. Future research, if conducted, should focus on rigorous, well-designed RCTs to evaluate the effectiveness of Alexander technique in a variety of targeted populations and settings. Studies with multi-site recruitment that are adequately powered would allow for stronger tests of treatment efficacy and improved reporting of study details and outcome data is also needed to allow examination of individual differences in treatment response. Research that is based on Alexander technique as it is practised in the Australian population would also assist in the formulation of recommendations on which to guide practice in Australia.

Submissions received on Alexander technique

Submissions for Alexander technique were received from the following 4 organisations and included a total of 665 references:

- Australian Association of Massage Therapists (AAMT) (35 references)
- Australian Feldenkrais Guild (AFG) (596 references)
- Friends of Science in Medicine (7 references)

- Australian Society of Teachers of the Alexander Technique (AUSTAT) (27 references).

A review of the reference titles and abstracts found that a large majority of articles (n = 551) were not reports of a primary study or full details of the study were not published (for example, poster presentations, theses) and were therefore of the wrong publication type for inclusion in this report. A further 92 articles did not examine Alexander technique (intervention out of scope). One SR (Woodman & Moore, 2012) and 3 studies (Little, 2008; Hollinghurst, 2008; Stallibrass, 2002) were identified that met our inclusion criteria; however, these were all included in the overview and were therefore not considered further. Twenty articles were retrieved for full-text review but no additional SRs or RCTs were identified that had not otherwise been included. A list of excluded studies and the reasons for the exclusion were provided in an appendix in the report.

Aromatherapy overview report

Objective

The objective of this overview is to summarise research on the effectiveness of aromatherapy for improving health outcomes for all clinical conditions compared with placebo, no treatment or an alternative active intervention. The safety, quality and costs of aromatherapy were only summarised if these components were evaluated in the included SRs.

Definition

Aromatherapy is a natural therapy that uses essential oils – the volatile oils distilled from plants – to promote health and wellbeing. It is used in the management of psychological states and is thought to change mood and promote improved mental wellbeing. Aromatherapy is commonly administered through massage therapy, but delivery may also include aromatic baths and vaporisation.

Aromatherapy is used to treat emotional disorders, such as stress and anxiety, but has wider applications, including the alleviation of pain and nausea, and the promotion of sleep. Aside from the perceived benefits to health and wellbeing, aromatherapy is popular because it is non-invasive, relatively inexpensive, readily available, pleasant to use and can be self-administered without prior consultation with a health-care professional or natural therapist.

Methods

The methods used to conduct this overview were based on the methodology described in Chapter 22 of the *Cochrane handbook for systematic reviews of interventions* (Becker 2011).

SRs were considered for inclusion in the overview if they were published between 2008 and May 2013 and included primary studies that assessed the effects of

...

A
R
O
M
A
T
H
E
R
A
P
Y

aromatherapy. Reviewers did not limit inclusion by population, condition, setting, types of essential oils or types of applications of aromatherapy. Reviewers included comparisons of aromatherapy with usual care, with placebo or with no intervention. Comparisons of aromatherapy as a supplementary therapy were also included where the extra effect of aromatherapy could be determined. Reviewers used 3 outcome domains to summarise and synthesise the results: patient health, patient experience of care and safety (harms).

Discussion

Main results

Reviewers conducted an overview of SRs investigating the effects of aromatherapy. Twenty-one reviews, comprising 45 unique aromatherapy trials (41 RCTs and 4 controlled clinical trials) were included: 6 on dementia (9 trials), 2 on post-operative nausea and vomiting (1 trial), 2 on cancer (3 trials), 1 on critical illness (3 trials), 1 on sleep disruption (1 trial), 1 on hypertension (1 trial), 3 on pain (10 trials) and 5 on anxiety and depression (30 trials).

Two types of comparisons were assessed in the studies included in the reviews on dementia, critical illness, pain management and management of anxiety and depression: those comparing aromatherapy versus usual care, no intervention or placebo, and those comparing aromatherapy plus massage therapy versus massage therapy alone. The reviews on post-operative nausea and vomiting, and on hypertension only, included a study that compared aromatherapy versus usual care, no intervention or placebo. (The other studies included in these reviews did not assess the effects of aromatherapy.) The reviews on cancer and sleep disruption only included studies that compared aromatherapy plus massage therapy versus massage therapy alone.

Dementia

Only 1 review reported a pooled result, showing an effect of aromatherapy in reducing anxiety in dementia patients compared aromatherapy to usual care, no intervention or placebo. These trials reported on 13 outcomes. The estimates for intervention effects were not reported for 4 outcomes (4 trials, $n = 34$); 9 outcomes showed an effect in favour of aromatherapy (4 trials, $n = 193$). Three trials ($n = 69$) investigated the effects of aromatherapy plus massage therapy versus massage therapy alone. However, none of these trials reported estimates of intervention effects.

Post-operative nausea and vomiting (PONV)

The 2 included reviews on PONV reported the results narratively. Only 1 primary trial (n = 23) investigating the effects of aromatherapy versus placebo on nausea was included in the reviews. No estimates of intervention effects were reported.

Cancer

The 2 included reviews on cancer reported the results narratively. Three trials (n = 197) were included in the reviews investigating the effects of aromatherapy plus massage therapy versus massage therapy alone on reducing anxiety. Estimates of intervention effects were not reported in the reviews for any of these trials.

Critical illness

One review assessed the effect of aromatherapy in people with critical illness. The review included 6 trials of which 3 met the criteria of this overview. One study compared aromatherapy to a placebo (n = 25) and 2 studies assessed the effect of aromatherapy massage on anxiety compared to massage therapy alone (n = 222). None of the studies reported estimates for intervention effect for patient health outcomes.

Sleep disruption

One review assessed the effect of nursing interventions to promote sleep. The review included 9 studies of which 1 trial met the criteria of this overview. This trial compared aromatherapy massage to massage therapy alone (n = 42). There was no statistically significant difference between the groups, although numerical data and the direction of effect were not reported.

Hypertension

One review assessed the effect of aromatherapy on hypertension. The review included 5 studies of which 1 met the inclusion criteria of this overview. The trial compared aromatherapy to placebo (n = 30) and reported a statistically significant difference between systolic and diastolic blood pressure between the groups in favour of aromatherapy. It was unclear at what time points these outcomes were measured.

Pain management

Three reviews assessed the effect of aromatherapy on pain. The underlying conditions in these reviews varied. One review assessed the effect of aromatherapy in the management of pain

during labour; 1 on hemiplegic shoulder pain, and the third included various health conditions. Nineteen unique studies were included in these reviews of which 10 trials met the inclusion criteria for this overview (n = 1,394). Six trials assessed the effect of aromatherapy on pain versus usual care, no intervention or placebo (n = 1,152). For none of these trials were effect estimates reported in the reviews. One trial assessed patient satisfaction (n = 513). It was unclear how patient satisfaction was measured and no data were reported for this outcome. One study assessed cost (n = 513) but no data were reported in the review.

Four trials investigated the effect of aromatherapy plus massage therapy versus massage therapy alone. For 3 outcomes (3 trials, n = 139) there was a reported decrease in pain in favour of aromatherapy; for 1 outcome (1 trial, n = 103) no effect estimate was reported.

Anxiety and depression

Five reviews were included that assessed the effect of aromatherapy for the management of anxiety and depression. The underlying conditions in these reviews varied. Thirty trials were identified that met the inclusion criteria for this overview (n = 26,560). Twenty-two trials assessed the effect of aromatherapy on anxiety and depression versus usual care, no intervention or placebo (n = 25,970). The effect was assessed across 26 outcomes: for 14 outcomes (13 trials; 24,876 participants) no effect estimate was reported and the direction of effect was unclear; for 12 outcomes (11 trials; 1,511 participants) the difference between groups was in favour of aromatherapy.

Eight trials investigated the effect of aromatherapy plus massage therapy versus other massage therapies alone (n = 590). The effect of aromatherapy was assessed across 10 outcomes: for 4 outcomes (4 trials; 258 participants) no estimates of intervention effects were reported; for 6 outcomes (4 trials; 332 participants) the difference between groups was in favour of aromatherapy.

Safety outcomes overall

Safety outcomes were assessed in the included reviews; however, the results were rarely reported in the reviews or, as indicated by the review authors, rarely reported in the primary studies.

Overall completeness and applicability of evidence

Reviewers sought to identify SRs that investigated the effectiveness of aromatherapy. They only selected reviews that included controlled trials. The reviewers included reviews that investigated the effects of non-pharmacological interventions provided that the review included primary studies of aromatherapy. Reviews were excluded that were not published in English. This resulted in 2 reviews being excluded; 1 was published in Korean (Kim, et al., 2013) and the other in Portuguese (Gayeski & Brüggemann, 2010). The review published in Korean included 7 primary studies of which 4 were published in Korean, 2 were unpublished theses, and 1 citation could not be found. The review published in Portuguese investigated the effects of non-pharmacological interventions and included 1 aromatherapy study (Burns, et al., 2007). This study is included in 1 of the reviews that met our inclusion criteria (Smith, et al., 2011).

In this overview, 20 SRs were identified comprising 45 unique primary studies investigating the effects of aromatherapy. These studies included a total of 27,595 participants. Only 1 study had a large sample size (23,857 participants) (Burns, et al., 2000). The sample size of the other studies was generally small and ranged from 9 to 513 participants. Despite the large body of evidence, the reviewers were unable to draw strong conclusions due to incomplete reporting at the review level of intervention effects, and the risk of bias of the included primary studies.

Finally, the approach to summarising the body of evidence across the included trials was undertaken using vote counting based on the direction of the estimated intervention effect. This approach addresses the question of whether there is any evidence of an effect (Deeks, et al., 2011), but is limited in that it provides no estimate of a combined effect, and all studies contribute equally. The clinical importance of the estimated intervention effects can therefore not be established.

Quality of evidence

The methodological quality of the included reviews ranged from 1 to 10 (out of 11) on the AMSTAR checklist (median score of 5). Not all included reviews assessed risk of bias of the primary studies. In the reviews that did assess risk of bias, the methods and tools used varied between the reviews. As already mentioned, the results of the risk of bias assessments were poorly reported, lacking necessary details to enable reliable interpretation of the results of the

reviews and the trials within. None of the reviews provided any information on conflicts of interests of the included primary studies.

Almost all reviews reported the results narratively. Only 1 review conducted a meta-analysis for 1 outcome, showing an effect of aromatherapy in reducing anxiety in people with dementia. Since neither of the small studies that contributed to the meta-analysis was at low risk of bias, the quality of evidence was downgraded to very low according to our GRADE assessment. The level of evidence for the (non-pooled) included trials was assessed as very low quality for all other comparisons and categories were identified. In all cases, downgrading was based on the lack of studies with low risk of bias, small sample sizes and often lack of reporting of intervention effect estimates.

Potential biases in the overview process

In the overview, there seemed reasonable consistency of outcomes across reviews. Reviewers did not seek extra information by contacting the review authors or by searching for extra information in the full-text publications of the primary studies. Although there was no requirement to do this, it is possible that these steps may have elicited information that might have altered the quality appraisal of the identified evidence, or had an impact on the results or conclusions of the overview. By restricting searches to bibliographic databases, it is possible that the reviewers may have missed SRs published as grey literature. However, they did not come across additional reviews in the submissions, and even if there are reviews in the grey literature, it is unlikely these would identify additional primary studies not already included in the 20 SRs in this overview.

Given the potential for the largest trial in the overview (Burns, et al., 2000) to influence the results, the reviewers checked the original trial report to confirm that the information provided in the SR was correct; that is, that no estimates of intervention effects were reported. At the same time, the reviewers discovered that what was labelled as a randomised trial in the SR report (Lee, et al., 2012b) was not randomised, or even prospectively controlled. Since no outcome data from this study contributed to the results, the overall findings were not affected. However, this occurrence serves to highlight that errors in the SR reports have the potential to result in serious errors and biases in the overview.

Conclusions

Implications for practice

There is some evidence to suggest that aromatherapy may be effective in reducing anxiety and agitation in dementia patients, and possibly in reducing generalised anxiety in some other situations, such as before health-care procedures. The effect of aromatherapy plus massage therapy compared to massage therapy alone may help alleviate pain. However, the evidence for these findings is based on small, poor-quality studies, and was rated as very low. Also, there is uncertainty surrounding the size of the effect and its importance in clinical practice. For a range of other health conditions, very little evidence on the effect of aromatherapy was identified. Overall, the effects of aromatherapy (either in comparison with no treatment, usual care or placebo, or in combination with massage therapy) on patient health outcomes in various conditions remains uncertain.

Implications for research

The reviewers were limited in drawing definite conclusions, not due to a lack of studies, but due to the lack of information reported in the reviews and potentially in the primary studies. This overview identified that there is a need for consistent assessment and reporting of risk of bias, and results in SRs. Enough detail should be reported for each included study about the different risk of bias items that were assessed, how the item was judged and an explicit statement outlining the basis of the judgment.

Importantly, the lack of reporting of effect estimates (intervention effect estimates, and measures of precision such as confidence intervals; direction of effect; clinical relevance; information about scales) made it generally impossible to interpret the clinical importance of the effects, and limits the application of meta-analysis.

Submissions received on aromatherapy

Submissions for aromatherapy were received from the following organisations:

- Australian Association of Massage Therapists (AAMT)
- Australian Naturopathic Practitioners Association (ANPA)
- Australian Natural Therapists Association (ANTA)
- Australian Traditional Medicine Society (ATMS)

- Friends of Science in Medicine
- International Aromatherapy and Aromatic Medicine Association (IAAMA).

In reviewing the submissions, the purpose was to identify possible SRs and randomised trials (RCTs) of aromatherapy. Three SRs were identified from the submissions, though each of these had already been retrieved through the database searching, and 3 randomised trials were referenced each of these was included in one or more of the SRs in the overview.

The reviewer identified 1 randomised trial that was not included in any of the SRs included in the overview (Vakilian, et al., 2011). This randomised trial of 120 women investigated the effect of lavender essential oil on episiotomy healing compared to povidone-iodine. The overall risk of bias was assessed as high as women were not blinded to the intervention and the primary outcome, pain, was patient reported. Because the primary outcome was pain, had this trial been included in the overview, it would have contributed to the section on pain.

Bowen therapy overview report

Objective

The objective of this overview is to summarise the evidence from SRs regarding the effectiveness (and, where available, the safety, quality and cost-effectiveness) of Bowen therapy for improving health outcomes for any clinical condition.

Definition

Bowen therapy is often used to alleviate symptoms of a range of acute and chronic conditions, including injuries, musculoskeletal conditions, stroke, carpal tunnel syndrome, stress disorders and asthma (Victorian Government, 2012) In view of the wide range of conditions for which CAMs such as Bowen therapy may be used, this overview included SRs evaluating the effectiveness of Bowen therapy in participants with any clinical condition.

Developed in Australia in the 1950s, Bowen therapy is described as a soft-tissue remedial therapy or a form of bodywork that primarily focuses on the myofascia. It is a non-invasive technique that involves the use of fingers or thumbs by the therapist to apply ‘pain-free, gentle rolling movements over muscle, ligament, tendon and other connective tissues in specific parts of the body’ (Marr, et al., 2011). Proponents of the technique suggest that these gentle movements promote healing, by stimulating the body’s nervous, endocrine and fascial systems (Bowen Association of Australia, 2013). Often, the movements are applied in precise sequences with each series of movements followed by a pause, to allow time for the effects of the treatment to be absorbed by the body (Australian Association of Massage Therapists, 2013).

Methods

This overview used the methodology outlined in Chapter 22 of the *Cochrane handbook for systematic reviews of interventions*, which is designed to compile



B

O

W

E

N

T

H

E

R

A

P

Y

evidence from multiple SRs into a single document (Becker & Oxman, 2011). It does not aim to repeat the searches, assess the eligibility or assess the risk of bias of the individual studies within included SRs.

Discussion

Main results

Two SRs were identified that met the inclusion criteria for this overview: Hansen and Taylor-Piliae (2011) and Finnegan and others (2013). The SR described by Hansen and Taylor-Piliae (2011) searched for all available literature on Bowen therapy for health-related outcomes and identified 15 studies, including 1 RCT (Marr, et al., 2008), which examined the effect of Bowen therapy on hamstring flexibility in healthy participants and was therefore excluded from this overview, as it did not evaluate the effect of Bowen therapy in people with a clinical condition. The Finnegan and others (2013) SR authors searched for RCTs or controlled studies investigating the effectiveness of CAM therapies in patients with cancer-related fatigue. No studies of Bowen therapy for cancer-related fatigue were identified in their search.

Overall completeness and applicability of evidence

The 1 RCT identified by Hansen and Taylor-Piliae (2011) was conducted in healthy subjects, so did not meet the eligibility criteria for this overview. The lack of evidence from SRs of RCTs therefore prevented the evidence review team from drawing any conclusions about the effectiveness of Bowen therapy for any clinical condition.

The literature search by Hansen and Taylor-Piliae (2011) was broad, not being limiting by study design, study quality, health outcome or clinical condition. Despite searching from 1985 to 2009, only 15 primary studies were identified, only 1 of which was an RCT. Therefore, there is a clear lack of primary studies investigating the effect of Bowen therapy. It is possible that RCTs examining the effectiveness of Bowen therapy for a specific clinical condition have been published subsequent to the literature search conducted in 2009 by Hansen and Taylor-Piliae (2011). However, the reviewers did not identify any RCTs, nor any additional SRs, from the literature submitted to the Department.

Quality of evidence

Within this overview, only 1 systematic review (Hansen & Taylor-Piliae, 2011) identified primary studies of the effectiveness of Bowen therapy, however, these studies were excluded from this overview because they did not meet the inclusion criteria (either due to study design or due to population characteristics). The fact that neither of the 2 included SRs (Hansen & Taylor-Piliae, 2011; Finnegan et al., 2013) identified RCTs eligible for inclusion in the overview is likely to reflect a lack of RCTs of Bowen therapy for the treatment of clinical conditions. It is possible, however, that RCTs of Bowen therapy were missed by the searches performed for these SRs.

Hansen and Taylor-Piliae (2011) searched specifically for studies of Bowen therapy, but the search did not include the term ‘myofascial’. If myofascial release was used to describe Bowen therapy in the keywords or title of the RCT publication they would not have been identified by this search strategy. In the literature search for this overview the ‘myofascial release’ term identified 3 PROSPERO-registered reviews. As they were unpublished at the time of the search it was not possible to determine whether they included studies of Bowen therapy. (Being reviews, they may have included Bowen therapy, among other therapies, without including ‘Bowen therapy’ in the title.) However, it is less likely that an RCT of Bowen therapy would not include the term ‘Bowen’ in the title or keywords.

Finnegan et al., (2013) searched for any CAM therapies for the treatment of cancer-related fatigue. The search strategy included ‘Bowen technique’ but no other specific Bowen terms. While generic terms for complementary therapy were included in the search strategy (which may have identified publications that used terms other than ‘Bowen technique’), it is possible that RCTs of Bowen therapy that did not describe the treatment as ‘Bowen technique’ were missed in this search.

In summary, the included SRs did not identify any evidence of sufficiently high quality to evaluate the effects of Bowen therapy, highlighting the need for well-designed and well-reported RCTs of this intervention.

Potential biases in the overview process

This overview was limited to SRs published within the last 5 years, meaning that SRs on Bowen therapy published before this date were not considered. This represents a potential source of bias for this overview. However, 1 of the included SRs, Hansen and Taylor-Piliae (2011), was broad in scope and searched 4 databases for studies of Bowen therapy published between 1985 and 2009. It is therefore likely that the review by Hansen and Taylor-Piliae (2011) identified much of the evidence that might have been identified by reviews published before 1 April 2008. Further, by limiting the review to SRs published within the previous 5 years, the reviewers sought to ensure that SRs included the most recent evidence on a particular research question. Therefore, although this approach may have introduced bias (through failure to identify SRs published before 2008) it addressed another potential source of bias (by ensuring that decisions were made based on the full body of evidence, rather than outdated SRs).

As the literature for this overview was derived exclusively from searches of online databases, informally published SRs (grey literature) may have been missed, which potentially introduces another source of bias. However, it is likely that any such omitted SRs would have been included in the stakeholder submissions. Also, such reviews are not likely to have identified RCTs not already included in the Hansen and Taylor-Piliae (2011) review (with the exception of any RCTs which may have been published since the 2009 literature search in that review).

An extra potential bias of this overview is that the reviewers did not include a specialist CAM bibliographic database in their search; however, the likelihood of identifying SRs only through a CAM database is very low. One further potential source of bias is that reviews of primary studies that used myofascial therapy but which did not use one of the Bowen-specific search terms ('bowen therapy', 'bowen technique', 'bowtech' or 'bowenwork') in either the title, abstract or keywords would not have been included. Without specialised clinical input to assess whether a particular myofascial manipulation could be classified as Bowen therapy (which was beyond the expertise of the evidence review team) it was not possible to include such potential SRs in this overview.

Finally, although checks were performed on a subset of records, the use of a single reviewer for screening records introduces another source of potential bias.

Conclusions

Authors' conclusions

There is currently insufficient evidence from SRs within this field to reach any conclusion regarding the effectiveness, safety, quality or cost-effectiveness of Bowen therapy. If conducted, future research should focus on rigorous, well-designed, RCTs that assess the effectiveness and safety of Bowen therapy in specific patient populations.

Implications for practice

The effectiveness of Bowen therapy in improving health outcomes in people with any clinical condition is unknown. There is currently insufficient evidence from SRs within this field to reach any conclusion about the safety, quality or cost-effectiveness of Bowen therapy.

Implications for research

This overview has identified significant research gaps in the field of Bowen therapy, providing numerous opportunities for future research in this field. There is a clear lack of high-quality research available. Future research, if conducted, should focus on rigorous, well-designed, RCTs that assess the effectiveness and safety of Bowen therapy in specific patient populations. Studies with multi-site recruitment that are adequately powered would be highly valued, and are necessary to allow for stronger tests of treatment efficacy. Good reporting of study details and outcome data is also needed to allow sufficient examination of the evidence. Research that is based on Bowen therapy as it is practised in the Australian population would also assist in recommendations on which to guide practice in Australia.

Submissions received on Bowen therapy

Submissions for Bowen therapy were received from the following organisations:

- Australian Association of Massage Therapists (35 citations)
- Bowen Therapists Federation of Australia (285 citations)
- The Bowen Association of Australia (68 citations).

A total of 388 citations were submitted to the Department and reviewed for inclusion in this report. After removal of duplicates across submissions, 369 unique citations were reviewed with 359 excluded after assessment of the titles and abstract (including 3 submissions with insufficient citation details to enable the publication to be identified).

Two citations were published in the *Journal of the Bowen Academy of Australia* (Stephens, 2006 and Williams, 2008) and were not able to be retrieved. Australian library catalogues and library networks were searched, but no Australian libraries could be identified which hold this journal. It is most likely an in-house publication that is not indexed or abstracted and not placed in legal deposit in the National Library of Australia

There was 1 citation (Hansen & Taylor-Piliae, 2011) identified in the submitted literature that was eligible for inclusion in this review. The SR by Hansen and Taylor-Piliae (2011) had already been identified and included in the overview report. Hansen and Taylor-Piliae (2011) had identified 1 RCT (Marr, et al., 2008) that examined the effect of Bowen therapy on hamstring flexibility in healthy subjects. This RCT was not eligible for inclusion in the overview as the subjects had no clinical condition, and so was not considered further. The RCT described by Marr and others (2008) was also listed in the submitted literature and was excluded for the same reason (population out of scope).

One other submitted study (Hipmair, et al., 2012) was identified that examined the effect of Bowen therapy on patients with gonarthrosis with planned total knee replacement. The trial was not published in a peer-review journal, being made available on a website only. The study claimed to be an RCT; however, further examination revealed that patients were selected by the physician administering the Bowen therapy for allocation to either the Bowen therapy or sham therapy groups, making this a non-randomised study and ineligible for inclusion (study type out of scope). In summary, 1 eligible citation was identified in the submitted literature for Bowen therapy, a SR by Hansen and Taylor-Piliae (2011). This SR was also identified in the literature search therefore no extra literature was identified in the submitted literature.

Buteyko therapy overview report

Objective

The objective is to summarise the evidence of the effectiveness (and, where available, the safety, quality or cost-effectiveness) of the Buteyko breathing technique for any clinical condition.

Definition

The Buteyko breathing technique, or Buteyko method, is a physical therapy that is used mainly in the management of respiratory conditions. The therapy involves instructing patients in controlled shallow breathing through the nose only, with breath-holding at the end of the exhalation.

The Buteyko breathing technique, or Buteyko method, is a form of breathing exercise. Breathing exercises have been taught for hundreds of years in both eastern and western societies for numerous conditions including asthma. Anecdotal evidence from the traditional practice of yoga and other similar physical therapies frequently indicates an alleviation and sometimes elimination of asthma symptoms.

The Buteyko breathing technique was introduced into Australia in the 1990s. According to the Buteyko Institute of Breathing and Health, the main accreditation and practitioner training body in Australia, there are Buteyko practitioners that are accredited and registered with the Institute in all states and territories in Australia (Buteyko Institute of Breathing and Health). However, not all providers in Australia are accredited with the Institute.

Methods

Reviewers identified SRs published between 2008 and June 2013 through a systematic search of the following databases: MEDLINE, EMBASE, CINAHL, AMED (Allied and Complementary Medicine) and the Cochrane Library.

...

B
U
T
E
Y
K
O

The methodological quality of reviews was assessed independently by 2 reviewers using the AMSTAR tool.

In this overview, the reviewers considered for inclusion any SR published since 2008 of RCTs focusing on the use of Buteyko for the management of any clinical condition, in terms of health outcomes.

To be considered for inclusion, systematic reviewers must have conducted a systematic search for studies of the Buteyko breathing technique as an intervention. Where SRs were identified that included both RCTs and other study designs, further consideration was limited to the subset of RCTs of the Buteyko breathing technique included in the systematic review.

Where there were 2 or more reviews that addressed the same question, the intention was to include all reviews that met the inclusion criteria with a focus on the highest level of evidence and most recent search date.

Discussion

Main results

The reviewers found that the Buteyko breathing technique has been assessed as a treatment for asthma in a number of published RCTs of fair quality. Individual studies assessing the Buteyko breathing technique report improvements in asthma symptoms and reductions in reliever medications of about 1.5 to 2 puffs per day in some subjects. However, the changes between baseline and follow-up were not statistically significant in most studies, nor were there significant between-group differences for either outcome in most studies.

None of the available evidence suggests that the Buteyko breathing technique improves pulmonary function in adults. This may be because the deep inspiration that is required to perform a lung function test might induce bronchoconstriction and override any beneficial effect from the Buteyko breathing technique. Alternatively, studies in included RCTs may have been insufficiently powered to detect changes in lung function, or the Buteyko breathing technique may not influence pulmonary function.

The Buteyko breathing technique did not reliably improve quality of life in participants of RCTs in the included SRs. However, interpretation of the results of quality of life assessment across

included RCTs is problematic due to the variation in scales used to assess quality of life and the small sample sizes of included studies.

There was no evidence from included SRs that the Buteyko breathing technique is harmful besides minor annoyances associated with mouth taping. However, adverse events associated with the Buteyko breathing technique in included SRs are limited to largely adult subjects who are taking asthma medications. There was a paucity of evidence included in this overview confirming the safety of the Buteyko breathing technique in patients who are not using asthma medications. The use of the technique in patients not receiving asthma medications is therefore not supported by the available evidence.

RCTs in included SRs were limited to participants with asthma aged 14–70 years. The use of the technique in paediatric patients with asthma aged under 14 is therefore not able to be supported by the available evidence.

The Buteyko breathing technique is used to treat a broad range of clinical conditions, including respiratory conditions, anxiety and panic disorder, dental and orthodontic problems, diabetes, digestive disorders, disturbed sleep, eczema and other skin problems, excessive tiredness, high blood pressure, reproductive disorders, sleep apnoea and snoring (Campbell et al., 2011; Courtney, 2008; Ernst et al., 2006). The reviewers found no evidence from which conclusions can be drawn about the effectiveness of the Buteyko breathing technique in the treatment of clinical conditions other than asthma.

Overall completeness and applicability of evidence

There remain gaps in the research evidence regarding the Buteyko breathing technique and the evidence presented in this overview has important limitations.

The overview included 2 SRs encompassing 7 RCTs. This is a relatively small body of research from which conclusions can be drawn.

Even though both reviews had 5 of 6 RCTs in common, the reviewers were unable to compare directly the results of the 2 SRs due to differences in how data were extracted and how conclusions were drawn. As a result, information was drawn from both reviews that described the clinical trials themselves in order to draw conclusions about the efficacy of the Buteyko breathing technique.

Systematic reviewers did not provide sufficient information for the clinical significance of changes in asthma symptoms to be determined. Symptom rating scales were not universally identified in the included SRs. Where rating scales were identified a clinical interpretation of the significance of changes in rating scales was not described. Reviewers were therefore unable to determine the clinical significance of the findings of this overview. However, O'Connor and others (2012) did conclude that the reductions in medication use observed in participants receiving the Buteyko breathing technique were clinically significant. This was based on an analysis of reported reliever medication use between baseline and follow-up in participants, compared with relevant US national guidelines.

Conclusions about the effectiveness of the Buteyko breathing technique are limited largely to adult patients who are receiving usual prescribed medications for asthma. The results of this overview are therefore not generalisable to children or to people with asthma who are not receiving medications. Nor can any conclusions be drawn about the effectiveness of the Buteyko breathing technique in managing subjects with other respiratory and non-respiratory diseases.

Much of the available evidence compared Buteyko to another breathing technique rather than inactive comparison. This makes assessment of the effectiveness of Buteyko difficult as the reviewers did not perform an assessment of the effectiveness of the comparison techniques for the treatment of asthma.

The quality and/or cost-effectiveness of Buteyko were unable to be determined because no SRs were identified that assessed these outcomes.

Quality of evidence

One of the 2 SRs (O'Connor, et al., 2012) reported that a comprehensive assessment of the quality of included trials was performed. Included trials were small and methodologically limited according to the quality rating they received from O'Connor. The evidence was compromised by the relatively short follow-up and inconsistent outcome reporting in included trials. None of the included trials received a 'good' rating. Included trials are therefore assessed as being at moderate to high risk of bias.

Research into the Buteyko breathing technique is confounded by variation in the definition of asthma, the Buteyko provider delivering the intervention and study populations with mixed disease severity.

Primary outcomes (symptom reduction and reliever medication use) were self-reported across included trials, making them susceptible to social desirability bias. Further, O'Connor reports that in the largest trial (McGowan, 2003), participants in the Buteyko arm were instructed to delay bronchodilator use. This difference in protocol between the intervention and control arm may account for the observed reduction in beta-agonist use, rather than the reduction being a clinical effect of the Buteyko breathing technique.

The SRs themselves were assessed using the AMSTAR rating scale. According to the results of this assessment, 1 scored a medium and the other a high rating.

Potential biases in the overview process

The reviewers were aware that there are risks of introducing bias at all stages of an overview process. They took steps to reduce bias by specifying systematic methods for the overview process before commencing the overview. Reviewers adhered to a protocol that was endorsed by the NHMRC. Two review authors independently assessed eligibility for inclusion of reviews and carried out data extraction.

A comprehensive search strategy was used for the review. Every effort was made to identify relevant studies. The search strategy was designed to identify non-English studies; 1 study was excluded due to an English language translation being unavailable.

Conclusions

Authors' conclusions

In people with asthma, the Buteyko breathing technique may potentially reduce bronchodilator use compared with inactive control but has no consistent significant effect on pulmonary function, asthma symptoms or quality of life.

In the absence of a more significant body of research from high-quality RCTs, there is insufficient evidence to support the clinical use of the Buteyko breathing technique for the management of asthma.

Implications for practice

The presented evidence shows that the Buteyko breathing technique may potentially reduce bronchodilator use but has no consistent significant effect on steroid use, asthma symptoms, quality of life or pulmonary function.

The quality of the evidence is limited by the small number of RCTs, small number of patients in those RCTs (with the exception McGowan 2003; reported as abstract only) and the low methodological quality of the studies.

In the absence of a more significant body of research from high-quality RCTs, there is insufficient evidence to support the clinical use of the Buteyko breathing technique for the management of asthma.

Implications for research

There is a need for high-quality RCTs to evaluate the effectiveness of the Buteyko breathing technique. Future research in this area should focus on larger sample sizes, improved reporting of data, and adequate follow-up periods to enable more robust conclusions to be drawn.

Plain language summary

In some people with asthma, the Buteyko breathing technique may reduce bronchodilator use, but has no consistent effect on steroid use, compared with inactive treatment. There was no consistent significant effect of Buteyko on pulmonary function, asthma symptoms or quality of life compared with inactive treatment. There is no evidence of significant harmful effects.

Conclusions were unable to be drawn about the effectiveness of the Buteyko breathing technique for conditions other than asthma.

Submissions received on Buteyko

There were no evidence submissions received as the result of a public submission process for the Buteyko breathing technique.

There was no submitted literature that provided evidence for the effectiveness of Buteyko for any clinical condition.

Feldenkrais overview report

Objective

The objective of this overview is to summarise the evidence from SRs that examined the effectiveness (and, where available, the safety, quality and cost-effectiveness) of Feldenkrais for improving health outcomes for any clinical condition.

Definition

Feldenkrais (also known as the Feldenkrais method) aims to improve posture, breathing and movement, by combining gentle touch with training (Beckner & Berman, 2003). Through a series of lessons, individuals are taught to focus on their breathing and movement, with the aim of bringing mindfulness to these everyday activities and thus adopting new habits.

Through these practices, individuals are said to experience an improvement in their overall sense of wellbeing. There are 2 formats for teaching the Feldenkrais method: ‘functional integration’, which requires one-on-one hands-on sessions, during which the practitioner gently moves the patient into particular positions or through movements; and ‘awareness through movement’ (ATM), which is taught in a group setting or performed by an individual using recorded instructions (Strauch, 1996). ATM lessons are usually taught in groups on a weekly basis. One practitioner can conduct a class with up to 12 participants. Lessons may be done sitting in chairs, standing or lying on carpet.

To become an accredited Feldenkrais instructor in Australia, individuals must complete a Feldenkrais professional training program accredited by the Australian Training and Accreditation Board (AusTAB).

Methods

Reviewers searched EMBASE, MEDLINE, the Cochrane Library (database of systematic reviews, other reviews, and technology assessments),

PubMed, PubMed Health and PROSPERO to identify all SRs addressing the primary clinical

• • •

F

E

L

D

E

N

K

R

A

I

S

research question. They also hand-searched reference lists of relevant articles to identify extra articles not identified in the literature search. The search was restricted to SRs published from 1 April 2008 to 5 September 2013. In addition, any relevant SRs identified through the Department's call for submissions were assessed for inclusion in this overview.

Ten SRs were identified that met the criteria for inclusion within this overview. Three high-quality SRs (AMSTAR score 9 or higher out of 11), 1 moderate-quality review (AMSTAR score between 6 and 8 out of 11) and 1 low-quality review (AMSTAR score 5 or less out of 11) identified 3 RCTs relevant to Feldenkrais. The remaining 5 reviews either did not identify any primary studies that were eligible for inclusion in this overview, or did not find any studies on Feldenkrais that met their inclusion criteria.

The clinical conditions for which no RCTs on Feldenkrais were found were chronic musculoskeletal pain (including neck, shoulder, or knee pain), fibromyalgia, motor skills after stroke, post-traumatic stress disorder and generalised anxiety disorder. Of the 5 SRs that did not identify any studies related to Feldenkrais, 4 were assessed as high quality (AMSTAR 9 or higher out of 11) and 1 was assessed as low quality (AMSTAR score 2 out of 11).

The 3 RCTs identified by the included SRs provided limited evidence for 3 patient populations: women with work-related complaints of the neck and shoulder (Lundblad, et al., 1999), people with chronic low back pain (Smith, et al., 2001) and older people at risk of falling (Vrantsidis, et al., 2009). The RCTs were rated by the review authors as having an overall high (Lundblad, et al., 1999) or unclear (Smith et al., 2001; Vrantsidis et al., 2009) risk of bias. Each included RCT reported a positive effect favouring Feldenkrais compared to no treatment, sham, or usual activity, respectively. The studies were small and underpowered and the level of confidence in the evidence was very low.

A reduction of unspecified pain over 1 year was observed in women with work-related neck and shoulder pain who received Feldenkrais; however, in the same trial, Feldenkrais was no more effective than no treatment or physiotherapy for the other outcome measures of pain and disability or function. Similarly, Feldenkrais was no more effective than sham control for reducing pain or anxiety in people with chronic low back pain. An effect favouring Feldenkrais was reported in the RCT described by Vrantsidis and others (2009) for all 4 measures for balance

ability; however, the effect was only statistically significant for 1 of these 4 measures. Adverse events were not reported by any of the studies.

Discussion

Main results

Ten SRs were identified that examined the effectiveness of Feldenkrais for health outcomes in 7 clinical conditions. Three RCTs were identified that examined the effectiveness of Feldenkrais: 1 RCT in women with neck and shoulder complaints (Lundblad, et al., 1999), 1 in participants with chronic low back pain (Smith, et al., 2001) and 1 in older adults at risk of falling (Vrantsidis, et al., 2009). There were no RCTs of Feldenkrais identified in the literature for the remaining clinical conditions, thus the effectiveness of Feldenkrais for improving health outcomes in people with chronic musculoskeletal pain (including neck, shoulder, or knee), fibromyalgia, improving motor skills in patients after stroke, post-traumatic stress disorder or adults with generalised anxiety disorder is unknown.

In people with mechanical neck disorders, 1 RCT (Lundblad, et al., 1999) reported an effect favouring Feldenkrais compared to no treatment for the long-term reduction of unspecified pain (over 1 year). Observed differences between treatment groups were not statistically significant for the other outcome measures of pain or disability/function when comparing Feldenkrais to physiotherapy or no treatment. The study was assessed by the SR authors to have an overall high risk of bias. Therefore, confidence for this evidence was very low and caution should be applied when interpreting these results. For chronic low back pain, no statistically significant difference between treatment groups was reported by Smith and others (2001) comparing Feldenkrais with sham control for pain or anxiety; however, the study was small and underpowered. The RCT described by Vrantsidis and others (2009) showed an effect favouring Feldenkrais compared with usual activity in 1 of 4 outcome measures for improvements in balance ability in older adults, but not for the remaining 3 measures. The study had an overall unclear risk of bias.

Therefore, the effectiveness of Feldenkrais in people with mechanical neck disorders, in people with chronic low back pain, or for the improvement of balance and stability in older adults at risk of falling remains uncertain.

None of the included SRs reported data on the safety, quality or cost-effectiveness of the Feldenkrais method.

Overall completeness and applicability of evidence

There is a paucity of evidence regarding the effectiveness of Feldenkrais for the improvement of health outcomes for any clinical condition. The Feldenkrais method is intended to re-train the brain to improve posture and movement, with the goal of improving quality of life. Although 10 SRs were identified that met the inclusion criteria for this overview, the majority failed to identify any RCTs of Feldenkrais. Notably, those reviews evaluated the effect of interventions on outcomes such as pain, physical function, improved movement and wellbeing, and including conditions which proponents claim the Feldenkrais method may benefit. Where data were available, they were insufficiently reported, making it difficult to analyse and interpret the limited evidence available. In addition, the included RCTs were small in size ($n < 100$) and likely to be insufficiently powered to detect a statistically significant outcome.

For mechanical neck disorders, the evidence showing an effect favouring Feldenkrais compared with control was reported in 1 small RCT with a high risk of bias. Furthermore, this result was found in a very specific population (female workers at a car and truck industrial workplace living in Sweden). Therefore, these findings may have limited applicability to the broader Australian population.

For improvements in balance ability in older adults, an effect favouring Feldenkrais compared with usual activity was reported in 1 of 4 measures used to assess balance ability (the timed up-and-go test). However, this test is an indirect measure of balance, and the more direct measure of balance (force platform) did not show a significant effect. The applicability of this evidence is therefore limited.

Quality of the evidence

The quality of the evidence included in this overview was limited by the lack of high-quality primary studies for Feldenkrais. Although the majority of included SRs were assessed to be of high quality and sufficiently critiqued and evaluated the available evidence, many were broad reviews covering a range of therapies (including Feldenkrais, exercise, meditative movement therapies) and were focused on a specific clinical condition. In these cases, the level of detail provided on RCTs of Feldenkrais was often limited. Further, the 1 review specific to Feldenkrais (Buchanan, 2012) was of low quality (AMSTAR score 5 out of 11) and did not report any usable

data. One issue not sufficiently addressed by the review authors was publication bias. Publication bias was not assessed in the reviews by Howe and others (2011) and Kay and others (2012) due to the paucity of trials in any 1 category, and the lack of quality reporting and power respectively. The reviews by Buchanan (2012) and Verhagen and others (2009) did not mention publication bias.

As discussed earlier, the RCTs included within the reviews had either an unclear or high risk of bias due to methodological limitations, and so results must be interpreted with caution. Of particular concern, the included RCTs had either a high or unclear risk of bias for many domains including: random sequence generation, incomplete outcome data, selective reporting and blinding of participants. Improvements in each of these domains are necessary to permit a high level of confidence in the outcomes reported. More high-quality evidence is needed to enable recommendations to be made regarding the use of Feldenkrais in treating patients with any clinical condition.

Potential biases in the overview process

This overview was restricted to SRs published on or after 1 April 2008, as a means to include the most recent evidence for the Feldenkrais method. This meant that SRs published before this date were not considered, representing a potential source of bias for this overview. However, the SR by Buchanan (2012) specifically searched several databases for all primary studies of Feldenkrais technique for people with any clinical condition, and does not appear to have limited its search by date. It is therefore likely that the review by Buchanan (2012) identified much of the evidence that might have been identified by reviews published before 1 April 2008.

Another potential source of bias is that the literature was derived exclusively from searches of online databases; therefore, informally published SRs (grey literature) may have been missed. Also, the reviewers did not conduct a systematic search for RCTs published since the search date of included SRs. However, it is likely that any such omitted SRs or RCTs would have been included in the stakeholder submissions; therefore, it is unlikely that these potential biases have impacted on the conclusions of this overview.

During the independent, methodological review of this overview, it was identified that the overview searches did not include a specialist CAM bibliographic database; however, it is

unlikely that any studies were missed due to this omission. Reviewers searched several other major bibliographic databases and included additional SRs identified in the literature submitted to the Department. The only SR identified through the submissions process was published in the grey literature and would not have been picked up by a specialist CAM bibliographic database.

A further potential source of bias was the exclusion of non-English publications (where full-text translations were not available). Five papers that were potentially relevant for Feldenkrais were excluded on this basis, although only 1 of the 5 is confirmed to specifically regard the Feldenkrais method. The omission of these publications could pose a significant risk of bias to the overview, if RCTs of Feldenkrais were included within these reviews. However, as it is likely that any omitted RCTs would have been included in the broad review by Buchanan (2012) or stakeholder submissions, this potential source of bias is also unlikely to have impacted on the overview findings.

Publication bias may also have impacted the findings of the evidence review. Publication bias is a complex issue, particularly for CAM therapies such as Feldenkrais. Trials with positive findings may be more likely to be published in journals, whereas smaller trials with non-significant results may remain unpublished. It is therefore possible that the paucity of published data in this field reflects a lack of positive results to report, rather than a general lack of research. The alternative is that studies showing positive results have been conducted, but not to the rigorous standards usually required for publication. Finally, although checks were performed on a subset of records in this overview, the use of a single reviewer for screening records introduced another potential source of bias.

Conclusions

Authors' conclusions

The effectiveness of Feldenkrais for the improvement of health outcomes in people with any clinical condition is uncertain. The available evidence is limited by the small number of RCTs in this field. Individual studies were small in size, and likely to be insufficiently powered to detect a statistically significant outcome. Significant research gaps exist and there is no solid evidence base on which to make recommendations. Further research, if conducted, should focus on

rigorous, well-designed RCTs that assess the effectiveness of the Feldenkrais method in improving health outcomes in specific patient populations.

Implications for practice

The effectiveness of Feldenkrais on improving health outcomes in people with any clinical condition is uncertain. There is insufficient evidence to inform clinical practice. The available research is restricted to women with neck and shoulder complaints, people with chronic low back pain or older adults at risk of falling and is focused on pain, disability, or balance as health outcomes. The applicability and generalisability of the current evidence to the Australian context is limited. Little or no data have been reported within SRs on the safety or cost-effectiveness of Feldenkrais. Therefore the safety, quality, or cost-effectiveness of Feldenkrais is unknown. Evidence from high-quality studies designed and reported using rigorous and controlled methods is required before any conclusions regarding the use of Feldenkrais can be made.

Implications for research

This overview highlights the significant research gaps in the field of Feldenkrais, providing numerous opportunities for future research in this field. Future research, if conducted, should focus on rigorous, well-designed RCTs that assess the effectiveness of the Feldenkrais method in improving health outcomes in specific patient populations. Studies with multi-site recruitment that are adequately powered would be highly valued, and are necessary to allow for stronger tests of treatment efficacy. Improved reporting of study details and outcome data is also needed to allow examination of individual differences in treatment response. Research that is based on Feldenkrais as it is practised in the Australian population would also help in developing recommendations to guide practice in Australia.

Submissions received on Feldenkrais

Submissions for Feldenkrais were received from the following organisations:

- Australian Association of Massage Therapists (AAMT) (35 references)
- Australian Feldenkrais Guild (AFG) (596 references)
- Friends of Science in Medicine (7 references).

A total of 638 references were submitted to the Department and reviewed for inclusion in this report. A review of the reference titles and abstracts found that a large majority of articles (540)

were not reports of a primary study or full details of the study were not published (for example, poster presentation) and were therefore of the wrong publication type for inclusion in this report. Nineteen articles were reports of studies in healthy participants. Three SRs were identified through the submissions process that had not been identified during the literature search. Buchanan (2012) met our inclusion criteria for the overview, and so was included in the report. Both Ernst and Canter (2005) and Ives and Shelley (1998) were published before April 2008 and so were excluded from the overview. Two RCTs were identified that were already included in the overview (Lundblad et al., 1999; Vratsidis et al., 2009) and therefore no extra data extraction or analysis was performed.

Twenty articles were retrieved for full-text review, of which only 2 (Chinn et al., 1994; Stephens et al., 2001) met the inclusion criteria for this report. The RCTs by Chinn and others (1994) and Stephens and others (2001) were identified in the overview within the SR by Buchanan (2012), however, no data were reported, so they were included in Part B for completeness. Of the remaining 18 articles that were excluded after full-text review, 1 RCT (Smith, et al., 2001) and 1 SR (Buchanan, 2012) were excluded as they were already included in the overview. One study examined Feldenkrais in healthy participants, 9 did not examine Feldenkrais (intervention out of scope) and 2 were not primary studies or SRs (publication type out of scope). The remaining 4 studies were assessed as Level III evidence or below.

Herbalism overview report

Objective

The objective of this overview is to summarise research on the effectiveness of herbalism, specifically western herbalism, as a health service for improving health outcomes for all clinical conditions compared with placebo, no treatment or an alternative active intervention. The overview also aims to summarise the safety, quality and costs of herbalism practice, if these components were evaluated in any included SRs.

Definition

Herbalism is an ancient form of therapy that involves the use of medicinal plants or plant-derived substances to prevent and treat illness.

The 3 main types of herbalism are Chinese, Ayurvedic and western. Herbal medicine practitioners (herbalists) use a holistic and individualised approach to prescribing remedies for individuals under their care, and typically treat the ‘whole’ person, not just the symptoms.

Herbal treatments, either in a raw or refined state, can be administered in many ways, including orally or via application to the skin, and are commonly used for the digestive, respiratory, circulatory, immune, endocrine and nervous systems.

Methods

The methods used to conduct this overview were based on the methodology described in Chapter 22 of the *Cochrane handbook for systematic reviews of interventions* (Becker & Oxman, 2011). SRs were eligible if they were published from 2008 to May 2013 and included primary research studies that assessed the effects of herbal medicine (as practised in western herbalism) as a health service for any population, condition or setting.

Where SRs included a range of study designs, the reviewers restricted analysis to the randomised trials included in the SRs. Had SRs and overviews of a range of complementary or natural therapies that included trials of herbalism as a health service been

...
H
E
R
B
A
L
I
S
M

identified, the reviewers intended to identify the subset of trials that related to the practice of herbalism.

SRs of the therapeutic effects of individual herbs or herbal remedies were excluded since the focus of the overview was herbalism, and in particular the role of the herbalist in providing herbal remedies for individuals under their care. SRs of Chinese and Ayurvedic herbal medicine were also excluded as these were outside the scope of this overview.

The reviewers searched the following databases for reports of SRs: *Cochrane database of systematic reviews*, *Database of abstracts of reviews of effects*, PubMed, Embase, CINAHL and AMED. The reviewers also consulted PROSPERO, the international prospective register of SRs, and planned to use 4 outcome domains to summarise and synthesise the results: patient health, patient experience of care, safety (harms) and costs.

Discussion

Main results

This overview did not identify any SRs meeting the selection criteria. While there is a large body of research on the effects of individual herbal agents and remedies (phytotherapy), the study of the real-life practice and outcomes of herbalism as a health practice is a relatively new area of research that is yet to be addressed in SRs.

Overall completeness and applicability of evidence

This overview considered the evaluation of the effects of herbalism as a health service, and excluded studies of the effect of individual herbal remedies or over-the-counter preparations. In the context of the overarching aim of the Review, this was considered appropriate given our understanding that PHI pay Rebates on a consultation with a herbalism practitioner rather than on an individual herbal agent or over-the-counter preparations. Further, to have exclusively focused on the effectiveness of individual herbal agents (that is, phytotherapy) would have ignored an essential component of traditional herbalism, namely the role of the herbalist in using a holistic and individualised approach to treating patients (Ernst, 2007).

However, this overview, and the search methods used, excluded traditional Chinese medicine (TCM), as it is outside the scope of the Review. TCM and Ayurveda may be considered a form

of herbalism, or have herbalism as a core component of their practice, and could therefore provide insights applicable to the practice of herbalism more generally.

Potential biases in the overview process

Given that no SRs meeting the inclusion criteria for this overview were identified, potential biases are limited to the possibility of omitting relevant research. The reviewers tried to minimise this risk by conducting cited reference searches for several key articles, contacting subject specialists, and taking care to note any potential studies and reviews referenced by papers discussing the emergence of whole-system research for western herbalism. By relying on bibliographic databases, it is possible that reviewers may have missed SRs published as grey literature but this is unlikely given the absence of primary studies evaluating whole-practice herbalism. In addition, the reviewers did not come across any eligible reviews or randomised trials in the submissions provided to NHMRC.

It is possible that the categorisation of the practice of herbalism into western herbalism (included in this overview), Ayurvedic medicine and TCM (not included in this overview) may have resulted in too narrow a scope and limited the applicability of this overview. The results of this overview should therefore be considered in the context of other related overviews.

Conclusions

Authors' conclusions

Since the evidence base for individualised herbal medicine, as practised in western herbalism, is sparse, the reviewers were not able to reach any conclusions as to its effectiveness or potential harms. While there is a large body of research on the effects of individual herbal agents and remedies, the study of the real-life practice and outcomes of herbalism as a health service is a relatively new area of research that is yet to be addressed in SRs.

This overview did not identify any SRs meeting the selection criteria. While there is a large body of research on the effects of individual herbal agents and remedies (phytotherapy), the study of the real-life practice and outcomes of herbalism as a health practice is a relatively new area of research that is yet to be addressed in SRs.

Implications for practice

The reviewers did not identify any SRs of the effects of herbalism as a health-care practice and were therefore unable to make any overall assessment (based on evidence from rigorous study designs) as to the potential benefits or harms of herbalism as a health service compared to alternative or standard practice. This conclusion applies to the practice of western herbalism specifically, since the scope of the overview excluded TCM and Ayurvedic medicine, and the effects of individual herbal agents. The lack of research to guide practice and policy decisions in respect of herbalism highlights the importance of considering other ways in which practice could be strengthened and risks to the community minimised; for example, through the introduction of some form of national registration and accreditation scheme.

Implications for research

This overview has highlighted the paucity of evidence for assessing the effectiveness or potential harms around the practice and outcomes of herbalism as a health practice. This is of some concern given the widespread use of complementary therapies within the community, the proliferation of alternative medicine practitioners and the lack of regulation of herbalism as profession or industry. Since the potential for adverse events is high due to negative interactions between different herbs or between herbs and conventional treatments, there is an urgent need for herbal medicine practitioners and researchers to plan and conduct rigorous studies that adopt a ‘whole-system research’ model.

Submissions received on herbalism

Submissions for herbalism were received from the following organisations:

- Australian Acupuncture and Chinese Medicine Association (AACMA)
- Australian Integrative Medicine Association (AIMA)
- Australian Natural Therapists Association (ANTA)
- Australian Naturopathic Practitioners Association (ANPA)
- Australian Traditional Medicine Society (ATMS)
- Chinese Medicine Board of Australia (CMBA)
- Endeavour College of Natural Health
- Friends of Science in Medicine

- Individual – John Wardle
- National Herbalist Association of Australia (NHAA)
- National Institute of Complementary Medicine (NICM).

In most cases, these submissions comprised a report and bibliography of relevant references. In reviewing the submissions, the purpose was to identify possible SRs and RCTs of herbalism. Submissions were excluded if the reference was to SRs or trials of herbal remedies or products (rather than herbalism as a whole practice). The reviewers did not identify any additional SRs or randomised trials relevant to the overview from submitted literature.

One submission (Chinese Medicine Board of Australia) contained no references so was not considered further.

Homeopathy overview report

Objective

The objective of this overview is to summarise the evidence from SRs regarding the effectiveness of homeopathy as a treatment for any clinical condition.

In considering the effectiveness of homeopathy for this review, the HWC determined the following uses are also within scope: (i) homeopathy used to treat the side effects of another treatment/intervention; and (ii) homeopathy used in conjunction with another treatment/intervention, where the design of the study does not confound the results (that is, where the specific effect of homeopathy can be determined). For example, studies that examined ‘homeopathy plus other intervention’ versus ‘other intervention’ were included. The use of homeopathy as a preventative/prophylactic intervention was considered out of scope. In addition, the report did not include studies that exclusively examined safety or homeopathic aggravations, defined as a temporary worsening of existing symptoms following the administration of a homeopathic remedy (Grabia and Ernst, 2003); however, safety results reported in otherwise included studies were presented in the report.

Background

NHMRC were tasked with examining the available evidence on effectiveness (and where available, the safety, quality and cost-effectiveness) of a selection of in-scope and prioritised natural therapies. Independently of the Department’s Natural Therapies Review, NHMRC had begun its own review of the evidence for the effectiveness of homeopathy. To avoid duplication, it was agreed that NHMRC would provide the Department with a copy of its homeopathy evidence review, to inform the Natural Therapies Review.

...

H
O
M
E
O
P
A
T
H
Y

At the start of the Review, the Department invited public submissions from stakeholder groups and members of the public. The purpose of this report is to review and evaluate any extra literature submitted to the Department that has not already been considered during NHMRC's homeopathy review process.

NHMRC's homeopathy review

NHMRC's homeopathy review comprised a SR of SRs (an overview) on the effectiveness of homeopathy in treating a variety of clinical conditions. NHMRC also considered published guidelines, other government reports and evidence submitted by stakeholders. The findings of this homeopathy review are being used to inform the development of an NHMRC information paper on homeopathy, which will be made available to the Australian community to help people make informed decisions about their health care.

NHMRC's homeopathy evidence review comprised 2 technical documents:

- Overview Report: a SR of SRs of the effectiveness of homeopathy
- Review of Submitted Literature: a report documenting the review and evaluation of literature submitted to the NHMRC by stakeholders.

This report should be read in conjunction with the NHMRC's Overview Report and the Review of Submitted Literature.

Definition

Homeopathy is a 200-year-old form of alternative medicine. The discipline is underpinned by the principle of *similitude* ('like cures like'); meaning substances that cause symptoms in a healthy person have the ability to treat an ill person with the same symptoms (when administered in homeopathic potencies). Homeopathy is also based on the belief that molecules in highly diluted substances retain a 'memory' of the original substance. Specifically, homeopathic remedies are repeatedly diluted and agitated in a process known as 'potentisation' or 'dynamisation'.

Methods

In line with the parameters of the Review, the following exclusion criteria were applied to the literature submitted to the Department:

- Publication type out of scope: Submitted literature that was not a report of a primary study (for example, opinion pieces, websites, videos, news articles or opinion pieces) was not considered further.
- Intervention, participants or outcomes out of scope: Literature that did not evaluate the effectiveness of homeopathy on health outcomes in people with a clinical condition was excluded.
- Study type Level III or below: Studies that were not RCTs or SRs of primary evidence were not considered further.
- Studies not available in the English language: Studies published in languages other than English were only considered where a full-text English translation was available.
- Publication date before 2008: Consistent with the parameters of the Review, literature was only considered if it was published between January 2007 and December 2012.

Screening

Each submission and all included references were collated and tabulated. A single reviewer then compared the tabulated references with the reference list of the NHMRC's *Overview Report* and *Review of Submitted Literature* to exclude those references that had already been considered through NHMRC's homeopathy review process. The titles and abstracts of remaining references were then screened and those references that were clearly out of scope were excluded. The remaining potentially relevant references were retrieved in full text and considered for inclusion in this evaluation report.

Data extraction and critical appraisal

Where additional SRs were identified, it was intended that data would be extracted and the results of the review summarised, including what, if anything, the SR adds to the body of evidence established in the *Overview Report*.

Data from additional RCTs identified through the submissions were extracted using the data extraction form. The data were extracted by one evidence reviewer and checked by a second reviewer. Extracted data included:

- general study details (citation, study design, evidence level, location/setting, intervention/s, comparator/s)

- affiliations/sources of funds and conflicts of interest for each of the included studies
- participant details, including key demographic characteristics.

Each of the included studies were also critically appraised using the Cochrane Collaboration 7-item risk of bias tool across the following 7 domains: random sequence generation; allocation concealment; blinding of participants and personnel; blinding of outcome assessment; incomplete outcome data; selective reporting; other bias. Two evidence reviewers independently assessed the risk of bias for each included RCT. Disagreements were resolved through discussion with a third reviewer.

Results of the Review

There is a paucity of good-quality studies of sufficient size that examine the effectiveness of homeopathy as a treatment for any clinical condition. The available evidence is not compelling and fails to demonstrate that homeopathy is an effective treatment for any of the reported clinical conditions.

Plain language summary

The paucity of good-quality primary studies, the preponderance of studies with small sample size and insufficient power, and the lack of replication of results in multiple studies made the interpretation of apparent ‘significant’ differences in favour of homeopathy over placebo difficult. Many studies also failed to use (or report) appropriate comparators, blinding, or randomisation, all of which would be necessary to permit a high level of confidence in the outcomes reported. Accordingly, in rating the body of evidence, the overall shortcomings of the primary evidence limited the ability of the evidence review team to draw conclusions about the efficacy of homeopathy for many of the clinical conditions included in this overview.

Research gaps

A major challenge in assessing the evidence and interpreting the results for this overview has been the paucity of good-quality primary studies that are of sufficient size to demonstrate the effectiveness of homeopathy for specific clinical conditions.

If further primary research is conducted, investigators should try to:

- recruit substantially larger samples of patients and include statistical tests to demonstrate the significance of results
- utilise blinding/double blinding methodology and randomised assignment of subjects to treatment groups
- improve trial reporting and follow-up (for example, reporting of drop outs)
- improve reporting of conflicts of interest
- provide more detailed descriptions of interventions (including doses, dilutions), better descriptions of outcomes and how they were measured, and better discussion of potential confounders or bias
- justify the use of active comparators and comment on the effectiveness of those comparators compared to placebo
- use a methodological approach that can differentiate between the effect of homeopathic medicines and treatment by a homeopath (that is, interaction at a consultation).

In addition, systematic reviewers should:

- justify the pooling of results in meta-analyses and provide a detailed discussion of heterogeneity between the primary studies
- adequately and accurately report study details including treatment regimens, length of follow-up, outcomes studied and the clinical and statistical significance of results.

Submissions received on homeopathy

Submissions for homeopathy were received from the following organisations/individuals:

- Australian Acupuncture & Chinese Medicine Association (AACMA)
- Australian Natural Therapists Association Ltd (ANTA)
- Australian Naturopathic Practitioners Association (ANPA)
- Australian Traditional Medicine Society (ATMS)
- Australian Register of Homeopaths (AROH)
- Endeavour College of Natural Health
- Friends of Science in Medicine

- National Institute for Complementary Medicine (NICM)
- Ms Trixie Whitmore.

Submissions that were received and that related to homeopathy were evaluated to ensure that the evidence review considered all relevant evidence. These submissions contained a total of 657 unique references, of which 609 were excluded after title and/or abstract review and 34 were excluded at full-text review, as being clearly out of scope. No additional SRs were identified within the submitted literature. A total of 14 RCTs were identified that met the inclusion criteria for this evaluation report.

A complete list of the 657 citations contained within submissions, along with the rationale for exclusion (for all excluded references) were documented.

Of the 14 RCTs that met the inclusion criteria, 4 were not reported in full: 2 were conference posters (Sharma & Sharma, 2012; Sharma et al., 2012) and 2 were non-English articles that were available in English language as abstracts only (Siebenwirth et al., 2009; Teixeira, 2009). As these RCTs were not available in full text, they were not considered further as it was not possible to assess the full body of evidence, or to appraise the quality of the RCT from the information available in the abstracts. The remaining 10 RCTs assessed the effect of homeopathy for a variety of clinical conditions. The majority of RCTs were small and had a high or unclear risk of bias, with only 2 RCTs assessed as having a low risk of bias overall (Padiha et al., 2011; Singer et al., 2010).

A chart outlining the process for evaluating the submitted references against inclusion/exclusion criteria and reference numbers at each stage is presented at Figure 1.

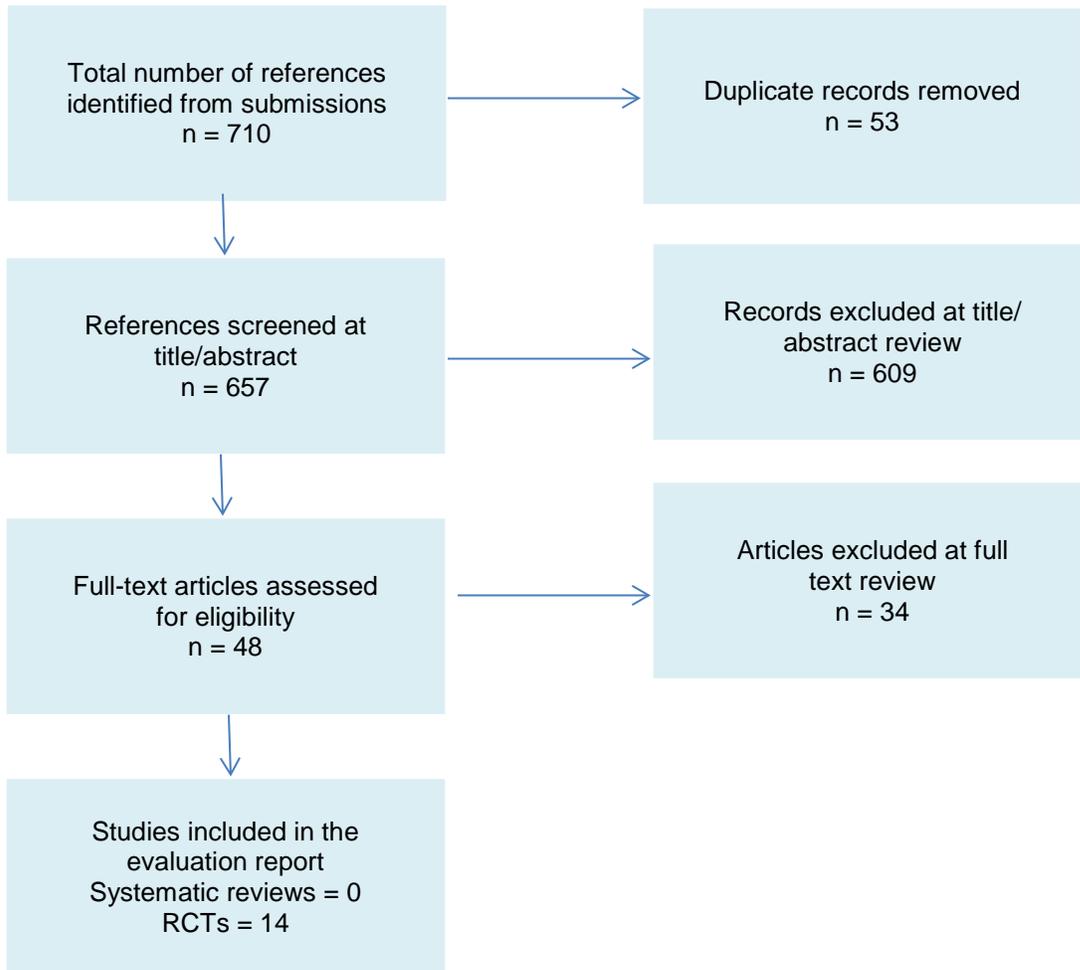


Figure 1. Diagram depicting the assessment of studies against inclusion/exclusion criteria at each stage

Iridology overview report

Objective

The aim of the overview is to summarise the evidence of the effectiveness (and, where available the safety, quality or cost-effectiveness) of iridology for the diagnosis and/or management of any clinical conditions.

Definition

Iridology involves the examination of the iris of the eye to determine information about a person's systemic health. Irregularities in the iris are thought by practitioners who use the technique to reflect abnormalities of specific organs and/or functions of the body.

Methods

Reviewers sought to identify any SRs published between 2008 and June 2013 through a systematic search of the following databases: MEDLINE, EMBASE, CINAHL, AMED and the Cochrane Library. It was intended that the methodological quality of reviews would be assessed independently by 2 reviewers using the AMSTAR tool.

Discussion

Summary of main results

There is a lack of evidence available from SRs published since 2008 for the effectiveness of iridology for the diagnosis and/or management of any clinical condition. The safety, quality and/or cost-effectiveness of iridology are also unable to be determined, as no SRs were identified.

Overall completeness and applicability of evidence

Although iridology is a diagnostic technique that is used by a range of natural therapists, including iridologists, naturopaths, homeopaths and lay iridology practitioners, there is a lack of available evidence to support its effectiveness. The findings suggest that this diagnostic method is under-researched, with no SRs being identified that met the inclusion criteria for this overview.

Ideally, diagnostic techniques should display high degrees of diagnostic accuracy, being both reliable and valid. The diagnostic accuracy of a technique is 'the degree to which a measurement

represents the true value of the variable which is being measured' (NHMRC, 2000). Diagnostic accuracy can be quantified by a range of metrics, including test sensitivity and specificity, predictive values, likelihood ratios and other statistical analytic techniques. Different measures of diagnostic accuracy relate to the different aspects of diagnostic technique: while some measures are used to assess the discriminative property of the test others are used to assess its predictive ability.

Reliability requires the reproducibility of diagnostic procedures to be evaluated; that is, whether 2 observers find the same result of a diagnostic procedure in the same patient population, or whether a single observer finds the same result of a diagnostic procedure in the same patient population on 2 separate moments in time (Beaglehole, et al., 1998).

Validity measures the extent to which the diagnostic test actually does what it is supposed to do. More precisely, validity is determined by measuring how well a test performs against a 'gold' or criterion standard (Beaglehole, et al., 1998).

Given the broad range of pathology and radiology techniques that are available for the assessment of body systems, the absence of recent SRs that compare iridology with other diagnostic techniques is a significant limitation in the evidence basis for iridology. Reviewers were therefore unable to make any conclusions regarding the effectiveness of iridology.

Quality of evidence

Not applicable

Potential biases in the overview process

A comprehensive search strategy was used for the overview. Every effort was made to identify relevant SRs. The search strategy was designed to identify non-English publications and no reviews were excluded due to language.

Conclusions

Authors' conclusions

Reviewers were unable to identify SRs conducted in the last 5 years that assess the efficacy of iridology, suggesting there is a critical lack of evidence for the effectiveness of iridology. It is not possible to draw conclusions about the efficacy of iridology in the absence of reviews that include up-to-date, high-quality studies.

Iridology involves an examination of the pigment irregularities in the iris of the eye with the aim of diagnosing health problems. This overview sought to summarise and report all of the available evidence arising from SRs of iridology regarding how effective iridology is in the diagnosis and/or management of clinical conditions.

Reviewers did not identify any SRs to include in this overview. Based on the existing evidence were unable to draw conclusions about the effectiveness of iridology as a diagnostic technique.

Implications for practice

There is a lack of evidence from SRs published since 2008 about the effectiveness of iridology and therefore can draw no conclusions about the effectiveness of iridology for the diagnosis and/or management of any clinical condition from this overview.

Implications for research

Reviewers were unable to identify SRs conducted in the last 5 years that assessed the efficacy of iridology for the diagnosis and/or management of any clinical condition.

Submissions received on iridology

There was 1 evidence submission received from Friends of Science in Medicine that related to this overview. This submission did not include any studies for consideration for inclusion in this overview.

Kinesiology overview report

Objective

The objective of this overview is to summarise the evidence from SRs regarding the effectiveness (and, where available, the safety, quality and cost-effectiveness) of kinesiology for improving health outcomes for any clinical condition.

Definition

Kinesiology is the study of body movement that identifies factors that block the body's natural healing process. These dysfunctions are rectified by attention to reflex and acupressure points and use of specific body movements.

Kinesiology comes from the Greek word *kinēsis*, which means 'to move'. Broadly, kinesiology is the scientific study of the principles of mechanics and anatomy in relation to human movement (Merriam-Webster Online Dictionary, 2013).

Kinesiology encompasses holistic health disciplines which use the gentle art of muscle monitoring to access information about a person's wellbeing. Originating in the 1970s, it combines western techniques and eastern wisdom to promote physical, emotional, mental and spiritual health. Kinesiology identifies the elements which inhibit the body's natural internal energies and accessing the life enhancing potential within the individual (Australian Kinesiology Association, 2013).

Methods

Reviewers searched EMBASE, MEDLINE, the Cochrane Library (*Database of systematic reviews*, other reviews, and technology assessments), PubMed, PubMed Health and PROSPERO to identify all SRs addressing the primary clinical research question. They also hand-searched reference lists of relevant articles to identify extra articles not identified in the literature search.

...

K
I
N
E
S
I
O
L
O
G
Y

The search was restricted to SRs published from 1 April 2008 to 20 August 2013. In addition, any relevant SRs identified through the Department's call for submissions were assessed for inclusion in this overview.

A single evidence reviewer conducted the literature search and reviewed the titles and abstracts of every record identified, using pre-specified eligibility criteria. Articles considered to meet these criteria were then retrieved for further assessment. From each included systematic review, the methodological quality of the review was assessed. Each stage in this process was documented and quality checks were performed by a second evidence reviewer, with any disagreements resolved by a third reviewer.

Where SRs included RCTs of kinesiology, the reviewers intended to extract outcome data on the effectiveness (and, where available, the safety, quality and cost-effectiveness) of kinesiology. The evidence for each outcome would then have been summarised, and the overall quality of the evidence rated using the GRADE system; however, no such reviews were identified.

Discussion

Main results

One SR (Hall, et al., 2008) was identified that met the criteria for inclusion within this overview. Hall (2008) aimed to critically review any study that evaluated either the diagnostic accuracy or therapeutic effectiveness of applied or specialised kinesiology. The overall quality of the SR was assessed as moderate (AMSTAR rating of 6 out of 11). Hall (2008) identified 22 studies that met their inclusion criteria, 3 of which evaluated specialised kinesiology: 2 assessed the effectiveness of specialised kinesiology in people with stress or recurring dreams and 1 was a diagnostic accuracy study. However, none of these studies were RCTs. As such, there was no primary evidence identified that met the inclusion criteria and therefore reviewers were unable to determine the effectiveness (or safety, quality or cost-effectiveness) of specialised kinesiology for any clinical condition.

Overall completeness and applicability of evidence

The identified SR did not identify sufficient evidence to address the objectives of the overview. This is not a shortcoming of the included systematic review; rather, it reflects the lack of published RCTs on the effectiveness of kinesiology. Due to the high risk of bias, low number of studies and limited sample size among the included studies in the review, Hall (2008) concluded

that there was insufficient evidence to suggest that kinesiology (of any type) had any specific therapeutic effect for any condition. It is clear that significant improvements are needed in the design, rigour and reporting of studies that aim to assess the effectiveness of kinesiology for any clinical condition; if undertaken, future research in this field should also assess kinesiology as a holistic modality (including evaluating the diagnostic accuracy of manual muscle testing as well as the therapeutic effect of any resultant interventions). Overall, significant research gaps remain in the field of kinesiology.

Quality of the evidence

Within this overview, only 1 SR (Hall, 2008) was identified that included evidence of the effectiveness of kinesiology. The included SR was considered to be of moderate quality, as it did not report an ‘a priori’ design and the review did not use 2 independent reviewers. The systematic reviewers did not report the conflicts of interest in the included studies and publication bias was not assessed.

The review by Hall (2008) did not identify any RCTs of kinesiology and so no primary evidence was considered further in this overview. This is likely to reflect a lack of RCTs of kinesiology for the treatment of clinical conditions. It is possible, however, that RCTs of kinesiology were missed by the literature search performed by Hall (2008). The search strategy included the terms ‘kinesiology’, ‘applied kinesiology’, ‘specialised kinesiology’ and ‘manual muscle testing’ but did not include any of the alternative terms also used for this therapy (for example, ‘three in one’). However, the authors conducted an extensive grey literature search that involved contacting kinesiology associations and kinesiology practitioners, checking kinesiology websites and hand-searching kinesiology conference proceedings. The likelihood that Hall (2008) failed to identify RCTs for kinesiology would therefore appear to be low.

The evidence within the SR (Hall, 2008) was generally of poor quality. The SR authors found significant challenges in examining the body of evidence, with the number of participants in included studies often small, and the quality of the data often assessed as low or poor. No RCTs were identified that evaluated the therapeutic effect of kinesiology, and of the 2 studies that

examined the effectiveness of specialised kinesiology both were poor quality, scoring 0 out of 5 on the Jadad scale and 4 or 6 out of 22 using the CONSORT statement.¹⁹

Potential biases in the overview process

This overview was limited to SRs published since April 2008, meaning that SRs of kinesiology published before this date were not considered. This represents a potential source of bias for this overview. However, the included SR (Hall, 2008) was broad in scope and does not report limiting their search by date. Further, this review searched 4 databases as well as the grey literature and identified studies published in 1979 and the early 1980s. Given that specialised kinesiology was developed in the 1970s, it is likely that the review by Hall (2008) identified much of the evidence that might have been identified by reviews published before 1 April 2008. The reviewers did not conduct a search for RCTs of kinesiology published since the publication of Hall (2008), and this may also represent a potential source of bias for this overview, as the overview did not consider any evidence published since this review was undertaken in 2008. However, reviewers did not identify any additional SRs, nor any RCTs, from the literature submitted to the Department. Given that there were no high-quality studies of any level identified in the included systematic review, and no additional SRs or RCTs identified through searching the submitted literature, it is unlikely that these potential biases have impacted on the conclusions of this overview.

During the methodological review, it was identified that the searches did not include a specialist CAM bibliographic database. It is considered unlikely that studies were missed due to this omission because reviewers searched several other major bibliographic databases and no additional SRs were identified in the literature submitted to the Department. The exclusion of studies that did not explicitly describe the method of kinesiology as ‘specialised’ kinesiology may also have biased the findings, by narrowing the scope of the overview and omitting potentially relevant evidence. However, reviewers did not exclude any studies solely on the basis that the form of kinesiology was not specified. Also, given that the review of Hall (2008) included evidence for both applied and specialised kinesiology, and the review authors

¹⁹ CONSORT statement – Consolidated Standards of Reporting Trials are evidence-based, minimum sets of recommendations for reporting randomised trials.

concluded that there was insufficient evidence to enable conclusions to be drawn regarding the therapeutic effectiveness of kinesiology, this scope is unlikely to have impacted on the overview findings.

Publication bias may also have affected the findings of the evidence review. Such bias is a complex issue, particularly for CAMs, and relates to the tendency for journals to publish trials with positive findings, with trials that find no effect remaining unpublished (particularly in the case of studies with smaller sample sizes, as is the case for much CAM research). It is therefore possible that there is a body of evidence that evaluates the effectiveness of kinesiology that remains unpublished.

Finally, although checks were performed on a subset of records in this overview, the use of a single reviewer for screening records (and a single reviewer planned for data extraction) introduced another potential source of bias.

Conclusions

Authors' conclusions

There is insufficient evidence from SRs within this field to reach any conclusion regarding the effectiveness, safety, quality or cost-effectiveness of kinesiology. If conducted, future research should focus on rigorous, well-designed RCTs that assess the effectiveness and safety of kinesiology in specific patient populations.

Implications for practice

The effectiveness of kinesiology in improving health outcomes in people with a specific clinical condition is unknown. There is insufficient evidence from SRs within this field to reach any conclusion regarding the effectiveness, safety, quality or cost-effectiveness of kinesiology.

Implications for research

There is a need for significant improvements in the design and reporting of studies in the field of specialised kinesiology. Because the application of kinesiology may vary in practice, the clinical conditions and subsequent treatments or interventions prescribed by kinesiologists need to be better defined. Also, a greater level of high-grade evidence is needed to support any guidance as to the effectiveness of kinesiology. If undertaken, future studies should focus on establishing the clinical effectiveness and safety of kinesiology through well-designed and well-reported RCTs.

Submissions received on kinesiology

Submissions for kinesiology were received from the following organisations:

- Australian Institute of Kinesiologists
- Australian Kinesiology Association
- Friends of Science in Medicine.

The Australian Institute of Kinesiologists did not supply any references and so this submission was not considered further. A total of 29 citations were reviewed for inclusion in this report, and 1 study was identified that met the inclusion criteria outlined above. This identified study was the SR by Hall (2008) that was identified through the first systematic search; therefore, the SR was not considered further.

Massage therapy overview report

Objective

This objective of this overview is to summarise the evidence from SRs regarding the effectiveness (and, where available, the safety, quality and cost-effectiveness) of massage therapy or myotherapy, for improving health outcomes for any clinical condition. A range of therapeutic approaches to massage therapy were considered in the overview, with a focus on the following subgroups: remedial massage, sports therapy massage, deep tissue massage, myofascial release, therapeutic massage, myotherapy, lymphatic drainage, traditional Thai massage and Swedish massage.

Definition

According to the Australian Association of Massage Therapists (2013a), massage therapy (including myotherapy as a form of remedial massage therapy) may be used in the rehabilitation, maintenance or prevention of a range of physical and psychological conditions, including subacute and chronic pain, stress and anxiety, headache, muscular strains or tears, musculoskeletal conditions and chronic or palliative conditions such as cancer. In view of the wide range of conditions for which CAMs such as massage therapy and myotherapy may be used, this overview included SRs evaluating the effectiveness of massage therapy or myotherapy in people with any clinical condition.

Massage therapy is described as the practice of ‘kneading or otherwise manipulating a person’s muscles and other soft-tissue with the intent of improving a person’s wellbeing or health’ (Beckner & Berman, 2003). The term ‘massage therapy’ is used to describe a wide variety of techniques that vary in the manner in which touch, pressure and the intensity of the intervention is applied. Numerous definitions for various massage therapy techniques exist and there is substantial overlap among them. Ultimately, massage therapy can be considered a form of manual therapy that includes holding, causing movement, and/or applying pressure to the muscles, tendons, ligaments and fascia.

...

M
A
S
S
A
G
E

T
H
E
R
A
P
Y

Methods

The reviewers searched EMBASE, MEDLINE, the Cochrane Library (database of systematic reviews, other reviews, and technology assessments), PubMed, PubMed Health and PROSPERO to identify all SRs addressing the primary clinical research question. Reviewers also hand-searched reference lists of relevant articles to identify extra articles not identified in the literature search. The search was restricted to SRs published between 1 April 2008 and the literature search date on 4 September 2013. In addition, any relevant SRs identified through the Department's call for submissions were assessed for inclusion in this overview.

A single evidence reviewer conducted the literature search and reviewed the titles and abstracts of every record identified using pre-specified eligibility criteria. Articles considered to meet these criteria were then retrieved for further assessment. From each included systematic review, data were extracted and the methodological quality of the review was assessed. Each stage in this process was documented and quality checks were performed by a second evidence reviewer, with any disagreements resolved by a third reviewer.

Where SRs included RCTs of massage therapy or myotherapy, the reviewers extracted outcome data on the effectiveness (and, where available, the safety, quality and cost-effectiveness) of massage therapy/myotherapy. The evidence for each outcome identified was then summarised and the overall quality of the evidence rated using the GRADE system. In rating the body of evidence, the overall size, quality and precision of the evidence was considered and a level of confidence was assigned to the body of evidence for each clinical condition.

Remedial massage

According to the AAMT, the objective of remedial massage is the treatment and rehabilitation of the signs, symptoms and causes of biomechanical dysfunction or injury. This intervention may use mobilisation techniques such as deep tissue massage, sports massage, trigger point therapy and proprioceptive neuromuscular facilitation (PNF) to restore normal health and function (AAMT, 2013a). In this context, sports massage is the combination of manual and manipulative therapy, primarily focused on treating pain and disability associated with the neuromusculoskeletal system. Trigger point therapy involves applying manual pressure, vibration, injection or other interventions to specific trigger points at the neuromuscular junction

to relieve myofascial pain at that point or to referred pain or other sensations, such as headaches, to other parts of the body. Trigger point therapy is described as being ‘similar to shiatsu or acupuncture, but uses western anatomy and physiology as its basis’ (Beckner & Berman, 2003). PNF is a form of stretching in which a muscle is alternately stretched and contracted. This technique aims to encourage flexibility and coordination of the limbs.

Deep tissue massage

Deep tissue massage is a form of remedial massage that ‘focuses on the deeper layers of muscle tissue’ and ‘aims to release the chronic patterns of tension in the body through slow strokes and deep finger pressure on the contracted areas, by either following or crossing over the muscle fibres, fascia, and tendons’ (AAMT, 2013a). This type of massage therapy is often used by therapists to address specific issues or complaints associated with sports and occupational hazards, such as repetitive stress injuries, chronic muscular pain, and physical or mental fatigue (AAMT, 2013a). The techniques used aim to create an improved range of motion through the joints, release toxins, and improve blood flow and oxygen delivery.

Sports therapy massage

Sports therapy massage refers to the application of remedial massage therapy with a specialised focus on the prevention and treatment of sports-related injuries. The Australian Traditional Medicine Society (ATMS) states: ‘sports therapists are trained in remedial massage therapy, anatomy, and physiology’ and ‘they assess and treat sports injuries, provide rehabilitation and advice and offer pre- and post-event massage therapy’ (ATMS, 2013).

Myofascial release

Myofascial release is defined as a ‘hand-on technique that seeks to free the body from the grip of tight fascia, or connective tissue, thus restoring normal alignment and function and reducing pain’ (Beckner & Berman, 2003). This type of massage therapy is often used to treat individuals with adhesions or scar tissue. Here, therapists apply mild, sustained pressure to stretch and soften the fascia, with the aim of releasing pain and restoring motion and function to the body.

According to the AAMT, myofascial release is ‘based on the principle that poor posture, physical injury, illness and emotional stress can shift the body out of alignment and cause the intricate web of fascia to become tight and constricted’ (AAMT, 2013a).

Therapeutic massage

Therapeutic massage refers to the ‘treatment of the whole body to relieve the symptoms of chronic complaints, including physical and psychological conditions’ (AAMT, 2013b). It incorporates a number of massage therapies and relaxation techniques, such as manipulating the body with pressure, tension, motion, or vibration to relieve discomfort, and improve function and wellbeing. Therapists use manual or mechanical methods to target the tissues (including muscles, connective tissues, or lymphatic vessels), joints and organs (Department of Veterans' Affairs, 2010).

Lymphatic drainage

Lymphatic drainage is defined by the AAMT (2013a) as a gentle whole-body massage technique that aims to relax the nervous system and aid the body’s immune system. It aims to relieve fluid congestion, promote wound healing and relieve stress and anxiety and ‘involves a range of specialised and gentle rhythmic pumping techniques to move skin in the direction of the lymph flow through a network of lymph vessels and lymph nodes’ so as to reduce swelling and congestion within the lymphatic system (AAMT, 2013a). The AAMT claims lymphatic drainage can help the body to ‘naturally eliminate excess toxins, dead cells, viruses, bacteria and chemicals’.

Thai massage

Traditional Thai massage is a deep, full-body massage that uses a sequence of gentle, flowing exercise movements starting at the feet and progressing up to the head. Influenced by traditional medicine systems of South-East Asia, India and China, this type of massage was developed in Thailand over 2,500 thousand years ago (ATMS, 2013b), and is based on the belief that the body’s energy (‘lom’ or ‘air’) travels along a network of 10 major ‘sen’ lines or ‘vessels’ (Mackawan, et al., 2007). The Australian School of Traditional Thai Massage (ASTTM) claims that by encouraging the movement of ‘lom’ through the body, traditional Thai massage ‘promotes and stabilises health and structural poise’ (ASTTM, 2013). Practitioners of traditional Thai massage are trained to use prolonged pressure on the muscles in combination with passive ‘yoga-like’ stretching manoeuvres along these ‘sen’ lines. Therapists can use ‘the hands, elbows,

knees and feet in unique and innovative ways’ to achieve the desired effect of ‘improving relaxation and strengthening for the muscles, increased suppleness of the joints and a deep sense of relaxation for the mind and body’ (ASTTM, 2013).

Swedish massage

Swedish massage is a form of massage therapy that aims to improve circulation and stretch the ligaments and tendons. Developed in the late 18th century by a Swedish fencing master (AAMT, 2013a), this form of massage therapy consists of passive and active movements of bending and stretching, and uses 5 distinct styles of long, flowing massage strokes: effleurage (gliding strokes with the palms, thumbs and/or fingertips and forearms), petrissage (kneading movements with the hands, thumbs and/or fingertips and forearms), friction (circular and transverse pressure with the palms of hands, thumbs and/or fingertips), vibration (oscillatory movements that shake or vibrate the body) and tapotement (brisk rhythmic percussion technique). The AAMT asserts that the strokes and movements of Swedish massage are each conceived as having a specific therapeutic benefit, with 1 primary goal being to ‘speed venous return from the extremities’ (AAMT, 2013a). The AAMT also claims that Swedish massage can shorten recovery time from muscular strain by flushing the tissue of lactic acid, uric acid and other metabolic waste (AAMT, 2013a).

Myotherapy

Myotherapy involves the assessment and physical treatment of myofascial pain, injury and dysfunction affecting movement and mobility. It is applied in the preventative, corrective and rehabilitative phases of therapy and is intended to restore and maintain the normal integrity of the soft-tissue structure. Therapists use a variety of treatments to ‘help loosen muscle tissues, release toxins from the muscles, and get blood and oxygen circulating properly’ (AAMT, 2013). Types of treatments involved include soft-tissue treatment, trigger point therapy, myofascial dry needling, thermal therapy, transcutaneous electrical nerve stimulation (TENS) and corrective exercises (AAMT, 2013). For the purposes of this overview, the evidence concerning myotherapy was considered separately to other massage techniques, unless an intervention was specifically stated to be soft-tissue massage or ‘myotherapy’ massage therapy alone. The rationale for this approach is that myotherapy may involve the use of equipment-based therapies and these represent quite different interventions to touch-based massage therapy, and the

therapies would therefore not necessarily be expected to exhibit effects consistent with one another.

Submitted literature

Three additional SRs of massage therapy were identified in the submitted literature that had not been identified within the overview as they were published within the grey literature. All 3 SRs were incorporated into the overview. Twenty-seven RCTs of massage therapy were identified within the submitted literature that had not already been considered. These RCTs evaluated the effect of massage therapy across 17 clinical conditions. Twelve of these 17 clinical conditions were also considered within the overview report. The remaining 5 clinical conditions (plantar heel pain; restricted ankle joint dorsiflexion; myofascial pain of the jaw; cardiovascular disease; prehypertension) were not included in the overview report as there were no relevant SRs for these conditions. The submitted RCTs were generally at a high or unclear risk of bias and they did not alter the findings of the overview.

Discussion

Main results

Myotherapy

No SRs were identified that assessed the effectiveness of myotherapy interventions that met the inclusion criteria for this overview. The literature searches identified 22 SRs that assessed TENS and 4 SRs that assessed dry needling that potentially met the inclusion criteria for this overview. However, all of these SRs were excluded at full-text review, as none of the included RCTs stated that the intervention was delivered by a myotherapist or was delivered in the context of a myotherapy session. Many of the studies that assessed TENS were associated with the delivery of the intervention in the context of physiotherapy or within a hospital setting (including during ambulatory transport). Often, the intervention was self-delivered. For dry needling, much of the evidence base focused on the use of the intervention in the context of acupuncture.

Massage therapy

A total of 99 SRs were included that assessed the effectiveness of massage therapy for health outcomes in a total of 46 clinical conditions. In 14 conditions, the evidence for the effectiveness of massage therapy could not be assessed because there were no RCTs identified or no usable data reported by the included SRs (see **Table 7**). For the remaining 32 conditions, the evidence base concerning the effectiveness of massage therapy comes from pilot studies or small RCTs

that are likely to be underpowered. The effectiveness of massage therapy was deemed uncertain in 29 conditions, with the body of evidence rated as very low quality for 28 of these clinical conditions. In people with depression, the body of evidence compared with control and other interventions was of low quality; however, there was no evidence of consistent effects within this population and so the effect of massage therapy in people with depression remains uncertain (see **Table 8**).

There were 3 clinical conditions (low back pain, neck pain, pre-term infants) for which the body of evidence was consistent and of low to moderate quality, enabling the effect of massage therapy to be estimated (see **Table 9**). A positive effect in favour of massage therapy was reported for various outcomes in 2 of these clinical conditions (low back pain, pre-term infants); however, for 1 clinical condition (low back pain), there was also evidence that massage therapy may not be more effective than control for longer-term outcomes. In the third condition (neck pain), massage therapy was found to be no more effective than other interventions for reliving the intensity of pain. However, an assessment of the effectiveness of these other interventions on pain intensity was not performed.

The quality of the evidence was very low for most of the outcomes assessed, and there were many other outcomes for which the evidence remains uncertain. Due to the paucity of good-quality primary studies with sufficient sample size, or the lack of replication of study results, it was not possible to make any firm statements as to the effectiveness of massage therapy for many clinical conditions included in this overview.

Table 7. List of conditions/populations for which no eligible RCTs for massage therapy were identified

No evidence found (14 conditions)		
• Non-specific rheumatic pain	• Irritable bowel syndrome	• Bipolar disorder
• Rheumatoid arthritis	• Bell's palsy	• Insomnia
• Idiopathic constipation	• Chronic tension-type headaches	• Intellectual or developmental disabilities
	• Restless leg syndrome	• Trauma
	• Chronic pain in older people	
	• Asthma	
	• Chronic obstructive airways disease	

Table 8. List of conditions/populations for which the effectiveness of massage therapy is uncertain

Evidence is available but the size of the effect is uncertain (29 conditions)		
Muscle recovery following exercise	Neurogenic bowel dysfunction	Attention deficit hyperactivity disorder
Hemiplegic shoulder pain	Carpal tunnel syndrome	Autism spectrum disorders
Non-specific shoulder pain	Cerebral palsy	Critical illness
Work-related musculoskeletal complaints	Chronic fatigue syndrome	Dementia
Fibromyalgia	Migraine	Depressive symptoms
Osteoarthritis	Respiratory diseases in children	Stress and anxiety
Juvenile idiopathic arthritis	Post-burn wound care	Lymphoedema (breast cancer-related)
	HIV/AIDS	Cancer (symptom relief)
	Injury (fracture)	Cancer (palliative care)
	Spinal cord injury	Infantile colic
		Pregnancy-associated anxiety and depression
		Pain management in labour

Table 9. List of clinical conditions for which consistent, low- to moderate-quality evidence enabled estimates of the effect of massage therapy

Evidence indicates that massage therapy may/may not be effective (3 clinical conditions)	
<p>Massage therapy vs. control Moderate-quality evidence that massage therapy may be more effective than control:</p> <ul style="list-style-type: none"> • Low back pain (chronic, non-specific) – symptom bothersomeness (short term) • Pre-term infants – length of hospital stay <p>Moderate-quality evidence that massage therapy may not be more effective than control:</p> <ul style="list-style-type: none"> • Low back pain (chronic, non-specific) – symptom bothersomeness (long-term) <p>Low-quality evidence that massage therapy may be more effective than control:</p> <ul style="list-style-type: none"> • Low back pain (acute/subacute, non-specific) – pain intensity • Pre-term infants – weight gain 	<p>Massage therapy vs. other intervention Low-quality evidence that massage therapy may be no more effective than other intervention:</p> <ul style="list-style-type: none"> • Neck pain (chronic non-specific, chronic mechanical) – pain intensity

Overall completeness and applicability of evidence

In addition to the methodological limitations that are often associated with low-quality RCTs (for example, poor reporting of randomisation or insufficient blinding of participants or assessors), many of the massage therapies RCTs presented extra challenges when assessing the overall completeness and applicability of the evidence. For example, within a clinical condition, the massage therapy techniques employed varied considerably or were substantially heterogeneous in their application, preventing pooling of results. Also, among the SRs included here, many different types of massage therapy were described and assessed, some of which did not specifically fit in to any one of the predefined subgroups. It was difficult to find any RCT that specifically assessed the effectiveness of ‘remedial massage’, ‘sports therapy massage’ or ‘myotherapy’ for any clinical condition in the literature, and any attempt to assign the evidence to a particular massage therapy subgroup was fraught with complications. This was because many RCTs or SRs did not adequately describe the massage therapy technique employed, often only describing the frequency of the intervention (number of sessions per week or duration of each session), but not reporting on the intensity or depth of massage therapy, the method of applying touch, the theoretical framework underlying the intervention or the training and experience of the massage therapist. Hence, there was sometimes no clear distinction between the non-manipulative manual therapies conducted by massage therapists and the soft-tissue work

done by chiropractors, physiotherapists and osteopaths, with a great deal of crossover between techniques often observed.

Nevertheless, all interventions assessed in this report would meet the definition of that administered by a ‘massage therapist’ as defined by the Australian Bureau of Statistics Standard Classification of Occupations (ABS, 1997), which states that massage therapists include those professionals who ‘perform therapeutic massage therapy and administer body treatments for relaxation, health, fitness and remedial purposes’.

Quality of the evidence

The majority of SRs included in this overview were of low quality (AMSTAR score 5 or less out of 11), with many SRs failing to report quality assessments of included RCTs or provide adequate details of included studies. Also, although pooling of results would not have been feasible or appropriate in many cases due to heterogeneity, many reviews did not state their intention to pool results or discuss the heterogeneity of included studies.

The overall conclusions of this overview were limited by the moderate- to low-quality RCTs described within these SRs. Insufficient blinding was of concern in many of the included RCTs. Blinding of subjects and providers is inherently difficult since massage therapy techniques involve some form of manipulation of the soft-tissue (for example, stroking, stretching, touching, stimulating by other means). Further, the effect of massage therapy on outcomes such as movement, function pain or mental health is often measured by patient-reported ‘subjective’ outcomes, leading to difficulties in blinding outcome assessment. In view of these limitations, it is important that RCTs are designed to minimise other potential sources of bias (for example, reporting bias, incomplete data), which were often rated as unclear or high by SR authors due to poor follow-up of participants or selective outcome reporting.

Potential biases in the overview process

This overview was limited to SRs published since April 2008, meaning that SRs of massage therapy published before this date were not considered. This represents a potential source of bias for this overview. It is possible that some evidence of the effect of massage therapy for clinical conditions was not identified due to this limitation. However, many of the included SRs were

broad in scope and did not limit their search by date; therefore is it likely that within identified conditions much of the evidence for massage therapy published before 2008 was found.

The literature for this overview was derived exclusively from searches of online databases and as such informally published SRs (grey literature) may have been missed, potentially introducing another source of bias. However, it is likely that any such omitted SRs would have been included in the stakeholder submissions. During the independent, methodological review of this overview, it was identified that the overview searches did not include a specialist CAM bibliographic database; however, it is considered unlikely that any SRs were missed due to this omission.

The overview was also limited by the quality of the included SRs, which, in turn, were limited by the quality of included RCTs. It was often difficult to determine whether data were inadequately reported by the SRs or the included RCTs. Many of the moderate-quality and low-quality SRs failed to report complete data to enable proper assessment of the effectiveness of massage therapy for various clinical conditions. This was particularly apparent in clinical guidelines, which tended to report p-values for outcomes with positive effects and narrative descriptions of results, rather than complete outcome data.

Incomplete data reporting was also problematic when the intent of an included SR was to simply assess the effectiveness of massage therapy for one particular outcome, so the review did not report other outcomes that may have been reported in the RCT. Another problem encountered was the inclusion of many SRs that aimed to assess the effectiveness of a variety of complementary and alternative therapies. These broad SRs often only reported on those therapies with good-quality evidence, or grouped the results for massage therapy with other treatment modalities. It is likely that missing data could be obtained from included RCTs if the primary source was obtained; however, this was outside the scope of this overview.

Other potential biases within the overview process resulted from the breadth and scope of this overview and the variety of reporting within the primary studies. Many RCTs reported a large variety of outcome measures, making it impossible to report on each outcome measured within a clinical condition. Outcomes reported are based on the primary outcomes reported and highlighted within a systematic review. Many outcomes reported come from single centre studies and a hierarchy as to the clinical relevance of the outcomes was not established a priori. Post-hoc

reporting of the outcomes introduces a bias towards selective reporting of positive results; however, due to the design of this overview, it was not possible to pre-determine the clinically relevant outcomes before conducting the review.

Another limitation of this review is that no attempt was made to determine whether an included comparator intervention was appropriate. Some SRs included data from RCTs that compared massage therapies with other interventions, whereas other SRs reported only sham or no treatment arms from an included RCT. No attempt was made to resolve differences in reporting preference or to provide a critique as to whether the other intervention (or sham intervention) was appropriate. Reviewers also did not try to determine the effectiveness of any other interventions used. Comparisons that were not considered to be inactive controls were grouped separately as 'other interventions' to enable any effects of massage therapy compared with inactive control to be discerned. However, it was not always possible to discern whether a comparator was an active or inactive control, due to poor reporting of comparators by SR authors and also potentially by trialists themselves.

Certain limitations surrounding the data synthesis methods need to be taken into consideration when reviewing the narrative summary of findings and the evidence statements. The vote counting approach used (based on the statistical significance of individual results) does not take into account the effect size, sample size or the quality of studies being synthesised. Studies that are underpowered may produce unreliable statistically significant results which may elevate the outcome status in the vote counting. It was also difficult to assess the clinical significance of reported results, due to poor reporting of effect sizes for the outcomes measured.

Finally, this overview has only briefly examined the evidence for adverse effects of massage therapy, where this was reported in a SR of effectiveness. Although noted for some clinical conditions, no attempt was made to systematically search for evidence relating to adverse effects.

Conclusions

Authors' conclusions

There is a paucity of good-quality studies of sufficient size that examine the effectiveness of massage therapy for many clinical conditions. Indeed, the evidence for massage therapy is inconclusive or uncertain for 29 clinical conditions assessed in this overview and unknown in a

further 14 conditions including individuals with arthropathies, injury, diseases of the nervous system, diseases of the digestive system, diseases of the respiratory system, or mental and behavioural disorders. Compared with control, there is moderate-quality evidence that massage therapy is effective in providing immediate-term relief in patients with chronic low back pain and for reducing the length of hospital stay in pre-term infants. However, massage therapy may be no more effective than control for long-term pain relief in people with chronic low back pain. There is also a small body of low-quality evidence that suggests massage therapy may be effective in providing immediate, short-term pain relief for patients with acute low back pain, and for promoting weight gain in pre-term infants, compared with control. There is low-quality evidence to suggest that massage therapy may be no more effective than other interventions (spray and stretch, spinal manipulation, traditional bone setting, physiotherapy, traction) for relieving the intensity of pain in people with chronic, non-specific or mechanical neck pain. However, it was beyond the scope of this overview to assess the effectiveness of comparison interventions.

Compared with inactive control, the effectiveness of massage therapy in people with chronic mechanical or non-specific neck pain remains uncertain. No studies were identified that assessed the effect of myotherapy in people with a clinical condition, and the effectiveness of this therapy is therefore unknown. Further high-quality research is required that reflects the way that myotherapists use various touch and equipment-based interventions in practice, to enable the effectiveness of this therapy to be assessed.

Implications for practice

There is a paucity of good-quality studies of sufficient size that examine the effectiveness of massage therapy for many clinical conditions. The evidence is uncertain or unknown for 43 of the 46 clinical conditions assessed in this overview.

Compared with control, there is moderate-quality evidence that massage therapy is effective in providing immediate-term relief in patients with chronic low back pain and for reducing the length of hospital stay in pre-term infants. However, massage therapy may not be more effective than control for longer-term relief of chronic low back pain. There is also a small body of low-quality evidence that suggests massage therapy may be effective in providing immediate, short-

term relief of pain for patients with acute low back pain, and for promoting weight gain in pre-term infants, compared with control.

There is low-quality evidence to suggest that massage therapy may be no more effective than other interventions (spray and stretch, spinal manipulation, traditional bone setting, physiotherapy, traction) for relieving the intensity of chronic, non-specific or mechanical neck pain. However, it was beyond the scope of this overview to assess the effectiveness of comparison interventions, and there is insufficient good-quality evidence to determine the effect of massage therapy compared with inactive control in people with chronic, non-specific or mechanical neck pain. As a result, the effectiveness of massage therapy within this population remains uncertain.

No studies were identified that assessed the effect of myotherapy in people with a clinical condition and the effectiveness of this therapy is therefore unknown.

Implications for research

In practice, massage therapists often combine various treatment modalities or techniques within a single session, and may also treat patients over longer periods of time than those assessed in an RCT. To allow for more firm and conclusive statements about the effectiveness of massage therapy for a particular clinical condition, more rigorous, multicentre, and well-designed clinical studies assessing the effectiveness of massage therapy for a particular patient population are required. RCTs need to combine treatment approaches so as to properly reflect the way that massage therapy is applied in practice. Also, there is little data about what constitutes an effective massage therapy session. Further research is required regarding optimal treatment parameters such as number of sessions or duration of sessions required, combined with longer-term follow-up of patients to assess the long-term effectiveness of massage therapy. Similarly, further high-quality research is required that reflects the way that myotherapists use various touch and equipment-based interventions in practice, to enable the effectiveness of this therapy to be assessed.

Submissions received for massage therapy

Submissions that were received and that related to massage therapy were evaluated to ensure that the evidence review considered all relevant evidence. Submissions were received for massage therapies from the following individuals and organisations:

- Association of Massage Therapists (252 references)
- Association of Remedial Masseurs (11 references)
- Australian Acupuncture and Chinese Medicine Association Ltd (12 references)
- Australian Association of Massage Therapists (33 references)
- Australian Natural Therapists Association (56 references)
- Australian Naturopathic Practitioners Association (432 references)
- Australian Traditional Medicine Society (39 references)
- Peter Berryman (0 references)
- Friends of Science in Medicine (7 references)
- Adam Hovav (0 references)
- Institute of Registered Myotherapists of Australia (38 references)
- Massage Association of Australia Ltd (1 reference)
- National Institute of Complementary Medicine (81 references)
- Society of Natural Therapists & Researchers Inc. (0 references)
- Bernard Scully (0 references).

Submissions that did not contain any references were not considered further.

A total of 962 references were submitted to the NHMRC. After removal of duplicate citations (n = 58), 904 unique citations were reviewed.

Of the 904 citations, 785 were excluded during abstract/title review and a further 71 citations were identified as already included in the overview (19 SRs and 52 RCTs).

The remaining 48 articles were screened in full text, with 20 of these excluded for the following reasons: publication type out of scope (2), population out of scope (3), intervention out of scope

(6), confounding (3), outcome out of scope (1), study type out of scope (3), or they were SRs of SRs (2).²⁰

The remaining 27 citations were considered to be within the scope of the evidence review, 3 were SRs (reports and guidelines) unique to the submitted literature (Ng & Cohen, 2011); (TRACsa, 2008); (Ju, et al., 2009), and were added to the overview and considered as part of the overview process. A total of 24 RCTs were identified within the massage therapy submissions that met the inclusion criteria.

In addition to assessing the literature submitted to the Department for inclusion in the overview for massage therapy, all literature submitted within the overview for Bowen therapy were also considered here. This is because of considerable overlap between the 2 interventions. There were 3 additional RCTs identified in the literature submitted to the Department, which were intended for consideration with the overview for Bowen therapy (submitted by the Bowen Therapists Federation of Australia). The RCTs were not eligible for inclusion within the Bowen therapy report, as the intervention was not specifically Bowen therapy, but evaluated the effectiveness of a form of massage therapy (myofascial release) included in this report. These 3 RCTs were not identified within a SR considered in the massage therapy overview report and were deemed eligible for inclusion here. The addition of these 3 citations to the 24 eligible RCTs already identified resulted in a final total of 27 RCTs eligible for inclusion in this review of submitted literature.

The 27 included RCTs examined the effectiveness of various massage therapy techniques in 7 therapeutic areas encompassing 17 clinical conditions. Twelve of the 17 clinical conditions were evaluated in the overview report. The remaining 5 clinical conditions (plantar heel pain; restricted ankle joint dorsiflexion; myofascial pain of the jaw; cardiovascular disease; prehypertension) were not included in the overview report as there were no relevant SRs for these conditions. These RCTs are critically appraised below, but the findings were not considered further as they are self-selected samples and other literature concerning the effectiveness of massage therapy for these conditions has not been systematically retrieved.

²⁰ The systematic reviews of systematic review were checked for eligible systematic reviews for inclusion in the overview report: none were identified.

All of the included RCTs had methodological limitations that require consideration in the evaluation of the evidence. In general, the evidence base for massage therapy is not of high quality and many of the individual studies were poorly designed and conducted. A number of the RCTs were also poorly reported, with some only reporting within-group comparisons (pre-treatment versus post-treatment) rather than differences between comparison groups. Statistical analyses used were sometimes inappropriate for the study design. Most of the studies were also small in size, with only 5 out of 27 RCTs including more than 100 participants (Ang et al., 2012; Bauer et al., 2010; Braun et al., 2012; Seers et al., 2008; Wentworth et al., 2009).

Naturopathy overview report

Objective

The objective of the overview is to summarise research on the effectiveness of naturopathy as a health service for improving health outcomes for all clinical conditions compared with placebo, no treatment or an alternative active intervention. The safety, quality and costs of naturopathy will only be summarised if these components are evaluated in the included SRs.

Definition

Naturopathy is one of the most broad-ranging disciplines of complementary medicine. It emphasises a whole-body approach rather than a focus on an individual treatment or specific practice.

Naturopathy can be defined as a ‘health care system which emphasises the curative power of nature and treats acute and chronic illnesses in all age groups. Naturopathic physicians work to restore and support the body’s own healing ability using a variety of modalities including nutrition, herbal medicine, homeopathic medicine, and Asian medicine’ (Beckner & Berman, 2003). Naturopathy incorporates various health management strategies, such as diet and exercise regimes, stress and anxiety management, botanical medicine, holistic healing practices (for example, acupuncture, massage therapy and homeopathy), and contemporary scientific medicine aimed at promoting overall wellness in the individual, and managing chronic conditions or disability (American Association of Naturopathic Physicians, 2011). For the purposes of this overview, the reviewers were interested in naturopathy as a health service practised by naturopathic practitioners. Reviewers used the terms ‘naturopathy as a health service’ and ‘naturopathic practice’ interchangeably throughout the report.

...

N
A
T
U
R
O
P
A
T
H
Y

Methods

SRs were considered for inclusion in the overview if they were published from 2008 onwards and included primary studies that assessed the effects of naturopathy as a health service. Where SRs included a range of study designs, reviewers restricted analysis to the randomised trials included in the SRs. (Had reviewers identified any prospectively controlled studies with unclear or unstated randomisation, these would have been included as controlled clinical trials.) For SRs and overviews of a range of complementary or natural therapies that included studies of naturopathic practice, reviewers would have identified the subset of studies that related to naturopathic practice.

Only SRs that evaluated naturopathy as a health service were included. SRs of components of naturopathy, for example, massage therapy, acupuncture, individual herbal agents or natural products, were not included.

As a health service, naturopathy was evaluated either as a naturopathic intervention for a single condition and/or setting (for example, naturopathic practice for hypertension) or as a naturopathic intervention for multiple conditions and/or settings (for example, use of naturopathic practice for chronic disease). SRs which compared one naturopathic modality to another (for example, massage therapy versus dietary supplements) were not included. Some of the naturopathic modalities, for example, massage therapy, homeopathy and iridology, are the subject of other overviews within the Natural Therapies Review.

Discussion

Summary of main results

The reviewers conducted an overview of SRs investigating the effects of naturopathy as a health service. They identified 1 abstract of an unpublished review on the effect of whole-practice naturopathy in chronic conditions. The review included 13 studies, 6 of which were randomised trials of naturopathic care conducted in North America. A further 2 studies were cost-effectiveness analyses based on data from 2 of the included randomised trials. Analysis of the included studies was limited to the subset of randomised trials.

The chronic conditions covered by the randomised trials included cardiovascular disease, multiple sclerosis, anxiety and various types of musculoskeletal pain (rotator cuff tendinitis, low

back pain, temporomandibular joint). None of the trials investigated the effect of naturopathic practice on acute conditions. The included trials compared naturopathic practice to active treatment or usual care.

The results of the included studies were summarised narratively in the systematic review. The 6 trials included data on 627 participants and 20 primary patient health outcomes. Seventeen of these outcomes were in favour of naturopathic practice, 1 favoured the control and for 2 outcomes the direction of effect was not reported.

Adverse effects

Two of the 6 included trials reported data on adverse events. Although there were more adverse events in those receiving naturopathic care, the number was low and the events were mostly mild and of short duration.

Costs

One trial of 75 postal workers with chronic low back pain was reported as a cost-effectiveness analysis. The analysis found that in the group receiving naturopathic care, societal costs were reduced and employers benefited from reduced absenteeism and productivity gains. Participants in the naturopathy group also reported additional 'perfect health' days.

Overall completeness and applicability of evidence

The reviewers sought to identify SRs that investigated the effectiveness of naturopathy as a practice of care and only selected SRs that included concurrently controlled trials. Reviews were excluded that investigated the effects of individual natural products, or individual components of naturopathic practice, such as herbal remedies or massage therapy.

Despite a comprehensive search, the overview identified just 1 unpublished systematic review. The review's narrow inclusion criteria with respect to where the studies were conducted raises issues about the applicability of the evidence outside of North America. For clinical trials, inclusion was limited to studies conducted in North America by licensed naturopathic doctors that modelled whole-practice naturopathic medicine in which at least 2 treatment modalities were present. Of the 6 trials, 4 were conducted among postal workers in Ontario, Canada, and 2 involved populations from Portland, Oregon, USA.

The rationale for restricting to North American studies was due to differences in the training and accreditation of naturopaths and the scope of naturopathic practice in other parts of the world. In the US, naturopathic physicians are trained as primary care physicians in 4-year, accredited doctoral-level naturopathic medical schools. In their study of the practice and regulatory requirements of naturopathy and western herbal medicine in Australia, Lin and others (2009) chart the significant growth in the number of institutions that provide education and training in naturopathy but found significant variations among courses and approaches, and note that the number of clinical contact hours is especially low compared with institutions in the USA and Canada.

With naturopathic practice in Australia being largely unregulated, there are valid concerns about the extent to which the findings of this overview apply to the Australian context. As Wardle and others (2012) note, ‘the current legislative and regulatory environment in Australia has contributed to significant heterogeneity of naturopathic standards, particularly in the naturopathic education sector’. Not only does this have implications for the quality of training naturopaths receive but also the absence of professional regulation means there is no protection for naturopathy as a professional endeavour. Individuals with little or no training may call themselves a naturopath, thus exposing the public to potential risks. Given the settings of the studies included in the systematic review, there is a strong argument for stating that the results of this overview are only applicable among practitioners with similar scope of practice and levels of training.

Quality of the evidence

The methodological quality of the review rated 8 out of 11 on the AMSTAR checklist. A record of the review was available in PROSPERO, and the methods of the review followed best practice with respect to study selection, data extraction and risk of bias assessment. The review did not provide information on conflicts of interests of the included primary studies, and it is noted that at least one of the review’s authors was among the authors of the primary randomised trials.

The overall quality of evidence was rated as very low according to our GRADE assessment. This was primarily because of limitations with indirectness (only North American studies) and imprecision (small sample sizes and wide confidence intervals). Risk of bias was also a factor

since blinding of participants and personnel is not feasible in naturopathic practice trials. Reviewers also considered publication bias to be a potential problem since only a few studies, all favourable to naturopathic practice, were identified.

Potential biases in the overview process

For this overview, reviewers did not seek extra information by contacting the review authors (other than obtaining a copy of the manuscript) but they did independently extract data from the full-text publications of the primary studies both for risk of bias and outcome data.

By restricting searches to bibliographic databases, it is possible that reviewers may have missed SRs published as grey literature. However, additional reviews in the submissions were not found.

Safety

Three RCTs reported on safety outcomes (Cooley et al., 2009; Seely et al., 2013; Szczurko et al., 2009). One study indicated that no serious adverse events were reported during the trial (Cooley, et al., 2009). Two studies reported adverse events, although the number was small and the events themselves were mostly mild and temporary. In the trial of naturopathy for rotator cuff tendinitis (Szczurko, et al., 2009), 2 (out of 43) patients receiving naturopathy reported adverse events (loose stool, mild sedation) compared with 5 (out of 42) receiving physiotherapy exercise (mild abdominal discomfort, diarrhoea, flatulence, constipation, brief moderate skin flushing). In the trial of cardiovascular disease risk (Seely, et al., 2013), 6 (out of 106) patients in the naturopathic care group reported adverse effects (eructation/belching following ingestion of fish oil capsules, n = 3; indigestion, n = 2; heart palpitations) compared with none (out of 101) in the usual care group.

Cost-effectiveness

Cost-effectiveness analyses of 2 of the randomised trials were included in the systematic review, although only 1 of these analyses was available as a published paper. The published study investigated the cost-effectiveness of naturopathic care (combination of acupuncture, relaxation exercises, exercise and dietary advice, and a back care booklet) versus standardised physiotherapy education and a back care booklet (Herman, et al., 2008). This analysis was based on the results of the pragmatic randomised trial of chronic low back pain included in this overview (Szczurko, et al., 2007). The trial included 75 postal employees working in a

warehouse with a clinical diagnosis of low back pain of at least 6 weeks. The unpublished study, also by Herman, was a cost-effectiveness analysis of the trial by Seely of naturopathic medicine for the prevention of cardiovascular disease (Seely, et al., 2013). No further information is available for this analysis.

For the trial of chronic low back pain, cost-effectiveness was calculated from the perspective of 3 stakeholders: society, employer and participants. For society and participants, cost-effectiveness was measured in terms of quality-adjusted life-years (QALYs) gained over 6 months. For employers, it was measured in absenteeism. Based on data from 68 participants, the naturopathic group experienced an extra 9.4 'perfect health' days compared to the usual care group over a 6-month period. Societal costs were reduced and employers benefited from reduced absenteeism and productivity gains.

In this study, naturopathic care reduced societal costs by US\$1,212 per participant. From the perspective of the employer, the study reported an incremental cost-effectiveness ratio of US\$154 per absentee day avoided (compared to employer costs of lost productivity of US\$172 per day) and had a return on investment of 7.9% under the health-care coverage limits set by this employer and assuming the employer paid the full cost of naturopathic care. Participants experienced savings in adjunctive care of US\$1,096 per participant.

Conclusions

Authors' conclusions

Based on the findings of 1 unpublished SR of studies conducted in North America, there is some evidence to suggest that naturopathy as a health service is effective in improving patient health for a range of chronic health conditions. However, this finding should be interpreted cautiously given the potentially important differences in naturopathy between North America and Australia with respect to training, accreditation and scope of practice. The effects of naturopathic practice, as delivered in Australia, are uncertain for those chronic conditions for which evidence was identified (anxiety, multiple sclerosis, cardiovascular disease and musculoskeletal conditions) and may differ substantially from the estimates of effect observed in the North American studies. Further evidence is required to estimate the effectiveness of whole-system naturopathic practice for particular chronic and acute conditions and outcomes, especially delivered in Australia.

Implications for practice

Based on the findings of 1 unpublished SR of studies conducted in North America, there is some evidence to suggest that whole-system naturopathic practice is effective in improving patient health for a range of chronic health conditions. However, this finding should be interpreted cautiously in an Australian context since it is based on several small trials of a limited number of single chronic conditions (anxiety, multiple sclerosis, cardiovascular disease and musculoskeletal conditions), all conducted in North America. As noted, there are limitations with the generalisability to naturopathic practice in Australia because of differences in the training and accreditation of naturopaths, and the scope of practice between North America and Australia. The effects of naturopathy, as practised in Australia, are uncertain for those chronic conditions for which evidence was identified (anxiety, multiple sclerosis, cardiovascular disease and musculoskeletal conditions) and may differ substantially from the estimates of effect observed in the North American studies.

Implications for research

While the observed effect estimates in the trials need to be carefully interpreted due to the risk of bias assessment and possible publication bias, the magnitude of the effect estimates, and their consistency in direction across the trials, suggest that naturopathic practice (as implemented in the included trials) may be worth evaluating further in Australia. Any future trials would need to be sufficiently powered to reliably estimate the intervention effects and designed to minimise bias.

Submissions received for naturopathy

Submissions for naturopathy were received from the following organisations/individuals:

- Australian Acupuncture & Chinese Medicine Association (AACMA)
- Australian Natural Therapists Association (ANTA)
- Australian Naturopathic Practitioners Association (ANPA)
- Australian Traditional Medicine Society (ATMS)
- Chinese Medicine Board of Australia (CMBA)
- Complementary Medicine Association
- Endeavour College of Natural Health

- Friends of Science in Medicine
- Individual – Jon Wardle
- National Institute of Complementary Medicine (NICM)
- Society of Natural Therapists and Researchers.

Three submissions contained no references so were not considered further (Chinese Medicine Board of Australia, Complementary Medicine Association, Society of Natural Therapists and Researchers Inc.).

In reviewing the submissions, the reviewers' purpose was to identify possible SRs and RCTs of naturopathy as a health service. The 1 SR identified through the submissions (the conference abstract of Oberg 2013) had already been retrieved by the database searches. All the studies in the Oberg 2013 SR (RCTs and other study designs) appeared several times in the submissions. Submissions were excluded if the reference was to narrative reviews or to trials of individual natural products (rather than naturopathic practice). Thus no additional SRs or randomised trials relevant to the overview were identified from the submitted literature.

Pilates overview report

Objective

The aim of the overview is to summarise the evidence of the effectiveness (and, where available the safety, quality or cost-effectiveness) of Pilates for any clinical condition.

Definition

Pilates is reported to benefit general health through improvements in strength, coordination, balance, flexibility, proprioception, range of motion, body definition and muscle symmetry (Costa, et al., 2012).

Due to its focus on strengthening core muscles and improving posture, Pilates may be of particular therapeutic benefit in people with musculoskeletal conditions, or in conditions affecting balance, such as Parkinson disease. Much of the research on Pilates to date has focused on its use in people with chronic low back pain. However, as Pilates may potentially benefit a diverse range of conditions, this review will aim to evaluate the evidence for the effectiveness of Pilates for any clinical condition.

Pilates is a method of exercise that was originally developed by Joseph Pilates, which aims to achieve optimum balance between mind and body. It is described as combining ‘breathing regulation and mental exercise into a program designed to deliver holistic benefits’, to teach awareness of the form and function of the body (Australian Pilates Method Association, 2013a). Pilates involves a range of more than 500 exercises, which may be performed on a mat on the floor or using specially designed equipment. These exercises typically involve isometric contractions (that is, contraction of the muscles without movement of joints) of the body’s core, stabilising muscles, with the aim of improving posture and conditioning the body (Costa, et al., 2012). Exercises are performed according to 6 key principles: centring (tightening and strengthening the body’s core ‘trunk’ muscles); concentration; control (ensuring postural integrity); precision (the accurate application

...

P
I
L
A
T
E
S

of the exercise technique); flow (ensuring a smooth transition between exercises); and breathing (Wells, et al., 2012).

The cost per session also varies significantly depending on the location and mode of delivery, but is estimated at between \$10 to \$20 for a gymnasium or larger group class, to between \$75 and \$120 for an individual, private session (Pilates Alliance of Australia, 2013).

In Australia, Pilates is gaining popularity as an exercise and recreational activity. Data from the Australian Bureau of Statistics estimates that the number of people practising Pilates has increased from 124,900 in 2005 to more than 190,000 in 2011–12 (Australian Bureau of Statistics, 2013).

Methods

The methods used to conduct this overview are based on the methodology described in Chapter 22 of the *Cochrane handbook for systematic reviews of interventions* (Becker & Oxman, 2011).

The reviewers identified SRs published between 2008 and December 2013 through a systematic search of the following databases: MEDLINE, EMBASE, CINAHL, AMED and the Cochrane Library. The methodological quality of reviews was assessed independently by 2 reviewers using the AMSTAR tool. To be considered for inclusion, systematic reviewers must have conducted a systematic search for studies of Pilates as an intervention. Where SRs were identified that included both RCTs and other study designs, further consideration was limited to the subset of RCTs of Pilates included in the systematic review.

Where there were 2 or more reviews that addressed the same question all reviews were included that met the inclusion criteria with a focus on the highest level of evidence and most recent search date.

Discussion

Quality of evidence

The evidence overall was compromised by the small sample sizes, short follow-up periods and inconsistent outcome reporting across RCTs in included SRs. Although a total of 11 RCTs were identified through included reviews, they were small and of variable quality. Of the 5 clinical conditions for which RCTs of Pilates were identified, 2 included evidence from only 1 RCT of

Pilates. The evidence was further limited by poor reporting by systematic reviewers which made it difficult to draw conclusions from the limited information review authors provided.

The methodological quality of RCTs varied widely across included reviews. A number of RCTs did not have any quality assessment performed. Among RCTs where assessment of methodological quality was performed, the majority were of 'lower' methodological quality.

RCTs were generally compromised by small sample sizes and no or short follow-up periods.

Interpreting the findings of RCTs of Pilates was further compromised by variation in the Pilates technique used, the number of sessions performed, their frequency and their duration.

Primary outcomes (such as symptom reduction) were self-reported across the majority of included trials, making them susceptible to social desirability bias.

The SR publications were assessed using the AMSTAR rating scale. According to the results of this assessment, only 1 of the 13 SRs scored a 'high' rating (Howe, et al., 2011). This was a SR which searched for but did not identify RCTs of Pilates.

Almost all reviews reported the results narratively. Meta-analyses were conducted for low back pain studies by a number of systematic reviewers. However, significant heterogeneity existed between pooled studies, making it difficult to interpret the results of the meta-analyses.

The GRADE assessment of studies indicates that the body of evidence was of low quality for all comparisons and categories that were identified. In all cases, downgrading was based on the lack of studies with low risk of bias, small sample sizes, and often lack of reporting of intervention effect estimates.

Main results

The reviewers conducted a SR of SRs investigating the effects of Pilates for the improvement of health outcomes in people with any clinical condition. Thirteen SRs were included, 3 of which did not identify any RCTs of Pilates and were therefore not considered further in this overview. The remaining 10 SRs included a total of 18 unique RCTs that met the inclusion criteria for this overview.

The topics that were the subject of the included SRs were overweight or obesity (1 systematic review; 2 RCTs), breast cancer (1 systematic review; 1 RCT), strength, balance, functional

performance and falls prevention in older people (1 systematic review; 3 RCTs), low back pain (6 SRs; 11 RCTs) and stress urinary incontinence in women (1 systematic review; 1 RCT).

Two types of comparisons were assessed in the studies included in the reviews: those comparing Pilates versus control and those comparing Pilates with an active intervention. The reviews on body composition (body weight, per cent body fat, body circumferences); strength, balance, functional performance and falls prevention in older people; survivors of breast cancer; and stress urinary incontinence in women only included RCTs that compared Pilates with control. The reviews on Pilates for low back pain included RCTs comparing Pilates with control and with active interventions.

Overweight and obesity

One SR including 2 eligible RCTs (n = 81) was included in the overview that investigated the effects of Pilates on improving body composition in overweight or obese people.

A statistically significant but clinically insignificant between-group difference in body weight was reported. However, baseline and follow-up values for body weight and actual between-group differences were not reported, nor was the test of statistical significance for assessing between-group effects. Between-group differences in per cent body fat and body circumferences were not reported. The effect of Pilates on body composition in people with overweight or obesity is therefore uncertain.

Survivors of breast cancer

One SR including 1 eligible RCT (n = 52) assessed the impacts of Pilates on health outcomes in people with previously treated breast cancer. The review authors report statistically significant improvements in aerobic capacity but no difference in flexibility, fatigue, depression or quality of life with Pilates plus home exercises compared with home exercises alone. Effect sizes and between-group differences were not reported. The impact of Pilates on health outcomes in breast cancer survivors is therefore unclear.

Strength, balance, functional performance and falls prevention in older people

One SR including 3 eligible RCTs (n = 144) assessed the impacts of Pilates on balance/functional performance, strength and falls prevention in older people.

All 3 trials compared Pilates with control for measures of balance and/or functional performance. A medium to large effect size of Pilates on balance/functional performance was reported for all 3 trials.

Two trials assessed Pilates for strength. One study (n = 60) showed a large effect size in favour of Pilates. The other study (n = 27) found no significant difference between Pilates and control on strength. One trial (n = 60) assessed Pilates for falls prevention. This study found a large effect size in favour of Pilates.

Low back pain

Six SRs including a total of 11 eligible RCTs assessed the effect of Pilates on pain or disability in people with low back pain. Five RCTs (n = 144) compared Pilates with minimal intervention. Three of 5 studies reported significant between-group differences in favour of Pilates for pain outcomes whereas the other 2 RCTs found no between-group differences in pain. Three of 4 studies reported significant between-group differences in favour of Pilates for disability outcomes. The other RCT found no between-group differences in disability. Seven RCTs (n = 295) compared Pilates with active intervention (physiotherapy, massage therapy, exercises or education). Of the 7 RCTs that reported between-group differences for pain, 1 RCT (n = 86) found a significant between-group difference in favour of Pilates and 6 RCTs found no between-group differences. Of the 5 RCTs that reported between-group differences for disability, 1 RCT (n = 86) found a significant between-group difference in favour of Pilates and 4 RCTs found no between-group differences.

Stress urinary incontinence in women

One SR including 1 eligible RCT assessed the effect of Pilates on quality of life in women with stress urinary incontinence. No between-group differences or outcome data were reported for this study. The effect of Pilates on quality of life in this patient group is therefore unclear.

Safety outcomes

The results for safety outcomes were not reported in included reviews.

Overall completeness and applicability of evidence

There remain gaps in the research evidence regarding Pilates and the evidence presented in this overview has important limitations. The findings from this overview are limited to adult

participants and reviewers were therefore unable to determine the impacts of Pilates in paediatric patients.

The background to this overview indicates that Pilates is used in the management of a broad range of clinical conditions. In spite of this, reviewers were able to identify SRs relating to only 5 clinical conditions. Reviewers are therefore unable to determine the effectiveness of Pilates for other clinical conditions in which the exercise therapy is used. The findings of this overview are generalised to Pilates exercises regardless of the type of Pilates used. There are different Pilates techniques, some involving the use of apparatus and others predominantly using floor exercises. Conclusions were unable to be drawn about the relative benefit of different Pilates techniques from SRs included in this overview.

There was considerable variation in the frequency and duration of Pilates sessions that were reported in included SRs. Evidence was insufficient to enable the optimal number of sessions, frequency and duration of Pilates treatment to be determined for any clinical condition.

Data were insufficient to determine whether having a trained Pilates professional (versus someone who was not a Pilates professional) providing the treatment influenced the effectiveness of the intervention.

The safety, quality or cost-effectiveness of Pilates was unable to be determined, as none of the included SRs reported on these outcomes.

Reviews were excluded that were not published in English for which there was no English translation available. This resulted in 1 review (da Silva & Mannrich, 2009) being excluded. The abstract for this study indicates the review relates to the use of the Pilates method in rehabilitation. The type of rehabilitation and purpose of rehabilitation was not described in the abstract, nor were the number of studies and study design of included studies provided. It was not possible to draw any conclusions from this abstract.

Quality of the evidence

The evidence overall was compromised by the small sample sizes, short follow-up periods and inconsistent outcome reporting across RCTs in included SRs. Although a total of 11 RCTs were identified through included reviews, they were small and of variable quality. Of the 5 clinical conditions for which RCTs of Pilates were identified, 2 included evidence from only 1 RCT of

Pilates. The evidence was further limited by poor reporting by systematic reviewers which made it difficult to draw conclusions from the limited information review authors provided.

The methodological quality of RCTs varied widely across included reviews. A number of RCTs did not have any quality assessment performed. Among RCTs where assessment of methodological quality was performed, the majority were of 'lower' methodological quality.

RCTs were generally compromised by small sample sizes and no or short follow-up periods. Interpreting the findings of RCTs of Pilates was further compromised by variation in the Pilates technique used, the number of sessions performed, their frequency and their duration.

Primary outcomes (such as symptom reduction) were self-reported across the majority of included trials, making them susceptible to social desirability bias.

The SR publications were assessed using the AMSTAR rating scale. According to the results of this assessment, only 1 of the 13 SRs scored a 'high' rating (Howe 2011). This was a SR which searched for but did not identify RCTs of Pilates.

Almost all reviews reported the results narratively. Meta-analyses were conducted for low back pain studies by a number of systematic reviewers. However, significant heterogeneity existed between pooled studies, making it difficult to interpret the results of the meta-analyses.

The GRADE assessment of studies indicates that the body of evidence was of low quality for all comparisons and categories we identified. In all cases, downgrading was based on the lack of studies with low risk of bias, small sample sizes, and often lack of reporting of intervention effect estimates.

Potential biases in the overview process

Reviewers took steps to reduce bias by specifying systematic methods for the overview process before commencing the overview. They adhered to a protocol that was provided by the NHMRC. Two review authors independently assessed eligibility for inclusion of reviews and carried out data extraction.

A comprehensive search strategy was used for the review. Every effort was made to identify relevant studies. The search strategy was designed to identify non-English studies; however, studies were excluded where no English language translation was available. One study was excluded on this basis, and reviewers are unable to determine the impact of excluding this study.

Reviewers did not seek extra information by contacting the review authors or by searching for extra information in the full-text publications of the primary studies.

Conclusions

Authors' conclusions

The effects of Pilates as an alternative treatment for a number of clinical conditions are uncertain. Additional well-designed studies with adequate power and length of follow-up are required to enable definite conclusions to be drawn.

Implications for practice

The effectiveness of Pilates for the clinical conditions that were the subject of included SRs is uncertain. For 4 of the 5 conditions, the entirety of the evidence consists of 3 or less RCTs, all of which are small, and generally of poor or unknown quality. The largest body of evidence assessed Pilates for the treatment of pain and/or disability in people with low back pain. There is some evidence to suggest that Pilates may improve outcomes in some adults with low back pain compared with control. However, the evidence for these findings is based on small studies of poor methodological quality and the body of evidence was therefore rated as being of very low quality. The effect of Pilates within this population therefore remains uncertain. For other clinical conditions there is very little evidence from SRs on the effect of Pilates on health outcomes.

Implications for research

Reviewers identified 13 SRs of RCTs of Pilates published since 2008 that indicate the effect of Pilates is uncertain for the 5 clinical conditions or populations that were the subject of SRs. SRs for other clinical conditions for which Pilates is used were not identified.

The majority of these SRs only identified single eligible RCTs of Pilates for any one condition, and the body of evidence was typically compromised by deficiencies in study design and poor reporting, both in SRs and in the primary studies themselves. If undertaken, future research in this area should focus on larger sample sizes, improved reporting of data, and adequate follow-up periods, to enable more robust conclusions to be drawn.

Submissions received on Pilates

Submissions for Pilates were received from the following organisations:

- Australian Pilates Method Association
- Friends of Science in Medicine.

It was intended to incorporate any additional in-scope level 1 SRs into the overview report.

However, none were identified through the public submission process.

The reviewers intended to extract data from in-scope level 2 studies not already considered in a SR within the overview report using NHMRC's Data Extraction Table form.

However, no additional in-scope level 2 studies were identified. A total of 32 references were considered from the submissions. All references were excluded, the majority of which because they contained study evidence that was level 3 or below according to the NHMRC's levels of evidence. There was no additional in-scope submitted literature that provided evidence for the effectiveness of Pilates for any clinical condition.

Reflexology overview report

Objective

This overview aims to summarise the evidence from SRs of RCTs of the effectiveness (and, where available the safety, quality or cost-effectiveness) of reflexology for any clinical condition.

Definition

Reflexology is a system of applying pressure, usually to the feet, which practitioners believe stimulates energy and releases ‘blockages’ in specific areas that cause pain or illness. Practitioners assert that these pressure or ‘reflex’ points correspond with various zones and organs throughout the body. The therapy is used in the treatment of a broad range of clinical conditions.

Methods

The reviewers identified SRs published between 2008 and June 2013 through a systematic search of the following databases: MEDLINE, EMBASE, CINAHL, AMED and the Cochrane Library. The methodological quality of reviews was assessed independently by 2 reviewers using the AMSTAR tool.

In this overview, the reviewers considered for inclusion any published SR that searched for RCTs focusing on the use of reflexology for the management of any clinical condition, in terms of health outcomes.

To be considered for inclusion systematic reviewers must have conducted a systematic search for studies. Where SRs were identified that included both RCTs and other study designs, further consideration was limited to evidence from the subset of RCTs of reflexology included in the systematic review. Where there were 2 or more reviews that addressed the same question the reviewers included all reviews that met the inclusion criteria with a focus on the highest level of evidence and most recent search date.

...

R
E
F
L
E
X
O
L
O
G
Y

Discussion

Main results

Eighteen SRs across 19 publications were included in this overview, 5 of which searched for but did not identify RCTs of reflexology. The clinical conditions that were the subject of the included SRs were anovulation, asthma, cancer, dementia, foot oedema in the third trimester of pregnancy, headache, infantile colic, insomnia, irritable bowel syndrome, low back pain, menopausal symptoms, multiple sclerosis, post-surgical management after cholecystectomy/gynaecological procedures, premenstrual syndrome, symptomatic idiopathic detrusor over-activity and type 2 diabetes.

The reviewers found that the effectiveness of reflexology was uncertain for all conditions that were assessed in this overview. The safety, quality and cost-effectiveness of reflexology could not be determined from SRs included in this overview.

Overall completeness and applicability of evidence

There remain gaps in the research evidence regarding reflexology and the evidence presented in this overview has important limitations. The findings from this overview are limited to adult participants, with the exception of 1 RCT of reflexology in infants with infantile colic aged between 1 and 3 months. The reviewers were therefore unable to determine the impacts of reflexology in paediatric patients. The findings of this overview are largely limited to foot reflexology. Although there are different types of foot reflexology and different techniques used, evidence was insufficient in SRs to enable any conclusions to be drawn about the relative efficacy of different types of foot reflexology or about particular techniques for reflexology.

Similarly, a number of SRs did not describe the site of the reflexology performed (foot or hand) and only 1 RCT reported that reflexology was performed on the foot, ear and hand (for premenstrual syndrome). As premenstrual syndrome was 1 of the 2 conditions where reflexology was found to be effective, the contribution of the ear and hand components of the reflexology to the overall efficacy of the reflexology intervention is uncertain.

There was large variation in the foot reflexology interventions that were reported in included SRs, both in terms of the number of reflexology sessions performed, their frequency and their duration. The number of sessions ranged from a single session (for lung and breast cancer) to 30

sessions (for type 2 diabetes). Similarly, the frequency varied between multiple sessions within a 24-hour period (during labour) to less than weekly. The duration of reflexology sessions varied from 15 minutes to over 45 minutes. Evidence was insufficient to enable the optimal number of sessions, frequency and duration of reflexology treatment to be determined for any clinical condition.

Data were insufficient to determine whether having a trained reflexology professional (versus someone who was not a reflexology professional) performing the reflexology influenced the effectiveness of the reflexology. In the majority of RCTs the person delivering the reflexology was trained.

The safety, quality or cost-effectiveness of reflexology was unable to be determined due to a lack of published SRs addressing these topics.

Quality of the evidence

The evidence overall was compromised by the small sample sizes, short follow-up periods and inconsistent outcome reporting across RCTs in included SRs. Of the 16 clinical conditions for which RCTs of reflexology were identified, 10 included evidence from only 1 RCT of reflexology. The evidence was further limited by poor reporting by systematic reviewers which made it difficult to draw conclusions from the limited information review authors provided. The reflexology technique used in included RCTs was also poorly described, including the number of reflexology sessions performed, their frequency and their duration across included RCTs.

The methodological quality of RCTs varied widely across included reviews. Although the measures used to assess methodological quality varied, all RCTs were assessed using the Jadad criteria by at least 1 systematic reviewer. According to the results of the Jadad assessments performed, 17 of the 29 RCTs were of 'higher' methodological quality (equivalent to a score of 3 or above).

However, RCTs were generally compromised by small sample sizes and no or short follow-up periods. Interpreting the findings of RCTs of reflexology was further compromised by variation in the reflexology technique used, the number of reflexology sessions performed, their frequency and their duration.

Primary outcomes (symptom reduction) were self-reported across the majority of included trials, making them susceptible to social desirability bias. The SR publications were assessed using the AMSTAR rating scale. According to the results of this assessment, 1 SR scored a ‘low’ rating, 5 SRs scored a ‘medium’ rating and 8 SRs scored a ‘high’ rating.

Potential biases in the overview process

Reviewers took steps to reduce bias by specifying systematic methods for the overview process before commencing the overview. Reviewers adhered to a protocol that was reviewed and endorsed by the NHMRC. Two review authors independently assessed eligibility for inclusion of reviews and carried out data extraction.

A comprehensive search strategy was used for the review. Every effort was made to identify relevant studies. The search strategy was designed to identify non-English studies; however, studies were excluded where no English language translation was available. Five studies were excluded on this basis, and the impact of excluding these studies cannot be determined.

Reflexology can be used for diagnosis of health problems. This overview was limited to the assessment of reflexology as a treatment for health problems.

Adverse events/safety

Safety was specifically considered for assessment in the SRs by Bamigboye and Smyth (2007), Hartmann and others (2009), Perry and others (2011), Smith (2012), Wang and others (2008) and Yeung and others (2012). Only Yeung and others (2012) identified and reported data relating to adverse events/the safety of reflexology. Adverse events were reported by Yeung and others (2012) (AMSTAR 8/11) from 1 RCT of reflexology for insomnia. In 1 study of 120 patients randomised to either foot reflexology (45– 60 minutes daily for 30 days) or Alprazolam (0.4–0.8 mg per day), 9 (15.0%) of 60 participants receiving reflexology complained of pain at stimulation points that resolved within 1 hour, while 32 (53.3%) of the 60 subjects given benzodiazepines reported adverse events. None of the participants in either group withdrew from the study due to adverse events.

Conclusions

Authors' conclusions

The effect of reflexology on improving outcomes is uncertain for the clinical conditions for which the therapy has been trialled.

Implications for practice

The effectiveness of reflexology for the clinical conditions that were the subject of included SRs is uncertain. There was insufficient information available from included studies to determine the safety, quality and cost-effectiveness of reflexology.

Implications for research

The reviewers identified SRs of RCTs of reflexology published since 2008 for a wide range of conditions. The majority of these SRs only identified single RCTs of reflexology for any one condition, and the body of evidence was typically compromised by deficiencies in study design and poor reporting, both in SRs and in the primary studies themselves. If undertaken, future research should focus on larger sample sizes, improved reporting of data, and adequate follow-up periods to enable more definite conclusions to be drawn.

Submissions received for reflexology

Submissions for reflexology were received from the following organisations:

- Australian Association of Massage Therapists
- Australian Traditional Medicine Society
- Friends of Science in Medicine
- Reflexology Australia.

Results of evaluation of evidence submissions

There were 3 RCTs identified in the evaluation of evidence submissions that were not already included in a SR within the overview (Dalal et al., 2010; Dolation et al., 2011; Li et al., 2011). Dalal and others (2010) assessed the effect of foot reflexology on pain; Dolation and others (2011) assessed the effect of reflexology on duration of labour and pain intensity during labour in primiparous women; and Li and others (2011) assessed the relationship between reflexology and postpartum sleep quality.

All studies were of poor methodological quality. The study by Dalal and others (2010) was unblinded and the size of the sample in each study group within the study was small. The study by Dolation and others (2011) was unblinded, the size of the sample in each study group was not reported and different midwives performed each of the vaginal examinations, with no assessment of inter-rater reliability of cervical assessment. Further, it was difficult to interpret the findings of the study as the authors did not provide data for all relevant outcomes.

Summary of evaluation of submitted literature

There was evidence from submitted literature that reflexology reduces pain for mastalgia, osteoarthritis, type 2 diabetic neuropathy and lower limb pain with intractable epilepsy; reduces the duration of labour and pain intensity during labour in primiparous women; and that reflexology improves postpartum sleep quality. However, these findings are from low-quality RCTs with high risk of bias. Further, the RCTs were self-selected by stakeholders on the basis that they represent positive evidence for reflexology. The overview authors did not identify any reviews that have performed a systematic search for all RCTs addressing these clinical questions; therefore, the results of these RCTs should be interpreted with caution.

Rolfing overview report

Objective

The objectives of this overview is to summarise the evidence from all identifiable SRs conducted since 2008 that examined the effectiveness (and, where available, the safety, quality and cost-effectiveness) of rolfing for improving health outcomes for any clinical condition.

Definition

Rolfing (also referred to as structural integration) is a system of hands-on manipulation and movement education that claims to organise the body in gravity. Rolfing is used in the management of a range of musculoskeletal and non-musculoskeletal health problems.

Methods

The reviewers sought SRs published between 2008 and June 2013 through a systematic search of the following databases: MEDLINE, EMBASE, CINAHL, AMED and the Cochrane Library. They assessed the methodological quality of reviews independently by 2 reviewers using the AMSTAR tool.

In this overview, reviewers sought to include any SR published since 2008 of RCTs focusing on the use of rolfing for the management of any clinical condition, in terms of health outcomes.

To be considered for inclusion, systematic reviewers must have conducted a systematic search for studies of rolfing as an intervention. Where SRs were identified that included both RCTs and other study designs, further consideration was limited to the subset of RCTs of rolfing included in the systematic review.

Where there were 2 or more reviews that addressed the same question, the reviewers intended to include all reviews that met the inclusion criteria with a focus on the highest level of evidence and most recent search date.

...

R
O
L
F
I
N
G

Discussion

Summary of main results

There is a lack of evidence available from SRs for the effectiveness of rolfing for any clinical condition. The safety, quality and/or cost-effectiveness of rolfing are also unable to be determined, as no SRs were identified.

Overall completeness and applicability of evidence

The reviewers did not identify any SRs that included RCTs of rolfing. There is thus a significant gap in research concerning the primary and secondary research objectives, namely examining the effectiveness (and safety, quality and cost-effectiveness) of rolfing.

There are rolfing practitioners in the majority of Australian states and territories that have received formal education and training in the techniques of rolfing. The absence of evidence examining this technique (both in SRs published since 2008 and in RCTs) limits the ability of consumers, health providers and policy-makers to make an informed assessment regarding the effectiveness (and safety, quality and cost-effectiveness) of rolfing.

Quality of evidence

Not applicable

Potential biases in the overview process

A comprehensive search strategy was used for the overview. Every effort was made to identify relevant SRs. The search strategy was designed to identify non-English publications and no SRs were excluded due to language alone.

Conclusions

Authors' conclusions

The reviewers were unable to identify SRs conducted in the last 5 years that included RCTs that assessed the efficacy of rolfing for the management of any clinical condition. The safety, quality and/or cost-effectiveness of rolfing are also unable to be determined, as no SRs were identified.

Implications for practice

There is a lack of evidence from RCTs about the effectiveness of rolfing and therefore the reviewers were unable to draw reliable conclusions about the effectiveness of rolfing for any clinical condition.

Implications for research

Reviewers were unable to identify SRs conducted in the last 5 years that included RCTs that assessed the efficacy of rolfing for the management of any clinical condition.

Submissions received for rolfing

Submissions for rolfing were received from the following organisations:

- Friends of Science in Medicine
- Australian Association of Massage Therapists.

Sixteen publications were identified within the submissions and were assessed by the review team against the a priori criteria specified in the overview protocol. Neither submission included any studies that were eligible for inclusion in this overview.

A SR conducted by Ng and Cohen and commissioned by the Australian Association of Massage Therapists (AAMT) was reviewed as part of the AAMT evidence submission. This SR makes reference to 5 studies of rolfing being included in their systematic review. Unfortunately, this SR does not directly identify which of the 5 studies related to rolfing. The level of evidence of included rolfing studies is not defined by the systematic reviewers and data are not presented that enable the efficacy of rolfing to be assessed. Instead, the reviewers consider rolfing studies in combination with massage therapies in general.

Given the lack of studies able to be included in this overview, the reviewers perused the reference list of this SR and were able to identify 2 studies categorised as RCTs but none categorised as SRs of rolfing/structural integration and that had been included by the reviewers. Neither of these trials met the inclusion criteria for this overview (both were published before 2008). Further, both had small sample sizes (48 and 30 participants respectively) and neither were, in fact, RCTs. One was an open, un-randomised volunteer study (Cottingham, et al., 1988). The other was a nested case-control study with matched pairs of subjects randomly assigned to rolfing or control groups (Weinberg & Hunt, 1979).

Summary of evaluation of submitted literature

There was no submitted literature that provided evidence for the effectiveness of rolfing for any clinical condition.

Shiatsu overview report

Objective

This overview summarises the evidence of the effectiveness (and, where available the safety, quality or cost-effectiveness) of shiatsu for any clinical condition.

Definition

Shiatsu is a holistic therapy that practitioners assert can improve a patient's wellbeing, lifestyle, diet and/or mind-body awareness (Long, 2008). When applied by a practitioner with appropriate training, shiatsu is believed to promote general wellbeing and can be used as a preventative health-care method. It is also claimed that shiatsu can assist people in coping during times of crisis, challenging life phases and in processes of change (European Shiatsu Federation, 2013).

Shiatsu is a form of massage therapy which primarily developed in Japan. It is a holistic therapy that incorporates massage therapy and acupressure.

Shiatsu massage uses gentle manipulations, stretches and pressure through the application of the practitioner's fingers, thumbs, elbows, knees and feet. Shiatsu acupressure involves the use of pressure applied principally with the hands across a selection of over 150 pressure points on the body. The acupressure points that are selected depends on the patient's clinical history and physical examination (Robinson et al., 2011; European Shiatsu Federation, 2013).

Along with massage therapy and acupressure, shiatsu practitioners may also use a variety of therapeutic techniques from Taoist or other traditional medicine modalities, including moxibustion, cupping, food as medicine and judo therapy/tai chi/qi gong (Shiatsu Therapy Association of Australia, 2013). Many of these techniques are also used by acupuncturists and other natural therapists.

...

S
H
I
A
T
S
U

Methods

In this overview, reviewers sought to include any SR published since 2008 of RCTs focusing on the use of shiatsu for the management of any clinical condition, in terms of health outcomes.

To be considered for inclusion, systematic reviewers must have conducted a systematic search for studies of shiatsu as an intervention. Where SRs were identified that included both RCTs and other study designs, further consideration was limited to the subset of RCTs of shiatsu included in the systematic review.

Where there were 2 or more reviews that addressed the same question, reviewers intended to include all reviews that met the inclusion criteria with a focus on the highest level of evidence and most recent search date.

Discussion

Summary of main results

There is a lack of evidence available from SRs of RCTs published since 2008 for the effectiveness of shiatsu for any clinical condition.

The safety, quality and/or cost-effectiveness of shiatsu are also unable to be determined from the SRs included in this overview.

Overall completeness and applicability of evidence

Reviewers did not identify any SRs that included RCTs of shiatsu that met the inclusion criteria. There is thus a significant gap in research concerning the primary and secondary research objectives of examining the effectiveness (and safety, quality and cost-effectiveness) of shiatsu.

There are shiatsu practitioners in the majority of Australian states and territories that have received formal education and training in the techniques of shiatsu. The lack of evidence examining this therapy (both in SRs published since 2008 and in RCTs) limits the ability of consumers, health providers and policy-makers to make an informed assessment regarding the effectiveness (and safety, quality and cost-effectiveness) of shiatsu.

Quality of the evidence

The quality of included reviews was 'medium' to 'good'. However, no included review contained RCTs that met inclusion criteria.

Potential biases in the overview process

A comprehensive search strategy was used for the overview. Every effort was made to identify relevant SRs. The search strategy was designed to identify non-English SRs; however, SRs were only included where an English language translation was available. Two reviews were excluded because reviewers were unable to locate an English language translation.

Results

There were 4 SRs that met the inclusion criteria for this overview. Two SRs (1 conducted to assess interventions for chronic musculoskeletal pain and the other conducted to assess shiatsu for any clinical condition) each identified a single RCT. However, the effect of shiatsu could not be independently evaluated from either RCT, as shiatsu was combined with other interventions in both studies. In the other 2 included SRs, the authors searched for, but did not identify, any RCTs of shiatsu for the management of pain in labour.

Conclusions

Authors' conclusions

Reviewers were unable to assess the efficacy, safety, quality or cost-effectiveness of shiatsu from SRs of RCTs of the therapy's effectiveness.

Reviewers were unable to identify SRs conducted in the last 5 years that included RCTs that assessed the efficacy of shiatsu for the management of any clinical condition.

Plain language summary

Shiatsu is a holistic physical therapy that incorporates acupuncture and massage therapy techniques with the aim of restoring balance to the flow of energy within the body.

Shiatsu is used in the management of a very broad range of musculoskeletal and non-musculoskeletal health problems.

This overview sought to summarise and report all of the available evidence arising from SRs of shiatsu regarding how effective the therapy is. Reviewers did not identify any SRs that included RCTs of shiatsu that met the inclusion criteria for this overview and were therefore unable to draw conclusions about the effectiveness of shiatsu.

Implications for practice

There is a lack of evidence from SRs of RCTs published since 2008 about the effectiveness of shiatsu. Therefore, no reliable conclusions about the effectiveness of shiatsu for any clinical condition can be made.

Implications for research

Reviewers were unable to identify SRs conducted in the last 5 years that included RCTs that assessed the efficacy of shiatsu for the management of any clinical condition.

Submissions received for shiatsu

The submissions for shiatsu were received from the following organisations:

- Association of Massage Therapists Ltd
- Australian Acupuncture and Chinese Medicine Association Ltd
- Australian Association of Massage Therapists
- Australian Natural Therapies Association
- Friends of Science in Medicine
- National Institute of Complementary Medicine
- Shiatsu Therapy Association of Australia.

Submissions from the Australian Acupuncture and Chinese Medicine Association, the Association of Massage Therapists and the Shiatsu Therapy Association of Australia contained evidence from publications broadly relevant to the subject of the overview and were assessed further. The submissions from the Australian Association of Massage Therapists, the Australian Natural Therapies Association, the Friends of Science in Medicine and the National Institute of Complementary Medicine did not include any citations relevant to shiatsu and were therefore not evaluated further.

No submission included any studies in addition to those already identified that were eligible for inclusion in this overview.

The majority of publications were excluded either because they contained no trials of shiatsu or because they were published before 2008.

Tai chi overview report

Objective

The aim of this overview is to summarise research on the effectiveness of tai chi for improving health outcomes for any clinical condition or health problem (that is, secondary or tertiary prevention). The comparisons of interest are:

- a. Tai chi versus control (includes no intervention and conventional treatment with or without the addition of tai chi)
- b. Tai chi versus an active intervention.

Also, the overview aims to summarise the safety, quality and costs of tai chi (where these components are evaluated in the included SRs).

Definition

Tai chi, or taiji or taijiquan as it is otherwise known, is a mind and body practice that combines deep breathing and relaxation with slow and gentle physical movements. Tai chi originated in China as a martial art and is based on an assumption from Confucian and Buddhist philosophy that 2 opposing life forces, yin and yang, govern our health (Lee & Ernst, 2011). It is thought that by balancing a person's yin and yang, tai chi aids the flow of the body's vital energy or 'life force', which is termed 'qi' (National Center for Complementary and Alternative Medicine, 2013).

There are many different styles of tai chi including Chen, Yang, Wu, Hao and Sun styles. Each of these has its own unique characteristics but all are based on the same underlying principles, involving a series of slow, calm and relaxed movements (Hall et al., 2009a; Ng et al., 2012). In addition to physical movement, tai chi requires concentration, with participants focusing their attention on deep breathing and postures (National Center for Complementary and Alternative Medicine, 2013).

Tai chi may be practised either individually or in groups, and is commonly performed outdoors in parks and recreational areas. Individuals may learn tai chi through participation in classes,

...

T
A
I

C
H
I

taught by an instructor, or through media such as DVDs, which may be used for home-based practice. As tai chi does not require specialist facilities or expensive equipment, it can be practised at any time and in any location where there is sufficient space (Ng, et al., 2012). This feature of tai chi also makes it a relatively low-cost treatment option, when compared with other interventions (Wolf, et al., 1996) or conventional medications.

Methods

The methodology of the overview was determined by a protocol developed by the NHMRC. A comprehensive literature search was undertaken in January 2014 and SRs were included in the overview if they were published between 2008 and January 2014, tai chi was the focus of the review and the intervention was not for primary prevention. The 2 comparisons were tai chi versus control and tai chi versus an active intervention. SRs were assessed for quality using the AMSTAR measurement tool. Data were only extracted for RCTs and select outcomes determined according to predefined criteria. The results were synthesised narratively.

Discussion

Summary of main results

An overview of SRs was conducted to investigate the effects of tai chi on any health outcome, excluding primary prevention. Of the 43 included SRs, 37 had usable data. These 37 SRs included 117 unique RCTs, including 8,852 participants across 16 clinical conditions. Results were presented for 2 types of comparison: tai chi versus control and tai chi versus an active intervention as defined in the protocol.

Thirty outcomes were reported for tai chi versus control. For 22 outcomes, tai chi had an uncertain effect, for 5 outcomes tai chi may have some effect and for 3 outcomes tai chi may have no effect. Twenty-five outcomes were reported for tai chi versus an active intervention. For 17 outcomes, tai chi had an uncertain effect, for 1 outcome tai chi may have some effect, for 6 outcomes there may be no difference between tai chi and an active intervention, and for 1 outcome tai chi may have an effect compared with 1 comparator, but the effect compared with another comparator is uncertain. The summary of findings table for each condition gives more detail and is included in the results section under each condition.

Of the 37 included SRs, 17 reported on safety outcomes in the tai chi RCTs. Of these, 12 reported that none of their included RCTs had reported any adverse events or safety issues. In the reviews where adverse events were described, these were uncommon and generally included events such as muscle soreness and foot or knee pain. Serious adverse events were rare and were not considered related to tai chi. Overall, tai chi could be considered a safe treatment in the populations considered in this report.

Overall completeness and applicability of evidence

An overview of SRs was done to cover a significant body of literature across a broad range of conditions. Only SRs with a primary focus on tai chi were included. This criterion resulted in the exclusion of 53 SRs in which the primary focus was broader than tai chi, including 9 Cochrane reviews.

The application of this criterion was necessary to ensure the overview had a manageable body of literature and could be finished in the specified timeframe. However, it is possible that this resulted in the retention of lower quality reviews focused on tai chi, at the expense of higher quality, broader reviews such as Cochrane reviews.

The protocol did not explicitly define what constitutes a systematic review, and therefore the inclusion of studies based on study type was decided based on the consensus of the reviewers rather than explicit criteria. The reviewers took a very generous approach to the inclusion criteria and several very-low-quality SRs may have been excluded had more stringent criteria for a SR been applied. The exclusion of lower quality or borderline SRs may have resulted in a higher quality overview, albeit at the expense of covering the breadth of the literature.

Reviewers included only English language SRs. This resulted in the exclusion of 5 non-English language SRs (2 for osteoarthritis, 1 for fibromyalgia, 1 for Parkinson disease and 1 for older people). However, because many of the included SRs included non-English language studies, this is not considered to be a significant limitation.

The classification of comparators into ‘control’ and ‘active intervention’ was not always clear. As specified in the protocol, an ‘active comparator’ included any active intervention; in essence, anything that did not fall under no treatment, inactive usual care or waiting list. Consequently, the types of interventions included under ‘active comparator’ varied considerably, and included

handicrafts, education, exercise, medications and complex rehabilitation programs. Including all of these comparators under one umbrella classification can make interpretation of the results difficult and means that the effects of tai chi relative to the individual comparators is not directly assessed. In addition, the reporting in the SRs often failed to provide sufficient details of the comparator to allow a clear classification of the comparison. Considering these issues, the overview may have benefited from separating out the ‘active’ comparators into several categories, such as medication, exercise or rehabilitation, and other comparators.

Overall, this overview identified 43 SRs (37 of which had usable data), including 117 RCTs investigating the effects of tai chi. The reviews covered 16 clinical conditions and included 8,852 participants. Due to the nature of overviews, it is possible that RCTs of tai chi exist that were not included in the identified SRs.

Quality of the evidence

The quality of the included SRs ranged from 1 to 9 (out of 11) on the AMSTAR checklist (median score of 5). Not all included reviews assessed the risk of bias in the primary studies or provided the characteristics of the included studies. In those which did assess risk of bias, the assessments were often poorly reported and insufficient for reliable interpretation of the review and its included trials.

Overall, the quality of evidence across all clinical conditions was very low predominantly due to the small sizes and poor quality of the included RCTs, which lead to a high risk of bias, imprecision and the risk of publication bias. Given the small study sizes, most of the included RCTs would not have been sufficiently powered to detect inferiority or equivalence. This has further hampered the interpretation of the results, particularly for the comparison of tai chi versus active comparator, where the issues of non-inferiority and equivalence are more pressing. The exception to this was in the older adult population, which included a number of larger trials and some outcomes were rated as low-quality evidence rather than very low.

Potential biases in the overview process

An overview of SRs is entirely dependent on the quality of the included SRs. No extra information was sought by contacting review authors or consulting the primary studies. The poor quality of many of the included SRs limits reviewers’ confidence in the overview findings. This

is compounded by the poor quality of the included RCTs, the vast majority of which were very small. It is possible that RCTs have been included in the overview which stringent criteria may have excluded, for example, as not truly randomised or containing insufficient numbers to provide a meaningful effect estimate. Again, the quality of the overview may have been improved by excluding RCTs of poor methodological quality or with few participants.

None of the systematic reviews provided raw data for the trials and all effect estimates are dependent on the reporting at the level of both the RCT and the SR. The majority of effect estimates were reported as mean difference or standardised mean difference, and these measures were difficult to interpret without a detailed understanding of the unit of analysis. In addition, the majority of the studies did not consider the clinical significance of their results, and instead most focused on the issue of statistical significance. It was generally not possible to determine if appropriate statistical methodologies had been employed; for example, intention to treat analysis or the standardising of different outcome scales.

Conclusions

Authors' conclusions

There is very-low-quality evidence to suggest that tai chi may have some beneficial health effects when compared to control in a limited number of conditions for a limited number of outcomes including older people (muscle strength), heart disease (quality of life), hypertension (SBP, DBP) and osteoarthritis (physical function). There is also very low-quality evidence that tai chi may have beneficial effects on selected outcomes in people with osteoarthritis (pain, physical function) relative to active comparators. Very-low-quality evidence suggests that there may be no difference between tai chi and another active comparator in a limited number of conditions and for a limited number of outcomes including hypertension (SBP, DBP), osteoporosis (bone mineral density) and type 2 diabetes (HbA1c, FBG, total cholesterol). There is also low to very-low-quality evidence that tai chi may have no effect on selected outcomes in people who are older (falls) and people with heart disease (HRV, exercise capacity) compared to control.

The evidence for these findings is largely based on small, poor-quality studies and was rated as very low for almost all outcomes. The magnitude and clinical significance of any potential health benefits are uncertain. For many outcomes, the health effects of tai chi are uncertain.

The key limitation of this research was the quality of information reported in the reviews and potentially also in the primary studies. The overall poor quality of the included SRs and the implied poor quality of the RCTs they included prevents more definite conclusions being drawn and does not enable confidence in effect estimates.

Implications for practice

There is very-low-quality evidence to suggest that tai chi may have some beneficial health effects when compared to control in a limited number of conditions for a limited number of outcomes including older people (muscle strength), heart disease (quality of life), hypertension (SBP, DBP) and osteoarthritis (physical function). There is also very-low-quality evidence that tai chi may have beneficial effects on selected outcomes in people with osteoarthritis (pain, physical function) relative to active comparators.

Very-low-quality evidence suggests that there may be no difference between tai chi and another active comparator in a limited number of conditions and for a limited number of outcomes including hypertension (SBP, DBP), osteoporosis (bone mineral density) and type 2 diabetes (HbA1c, FBG, total cholesterol). There is also low- to very-low-quality evidence that tai chi may have no effect on selected outcomes in people who are elderly (falls) and people with heart disease (HRV, exercise capacity) compared to control.

The evidence for these findings is largely based on small, poor-quality studies and was rated as very low for almost all outcomes. The magnitude and clinical significance of any potential health benefits are uncertain. For many outcomes, the health effects of tai chi are uncertain. The overall poor quality of the included SRs and the implied poor quality of the RCTs they included prevents more definite conclusions being drawn and does not enable confidence in effect estimates.

Implications for research

The key limitation of this research was the poor quality of information reported in the reviews and potentially also in the primary studies. Any new SRs of tai chi should implement clear and consistent reporting of study quality assessment and full reporting of the results from individual trials for the key patient relevant clinical outcomes. New RCTs of tai chi should adhere to the CONSORT guidelines for the reporting of RCTs. This will enable more complete and accurate consolidation of the available clinical evidence.

Safety

Of the 37 included SRs, 17 reported on safety outcomes in the tai chi RCTs. Of these, 12 reported that none of their included RCTs had reported any adverse events or safety issues. In the reviews where adverse events were described, these were uncommon and generally included events such as muscle soreness and foot or knee pain. Serious adverse events were rare and were not considered related to tai chi. Overall, tai chi could be considered a safe treatment in the populations considered in this report.

Submissions received for tai chi

Submissions for tai chi were received from the following organisations:

- Australian Feldenkrais Guild (AFG)
- Friends of Science in Medicine
- National Institute of Complementary Medicine
- Tai Chi Association of Australia.

All references included in the stakeholder submissions plus evidence contained within the stakeholder submissions themselves were collated and tabulated. The submission from the AFG included a whole section of references published in 1997 or earlier. As these references did not meet the requirement that literature be published from 2008 onwards, and the submission did not specifically relate to tai chi, all of these references were excluded at the initial screening stage.

All other references (including those published before 2008) were reviewed as titles, abstract or full text as deemed necessary and those references that were clearly out of scope (that is, not regarding the effectiveness of tai chi for a clinical condition) were excluded. The remaining 'in scope' references were graded according to NHMRC's levels of evidence (NHMRC, 2009) with the level of evidence documented in a table. Where submitted literature was not a SR or a report of a primary study and was therefore unable to be assigned a level of evidence (for example, secondary sources that are not SRs, opinion pieces, textbooks, letters and general articles and websites). Literature that was unable to be assigned a level of evidence and evidence graded at Level III or below was not considered further.

Results of submissions

The submission from the Tai Chi Association of Australia included 5 references to reports from the Greater Southern Area Health Service that could not be retrieved as the hyperlinks provided in the submission did not work and the reports could not be located using internet searching.

These reports did not appear to be reports of clinical studies of the effectiveness tai chi and were marked as not in scope.

The screening of the submitted literature aimed to identify SRs and RCTs (Level I and Level II evidence, respectively) that were not identified in the overview.

The submission from the Tai Chi Association of Australia included 3 references to 2 SRs that included tai chi as one of many interventions considered in the reviews (Gillespie et al., 2009; Sherrington et al., 2008a and 2008b). The submission from the NICM included reference to 1 SR that included tai chi as one of many interventions considered in the review (Herman, et al., 2012). These reviews were not eligible for inclusion in the overview as they did not focus specifically on tai chi.

Yoga overview report

Objective

The objective of the reviewers was to summarise the evidence of the effectiveness (and, where available the safety, quality or cost-effectiveness) of yoga for any clinical condition.

Definition

Yoga is a traditional Indian mind and body practice that involves a combination of physical postures, breathing techniques and meditation or relaxation with the aim of restoring balance and improving wellbeing (NCCAM 2013). Traditionally, yoga is a spiritual practice and is viewed as a complete lifestyle philosophy that incorporates 8 dimensions: pranayama (breathing); asana (postures); yama (restraint); niyama (healthy observances); pratyahara (sensory withdrawal); dharana (concentration); dhyana (meditation); and samadhi (higher consciousness). Over time, various forms of yoga have developed based on this philosophy, including Iyengar, ashtanga, Viniyoga, kundalini and Bikram yoga (UMMC 2013). These forms each focus on different elements of breathing, postures and meditation or relaxation (Ernst 2010) and may vary in their level of physical intensity.

In Australia, yoga is often practised as a form of exercise and may be separated from its more traditional spiritual philosophy. In this context, yoga can be taught in gymnasiums, yoga centres and other community settings, and is taught by instructors with varying degrees of training. Yoga is typically practised in group classes. It may also be taught through individual or smaller group classes, at an increased cost. Classes are typically between 45 and 90 minutes in length and usually involve warm up exercises, followed by a guided series of postures combined with controlled breathing, ending with a period of relaxation or meditation (UMMC 2013). It is also common for people to undertake home-based practice, either as a supplement to sessions with an experienced instructor, or by using digital media such as DVDs for guidance. In Australia, yoga is gaining popularity as an exercise and recreational activity,

with the number of people participating in yoga practice increasing by nearly 30% since 2005. It is currently estimated that close to 350,000 Australians practise yoga²¹ (ABS 2013).

Methods

In this overview, the reviewers sought to include any SR published since 2008 of RCTs focusing on the use of yoga for the management of any clinical condition, in terms of health outcomes. To be considered for inclusion, systematic reviewers must have conducted a systematic search for studies of yoga as an intervention. Where SRs were identified that included both RCTs and other study designs, further consideration was limited to the subset of RCTs of yoga included in the systematic review.

Where there were 2 or more reviews that addressed the same question, all reviews that met the inclusion criteria with a focus on the highest level of evidence and most recent search date were included. SRs that searched for, but do not identify, RCTs of yoga were included as these reviews provide information about the lack of evidence from RCTs for the specific question the review is trying to address.

Discussion

Summary of main results

The reviewers conducted an overview of SRs investigating the effects of yoga. Sixty-seven reviews were identified, 59 of which contained RCTs of yoga for clinical conditions.

The types of clinical conditions that were the subject of the SRs were: arthritis and musculoskeletal conditions (19 trials), cancer (15 trials), cardiovascular disease (11 trials), insomnia (1 trial), menopause (6 trials), mental health conditions (25 trials), neurological conditions (5 trials), health problems in paediatric patients (4 trials including attention deficit hyperactivity disorder), pregnancy and labour (4 trials), renal disease (1 trial), respiratory conditions (14 trials), yoga for smoking cessation (2 trials) and type 2 diabetes/metabolic syndrome (6 trials).

²¹ based on data from 2011–12

Two types of comparisons were assessed in the studies included in this overview: those comparing yoga with control and those comparing yoga with an active intervention. The scope of the reviews regarding interventions covered varied across the reviews. For 40 reviews yoga was the only intervention assessed; the other 19 reviews assessed natural therapies more broadly, including yoga for different health problems.

Arthritis and musculoskeletal conditions

Twelve SRs including a total of 19 eligible RCTs (1,449 participants) assessed the effect of yoga on outcomes in people with arthritis or musculoskeletal conditions. SRs assessed outcomes of yoga for 6 arthritis and musculoskeletal conditions: carpal tunnel syndrome, fibromyalgia syndrome, kyphosis, low back pain, osteoarthritis and rheumatoid arthritis.

Carpal tunnel syndrome: Four SRs including 1 eligible RCT with 51 participants assessed the effect of yoga on pain, disability and function in people with carpal tunnel syndrome. Between-group differences in pain were reported as significant (favouring yoga) by one reviewer and not significant by the other reviewer. There were no significant between-group differences in function. Between-group differences in disability were not reported. Due to the small body of available evidence, the effects of yoga in patients with carpal tunnel syndrome are uncertain.

Fibromyalgia syndrome: Four SRs including 2 eligible RCTs (96 participants) assessed the effect of yoga compared with control for pain, sleep, fatigue, mood and quality of life in people with fibromyalgia syndrome. Pooled results demonstrated statistically significant between-group differences in favour of yoga for pain, fatigue, depression and quality of life but not sleep. These were based on studies with small sample sizes. Due to the small body of available evidence, the effects of yoga in patients with fibromyalgia syndrome are uncertain.

Kyphosis: One SR including 1 eligible RCT (118 participants) compared yoga with a 'social environmental' comparison intervention in people with kyphosis. There were no significant between-group differences in function. Other outcomes were not reported. Due to the small body of available evidence, the effects of yoga in patients with kyphosis are therefore uncertain.

Low back pain: Eight SRs including 8 RCTs (738 participants) compared yoga with control in people with low back pain. Treatment effects were inconsistent across studies. Pooled results found significant between-group differences in favour of yoga for short-term pain, disability and

quality of life. These results remained significant at long-term follow-up for disability but not for pain or quality of life. Eight SRs included 4 RCTs (361 participants) that compared yoga with active intervention (exercise). Results were mixed for the outcomes of pain and disability.

Due to the poor quality of included studies and poor reporting of outcomes by systematic reviewers the effects of yoga versus exercise on pain and functional disability and the effects of yoga versus control on pain, functional disability and quality of life in people with low back pain are uncertain.

Osteoarthritis: Three SRs including 1 RCT (25 participants) compared yoga with control for pain and disability in people with hand osteoarthritis. No significant between-group difference was reported for disability or pain at rest but a significant between-group difference in favour of yoga was reported for pain during activity. Two SRs including 2 RCTs (279 participants) compared yoga with active intervention (exercise or Reiki) for pain, disability and mood. When compared with exercise, yoga significantly improved pain and reduced disability and anxiety (1 RCT, 250 participants). Compared with reiki, yoga significantly reduced disability but had no effect on pain or depression (1 RCT, 29 participants). Due to the small body of available studies, the effects of yoga on outcomes in people with osteoarthritis are uncertain.

Rheumatoid arthritis: Two SRs including 2 RCTs (110 participants) compared yoga with control in people with rheumatoid arthritis. Significant between-group differences in favour of yoga were reported in disability and distress but not pain in 1 trial (n = 80) and significant between-group differences in pain were reported for the other trial (n = 30). Given the small sample size, small number of included studies and risk of bias of included trials, the effects of yoga on outcomes in people with rheumatoid arthritis are uncertain.

Cancer

Breast cancer: Eleven SRs including 8 RCTs (401 participants) compared yoga with control in people with breast cancer. Pooled results were reported by 3 review authors. For yoga compared with control, Lin and others (2011) found no significant between-group differences in quality of life whereas Shneerson and others (2013) found a significant between-group difference in quality of life (overall, mental) in favour of yoga but no significant between-group differences for quality of life (physical). Zhang and others (2012) found a significant effect in favour of yoga for

quality of life but no significant between-group differences in anxiety, depression, fatigue or sleep. Due to the poor quality of trials included in SRs, and poor outcomes reporting by 285 systematic reviewers, the effects of yoga compared with control on outcomes in people with breast cancer are uncertain.

Eight SRs including 4 RCTs (275 participants) compared yoga with active interventions (supportive care or health education) for breast cancer. All 4 RCTs reported significant effects in favour of yoga on depression and 2 RCTs reported an effect in favour of yoga for reducing distress. Two RCTs found no significant between-group difference in sleep outcomes. Results were mixed for a range of other psychosocial outcomes. There were no between-group differences in physical outcomes. Due to the poor quality of RCTs included in reviews and small body of available evidence, the effects of yoga versus active intervention in people with breast cancer are therefore uncertain.

Cancers other than breast cancer: Eight SRs including 3 RCTs (100 participants) compared yoga with control in people with cancers other than breast cancer. Treatment effects were inconsistent across studies. Two RCTs reported no significant difference for fatigue and a single RCT reported mixed results for sleep and depression. A single RCT found a significant between-group difference in favour of yoga for overall quality of life but not for an emotional subscale. No other significant between-group differences were observed. Between-group differences in physical outcomes were not reported. Due to the small body of available evidence, the effects of yoga versus control in people with cancer other than breast cancer are uncertain.

Cardiovascular diseases

Hypertension: Three SRs included 7 RCTs (431 participants) that compared yoga with control in people with hypertension. Results were inconsistent for systolic and diastolic blood pressure, with 2 RCTs reporting statistically and clinically significant between-group differences in favour of yoga, 1 RCT reporting a statistically but not clinically significant decrease and 1 RCT reporting no significant between-group differences. Between-group differences in blood pressure were not reported in 3 RCTs. Three SRs included 2 RCTs (52 participants) that compared yoga with active intervention (anti-hypertensive medication) in people with hypertension. Statistically and clinically significant between-group differences in favour of yoga for systolic and diastolic

blood pressure were reported for both RCTs. However, due to small sample sizes and methodological limitations of the included trials, and poor reporting of outcomes by systematic reviewers in the included reviews, the effects of yoga in people with hypertension are uncertain.

Stroke rehabilitation: One SR including 3 RCTs (108 participants) compared yoga with comparison interventions in people receiving stroke rehabilitation. Two RCTs compared yoga with control (total 94 participants) and 1 compared yoga with exercise (14 participants). Data for between-group differences were not reported for any outcome for any systematic review. As a result, the effects of yoga in this patient group were unable to be assessed.

Insomnia

Two reviews including 1 three-arm RCT (69 participants) compared yoga with control and with Ayurvedic medicine. Data for between-group differences were not reported. As a result, the effects of yoga in this patient group were unable to be assessed.

Menopause

Three SRs including 5 RCTs (532 participants) compared yoga with control in women with symptoms of menopause. Cramer and others (2013a) pooled results and found no significant difference between yoga and no treatment for psychological symptoms. However, there was moderate heterogeneity of studies. Lee and others (2009) meta-analysed 2 RCTs and found no significant between-group differences in total menopause symptoms.

Three reviews including 3 RCTs (345 participants) compared yoga with active intervention in women with symptoms of menopause. For yoga versus exercise, Cramer and others (2013a) pooled results and found no significant difference in psychological, somatic, vasomotor or total menopause symptoms. Lee and others (2009) pooled the results of 2 RCTs comparing yoga with physical therapy and found no significant between-group differences in somatic symptoms or vasomotor symptoms. Due to the poor quality of trials included in SRs, and poor outcomes reporting by systematic reviewers, the effects of yoga compared with active intervention on outcomes in women with menopause symptoms are uncertain.

Mental health conditions

A total of 11 SRs that included 25 RCTs with 1,392 participants assessed the effects of yoga in people with mental health conditions. Specific health conditions assessed included: depression,

anxiety disorders, schizophrenia, attention deficit/hyperactivity disorder, eating disorders and post-traumatic stress disorder.

Depression: Five SRs including 10 RCTs (562 participants) compared yoga with control in people with depression. Statistical heterogeneity was observed for the pooled results of 5 RCTs. However, significant between-group differences in depression were observed for 7 RCTs and no significant between-group differences for 1 RCT. Between-group differences were not reported for 2 RCTs. On this basis, it is concluded there is weak evidence that yoga improves symptoms in people with depression, compared with control.

Four SRs including 4 RCTs (229 participants) compared yoga with active intervention (relaxation, antidepressant medications, massage therapy, electroconvulsive therapy and aerobic exercise). Cramer and others (2013c) pooled results comparing yoga with relaxation and found a significant between-group difference in favour of yoga. One RCT reported a significant between-group difference in favour of electroconvulsive therapy for depression symptoms. There were no significant between-group differences for yoga versus antidepressant medication, exercise or massage therapy. Because of poor reporting of the results of included RCTs by systematic reviewers, the effects of yoga compared with an active intervention for depression are uncertain.

Anxiety disorders: One SR including 1 RCT (27 participants) compared yoga with control in people with an anxiety disorder. A significant between-group difference in anxiety symptoms in favour of yoga was observed. Due to the small body of evidence, the effects of yoga versus control in people with anxiety disorders are uncertain. Two reviews including 2 RCTs (171 participants) compared yoga with active intervention (relaxation) in people with an anxiety disorder. No significant between-group differences in anxiety symptoms were observed in one study. In the second study the authors report: ‘Yoga was superior for cognitive symptoms and relaxation was superior for physical symptoms of anxiety’ (da Silva et al., 2009). However, between-group differences were not reported further. For both studies, the review authors did not report effect sizes or between-group differences in sufficient detail to determine whether any differences were clinically significant. As a result, the effects of yoga versus active intervention in people with anxiety disorders are uncertain.

Schizophrenia: Three SRs including 4 RCTs (276 participants) compared yoga with control in people with schizophrenia. Cramer (2013a) pooled results comparing yoga with control and reported no significant between-group differences for positive symptoms. Significant heterogeneity was observed for pooled results of negative symptoms, social function and quality of life outcomes. Four SRs including 3 RCTs (229 participants) compared yoga with active intervention (exercise). Cramer (2013a) pooled results comparing yoga with another exercise intervention and found no significant difference for positive symptoms or social function. Meta-analyses for negative symptoms had substantial, statistically significant heterogeneity. The effects of yoga in people with schizophrenia are uncertain due to the small sample sizes and methodological limitations of the trials in the included reviews and poor reporting of outcomes by systematic reviewers.

Attention deficit hyperactivity disorder (ADHD): Two reviews including 2 RCTs (36 participants) compared yoga with physical activity in school-aged children with ADHD. Between-group differences were not reported. As a result, the effects of yoga in this patient group were unable to be assessed.

Eating disorders: Three reviews including 3 RCTs (203 participants) compared yoga with control in people with eating disorders. Mixed results were reported for disordered eating, with 1 RCT reporting an effect in favour of yoga, 1 RCT reporting a borderline significant effect in favour of yoga and 1 RCT reporting no between-group differences. One RCT reported a significant between-group difference in favour of yoga for depression and anxiety and another RCT reported an effect in favour of yoga for anthropometry. One review including 1 RCT (63 participants) compared yoga with an active intervention (cognitive dissonance therapy). Between-group differences were not reported. Due to the high risk of bias of trials included in the reviews, the effects of yoga in this patient group are uncertain.

Post-traumatic stress disorder: One review including 1 RCT (11 participants) compared yoga with group therapy in people with post-traumatic stress disorder. The review authors report that ‘participants in the yoga group demonstrated significant decreases in frequency of intrusions ($P < .05$) and severity of hyperarousal symptoms ($P < .05$) compared to the group therapy group’.

Due to the small body of available evidence, the effects of yoga in this patient group were uncertain.

Neurological conditions

Four SRs including 5 RCTs (203 participants in total) assessed the effects of yoga in people with neurological conditions. The conditions that were assessed include epilepsy, multiple sclerosis and headache.

Epilepsy: One SR including 1 RCT (32 participants) compared yoga with control in people with epilepsy. Compared with sham yoga, a significant between-group difference was observed in favour of yoga in seizure frequency and a significant between-group difference in favour of sham yoga was observed in the odds of a greater than 50% reduction in seizure frequency and duration at 6 months. There were no between-group differences in the odds of participants being seizure-free for 6 months. Compared with no treatment, a significant between-group difference was observed in favour of the control group in the odds of a greater than 50% reduction in seizure frequency and duration at 6 months. There were no significant between-group differences in the odds of being seizure-free at 6 months or in seizure frequency.

One review including 1 RCT (18 participants) compared yoga with active intervention (acceptance and commitment therapy – ACT). There were no significant between-group differences in seizure-free rates, 50% or greater reduction in seizure frequency or seizure duration at one year follow-up. The yoga group showed significant improvement in some quality of life measures whereas the ACT group improved in other quality of life measures. Due to the small body of available evidence, the effects of yoga in patients with epilepsy are uncertain.

Multiple sclerosis: One SR including 1 RCT (48 participants) compared yoga with control in people with multiple sclerosis. Significant between-group differences in favour of yoga were reported for fatigue and energy levels but significance of between-group differences for other outcomes were not reported.

One SR including 1 RCT (47 participants) compared yoga with active intervention (exercise). Outcomes were not reported by the systematic reviewers. As a result, the effects of yoga in people with multiple sclerosis are uncertain.

Headache: Two SRs including 1 RCT (72 participants) compared yoga with control in people with migraine headache. A significant between-group difference in pain in favour of yoga was reported. One SR including 1 RCT (12 participants) compared yoga with active intervention (anti-inflammatory medication) in people with headache (type not specified). No significant between-group differences were observed. Due to the small body of available evidence, the effects of yoga in patients with headache are uncertain.

Health problems in paediatric participants

Two reviews including 2 RCTs (number of participants in total not reported) compared yoga with control in paediatric patients. This was in addition to 2 reviews reported under the headings ‘yoga for ADHD’.

Irritable bowel syndrome: One review including 1 RCT (28 participants) compared yoga with control in paediatric patients with irritable bowel syndrome. The significance of between-group differences in pain, gastrointestinal symptoms or disability was not reported. As a result, the effect of yoga versus control on outcomes in paediatric patients with irritable bowel syndrome is uncertain.

Intellectual disability: Two reviews including 1 RCT (90 participants) compared yoga with usual care in children with an intellectual disability (described in the reviews as ‘mental retardation’). The significance of between-group differences was not reported. As a result, the effect of yoga versus usual care on outcomes in paediatric patients with an intellectual disability are uncertain.

Pregnancy and labour

Three SRs including 4 RCTs (381 participants) compared yoga with control in women during pregnancy and labour. Significant between-group differences in favour of yoga were observed in pain (1 of 1 RCTs for which data were reported), satisfaction with pain relief and labour (1 of 1 RCTs reporting this outcome) and stress (1 of 1 RCTs reporting this outcome).

Interpreting these results is problematic as systematic reviewers did not report outcomes data for all outcomes that were assessed. It is therefore unclear whether results from trials that had no effect on outcomes were available but not reported in included SRs. As a result, the effects of yoga in this patient group are uncertain.

Renal disease

Two reviews including 1 RCT (40 participants) compared yoga with active intervention (physical activity) in patients with renal disease who were receiving haemodialysis. There were no significant between-group differences in pain experienced by participants. Due to the small body of available evidence and conflicting reporting of significance of outcomes by reviewers, the effects of yoga in patients with renal disease who are receiving haemodialysis are uncertain.

Respiratory conditions

Six reviews including 14 RCTs with a total of 616 participants assessed the effects of yoga in people with respiratory disease.

Chronic obstructive pulmonary disease (COPD): One review including 2 RCTs (89 participants) compared yoga with control in people with COPD. Holland and others (2012) pooled results and found a significant between-group difference in favour of yoga for exercise capacity. No between-group differences in dyspnoea intensity and distress were observed. There was a significant between-group difference in favour of yoga in quality of life in one but not the other RCT. Due to the small body of available evidence, the effects of yoga versus control in people with COPD are uncertain.

Asthma: Five SRs including 11 RCTs (468 participants) compared yoga with control in people with asthma. Two reviewers (Balbuena et al., 2012, Burgess, et al., 2011) reported pooled results of studies that met the inclusion criteria for this overview. Balbuena and others (2012) reported significant between-group differences in favour of yoga for forced expiratory volume in 1 second (FEV1) and FEV1/forced vital capacity. Burgess and others (2011) reported no significant between-group differences for FEV1 measured in millilitres. Burgess and others (2011) also meta-analysed RCTs including both control and active comparisons and reported significant between-group differences in favour of yoga for quality of life outcomes and percentage predicted FEV1. Overall, the effects of yoga on respiratory function, quality of life, asthma symptoms and medication use in people with asthma were uncertain due to the high or uncertain risk of bias of RCTs and poor outcome reporting by systematic reviewers.

One review including 2 RCTs (93 participants) compared yoga with active intervention (physiotherapy/breathing exercises or relaxation/cognitive behaviour therapy) in people with

asthma. Compared with relaxation/cognitive exercises, yoga significantly improved quality of life but not peak expiratory flow or FEV1. Between-group differences for yoga compared with physiotherapy/breathing exercises were not reported. Due to the poor quality of included trials and poor reporting of outcomes by systematic reviewers, the effects of yoga versus active intervention in people with asthma are uncertain.

Yoga for smoking cessation

One SR including 2 RCTs (147 participants) assessed the impact of yoga compared with control on cigarette cravings in people who smoke tobacco. A significant between-group difference in cigarette cravings, favouring yoga, was observed. One SR including 1 RCT (51 participants) compared yoga with an active intervention (exercise) and reported no significant between-group difference for cravings. However, effect sizes and between-group differences were not reported for any study. Due to poor outcome reporting in included SRs, the effects of yoga for smoking cessation are uncertain.

Yoga for endocrine and metabolic diseases

The effects of yoga for people with endocrine and metabolic diseases were assessed in 2 reviews.

Type 2 diabetes mellitus: One SR including 5 RCTs (sample size of RCTs not reported) compared yoga with control in people with type 2 diabetes mellitus. For fasting plasma glucose, 3 RCTs found significant between-group differences in favour of yoga and 1 RCT found no between-group differences. For HbA1c, 1 RCT found significant between-group differences in favour of yoga and 2 RCTs found no between-group differences. As the features of included trials, outcome results, effect sizes and between-group comparisons were poorly described in the included systematic review, the effects of yoga for type 2 diabetes are uncertain.

Metabolic syndrome: One SR including 2 RCTs (125 participants) compared yoga with usual care or control in people with metabolic syndrome. Between-group differences were not reported. The effect of yoga on outcomes in this patient group are therefore unable to be determined.

Adverse effects

Reviewers identified 1 overview that assessed adverse effects associated with yoga (Cramer, 2013e). The study authors conducted a SR of case reports and case series on adverse events

associated with yoga. Medline/PubMed, Scopus, CAM Base, Ind Med and the Cases Database were screened (last search February 2013) and 35 case reports and 2 case series reporting a total of 76 cases were identified.

Ten cases had medical preconditions, mainly glaucoma and osteopaenia. Pranayama, hatha yoga, and Bikram yoga were the most common yoga practices; headstand, shoulder stand, lotus position and forceful breathing were the most common yoga postures and breathing techniques cited.

Twenty-seven adverse events (35.5%) affected the musculoskeletal system; 14 (18.4%) affected the nervous system; and 9 (11.8%) affected the eyes. Fifteen cases (19.7%) reached full recovery; 9 cases (11.3%) partial recovery; 1 case (1.3%) no recovery; and 1 case (1.3%) died.

The review authors concluded that:

- yoga should be practised carefully under the guidance of a qualified instructor
- beginners should avoid extreme practices such as headstand, lotus position and forceful breathing
- individuals with medical preconditions should work with their treating medical practitioners and yoga teacher to appropriately adapt postures
- patients with glaucoma should avoid inversions and patients with compromised bone should avoid forceful yoga practices.

Adverse effects were reported inconsistently across reviews included in this overview and in RCTs that were included in the systematic reviewers. Where adverse events were reported in included reviews, these were mainly musculoskeletal.

Overall completeness and applicability of the evidence

Reviewers sought any SR that investigated yoga. Reviewers included reviews that investigated the effects of yoga versus any inactive or active comparison group. Reviews were excluded that were not published in English. This resulted in 1 SR being excluded (Chen, et al., 2011) that was published in Chinese. Chen and others (2011) conducted a SR of studies describing clinical experimental research on yoga as a cancer patient care intervention. A total of 11 clinical trials were included. According to the abstract of the systematic review, all 11 studies supported the ability of yoga to ameliorate anxiety, depression and fatigue significantly and enhance quality of

sleep and daily life in cancer patients. The review authors concluded that yoga is recommended to relieve cancer-related symptoms.

Sixty-seven SRs were identified, 59 of which identified RCTs of yoga that met their inclusion criteria. These 59 SRs included 111 unique RCTs of yoga that met the inclusion criteria for this overview, with more than 6,562 participants in total (4 RCTs did not have a recorded sample size). All of these trials had relatively small sample sizes, ranging from 11 to 313 participants. The evidence for our findings is largely based on small, poor-quality studies that were poorly reported by both RCT and SR authors. The quality of the evidence was typically rated as very low and there is uncertainty surrounding the magnitude of the effects and their relevance in clinical practice. Reviewers were therefore unable to reach conclusions about the effectiveness of yoga for the majority of clinical conditions for which it has been evaluated.

Quality of the evidence

The AMSTAR measurement tool was used to assess the quality of each included systematic review. The median AMSTAR score of the included reviews was 6 out of 11 (range 1 to 10). Reviewers answered ‘yes’ to the last AMSTAR item (‘was the conflict of interest included?’) if the systematic reviewers had declared their own conflicts of interest and the conflicts of interest from included RCTs in the systematic review.

The majority of reviews reported an ‘a priori’ design, duplicate study selection and data extraction, a comprehensive literature search that included all publication types and described the characteristics of the included studies provided. However, the majority of SRs did not provide an ‘a priori’ study design, a list of excluded studies or assess for publication bias, some reviews did not provide quality scores of included RCTs and no included SR declared the conflicts of interest from the review authors and the authors of RCTs included in the review.

Not all included reviews assessed risk of bias of the primary studies. In the reviews that did assess risk of bias, the methods and tools used varied between the reviews. Systematic reviewers frequently performed meta-analyses of included studies and reported the findings of these meta-analyses in their systematic review. In many cases, this was viewed as inappropriate by the overview authors due to differences in treatment protocols, outcome measures and timing of re-assessments. Further, a number of review authors pooled the results of different interventions

(yoga with other physical therapies) and compared these with pooled results from across inactive and active comparison groups.

Potential biases in the overview process

The reviewers took steps to reduce bias by specifying systematic methods for the overview process before commencing the overview. Reviewers adhered to a protocol that was provided by the NHMRC. Two review authors independently assessed eligibility for inclusion of reviews and carried out data extraction.

A comprehensive search strategy was used for the review. Every effort was made to identify relevant studies. The search strategy was designed to identify non-English studies; however, studies were excluded where no English language translation was available. One study was excluded on this basis, and the reviewers are unable to determine the impact of excluding this study.

Reviewers did not seek extra information by contacting the review authors or by searching for extra information in the full-text publications of the primary studies.

Conclusions

Authors' conclusions

There is weak evidence that yoga improves symptoms in people with depression compared with control. For all other clinical conditions in which yoga was assessed there was insufficient evidence to draw any conclusions about the effect of yoga on outcomes.

Reviewers were limited in drawing definite conclusions, not only due to a lack of studies for some clinical conditions, but also due to the lack of information reported in the reviews and potentially in the primary studies. A number of included SRs only identified single eligible RCTs of yoga for any one condition, indicating a need for further studies of the effects of yoga for a number of clinical conditions. Where RCTs had been conducted, the body of trial evidence was typically compromised by deficiencies in study design and poor reporting.

Implications for practice

There is weak evidence that yoga is effective compared with control in improving symptoms in people with depression. For all other conditions for which yoga was assessed, the effect of yoga is uncertain. Overall, the effects of yoga (either in comparison with no treatment, usual care or

placebo; compared with other active treatments; or in combination with active treatments) on patient health outcomes in various conditions remains uncertain.

Implications for research

Reviewers were limited in drawing definite conclusions, not due to a lack of studies, but due to the lack of information reported in the reviews and potentially in the primary studies.

A number of included SRs only identified single eligible RCTs of yoga for any one condition, indicating a need for further studies of the effects of yoga for a number of clinical conditions. Where RCTs had been conducted, the body of trial evidence was typically compromised by deficiencies in study design, small sample sizes and poor reporting. For 9 of the 31 conditions considered in the overview, there were no studies that were assessed as being at a low risk of bias.

Future research of yoga for these clinical conditions should focus on larger sample sizes, improved reporting of data, and adequate follow-up periods to enable more robust conclusions to be drawn. Research should be prioritised to clinical areas in which yoga might plausibly have an effect on health outcomes.

This overview identified that there is a need for consistent assessment and reporting of results in SRs. Sufficient detail should be reported for each included study about effect estimates (intervention effect estimates), measures of precision (for example, confidence intervals), direction of effects, the clinical relevance of any statistically significant results and information about assessment tools used to assess intervention effects.

A lack of reporting of this information made it generally impossible to interpret the clinical importance of the effects, and limited the application of meta-analyses that review authors had performed. Further, this overview identified that inappropriate pooling of primary studies across heterogeneous intervention and comparison groups, and over-reliance on the results of pooled results with demonstrated significant statistical heterogeneity in drawing conclusions by review authors should be addressed in future reviews.

Submissions received for yoga

Submissions for yoga were received from the following organisations:

- Australian Feldenkrais Guild
- Friends of Science in Medicine
- International Yoga Teachers' Association Inc.
- National Institute of Complementary Medicine.

Submissions that were received and that related to yoga were evaluated to ensure that the evidence review considered all relevant evidence.

Reviewers intended to incorporate any additional in-scope level 1 SRs into the overview report. However, none were identified through the public submission process. Reviewers intended to extract data from in-scope level 2 studies not already considered in a SR within the overview report, using NHMRC's Data Extraction Table form. However, no additional in-scope level 2 studies were identified. There was no additional in-scope submitted literature that provided evidence for the effectiveness of yoga for any clinical condition.

Glossary²²

Bias

A bias is a systematic deviation of a measurement from the ‘true’ value, leading to either an over- or underestimation of the treatment effect. Bias can originate from many different sources, including allocation of patients, and the measurement, interpretation, publication and review of data.

Blinding

Blinding, or masking, is the process used in epidemiological studies and clinical trials in which the observers and the subjects have no knowledge as to which treatment groups subjects are assigned. It is undertaken to minimise bias occurring in patient response and outcome measurement. In single-blind studies only the subjects are blind to their allocations, while in double-blind studies, both observers and subjects are ignorant of the treatment allocations.

Clinically important effect (see also ‘statistically significant effect’)

A clinically important or clinically significant effect is one which improves the clinical outlook for the patient. It is important to note that it is possible for an effect to be statistically significant, yet have little clinical significance for a patient.

Control

A scientific control is an experiment or study designed to minimise the effects of variables other than the single independent variable. This increases the reliability of the results, often through a comparison between control measurements and other measurements.

MEDLINE

MEDLINE is the US National Library of Medicine’s bibliographic database containing journal citations and abstracts for biomedical literature from around the world.

Meta-analysis

A statistical analysis that enables the results from 2 or more separate, primary studies to be combined to derive an overall estimate of the pooled effect.

Null hypothesis

²² NHMRC process report – Glossary

The hypothesis that states that there is no difference between 2 or more interventions or 2 or more groups (for example, males and females). The null hypothesis states that the results observed in a study (for example, the apparent beneficial effects of the intervention) are no different from what might have occurred as a result of the operation of chance alone.

Overview

Overviews are reviews that are designed to compile evidence from multiple systematic reviews into one document. They 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.

Placebo control (in research studies, see also 'placebo effect')

An inactive intervention that is compared with the intervention being tested. A placebo control is the most rigorous comparator by which to assess the efficacy of an intervention, as it controls for the 'placebo effect'.

Placebo effect

The effect observed whereby people who receive an inactive 'placebo' treatment (believing the treatment to be efficacious) will experience a perceived or actual improvement in health outcomes.

Publication bias

Bias caused by the results of a trial being more likely to be published if a statistically significant benefit of treatment is found.

P-value

The probability (obtained from a statistical test) that the null hypothesis (that there is no treatment effect) is incorrectly rejected. A p-value of <0.05 is the conventionally accepted point at which the null hypothesis is rejected, and the difference is considered to be statistically significant.

Prospective trial (prospective study)

A research study that measures effects as they occur over time, beginning from an agreed time point (not by using records made in the past). The health outcomes to be measured are defined in

advance, and the way to measure the effects of treatment on these outcomes is also planned in advance. The results are then measured at specific times.

PubMed

The US National Library of Medicine's online retrieval system for public medical literature. PubMed comprises more than 23 million citations for biomedical literature from MEDLINE, life science journals and online books.

Randomised controlled trial

An experimental comparison study in which participants are allocated to treatment/intervention or control/placebo groups using a random mechanism, such as coin toss, random number table, or computer-generated random numbers. Participants have an equal chance of being allocated to an intervention or control group, and therefore allocation bias is limited.

Sham treatment/control

A treatment or procedure that is performed as a control, which is similar to the treatment or intervention under investigation, but omits a therapeutic element of that treatment or intervention. Sham controls are useful for interventions which have subjective outcomes; for example, symptoms.

Statistically significant effect (see also 'clinically important effect')

An outcome for which the difference between the intervention and control groups is statistically significant; that is, the p-value is less than 0.05. A statistically significant effect is not necessarily clinically important.

Systematic review

A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies.

Acronyms and abbreviations

AACMA	Australian Acupuncture and Chinese Medicine Association
AAMT	Australian Association of Massage Therapists
ADHD	attention deficit hyperactivity disorder
AFG	Australian Feldenkrais Guild
AHPRA	Australian Health Practitioner Regulation Agency
AMSTAR	Assessment of multiple systematic reviews
ANPA	Australian Naturopathic Practitioners Association
ANTA	Australian Natural Therapists Association
ATMS	Australian Traditional Medicine Society
AusTAB	Australian Training and Accreditation Board
CAMs	complementary and alternative medicines
CMBA	Chinese Medicine Board of Australia
DVA	Department of Veterans' Affairs
FEV	forced expiratory volume
GRADE	Grading of Recommendations Assessment Development and Evaluation
HWC	Homeopathy Working Committee
MBS	Medical Benefits Schedule
MoU	Memorandum of Understanding
NCCAM	National Centre for Complementary and Alternative Medicine
NHMRC	National Health and Medical Research Council
NICM	National Institute for Complementary Medicine
NRAS	National Registration and Accreditation Scheme
NTRAC	Natural Therapies Review Advisory Committee

OHNMRC	Office of the National Health and Medical Research Council
PHI	private health insurance
PHIAC	Private Health Insurance Administration Council
RCT	randomised controlled trial
SR	systematic review
TCM	traditional Chinese medicine
TENS	transcutaneous electrical nerve stimulation

Attachment A

Natural Therapies Review Advisory Committee: Membership

Chair

Prof. Chris Baggoley Chief Medical Officer, Department of Health

Members

Mr Jim Olds Australian Natural Therapists Association

Ms Eta Brand Australian Naturopathic Practitioners Association

Dr Raymond Khoury Australian Traditional Medicine Society

Mr Trevor Le Breton Australian Traditional Medicine Society

Dr Ken Harvey Consumers Health Forum of Australia

Ms Alison Marcus Consumers Health Forum of Australia

Dr Brian Hanning Health Insurance Restricted Membership Association of Australia

Mr Greg Kovacs Private Healthcare Australia

Mr Glenn Ruscoe Technical Expert Physiotherapy

Prof. Paul Glasziou Technical Expert Medical

Ms Debbie Rigby Technical Expert Pharmacy

Observers

NHMRC

Department of Health

Prof. Alan Bensoussan Technical Expert Complementary Medicines

Attachment B

Private health insurance

Current situation

Most Australians with private health insurance currently receive a Rebate from the Australian Government to help cover the cost of their premiums. The Rebate is income tested and applies to hospital, general treatment and ambulance policies.

There are 2 ways to claim the Rebate, either through:

- a reduced premium
- your tax return with the Australian Taxation Office.

General treatment cover²³

General treatment policies (also known as ‘ancillary’ or ‘extras’ cover) provide benefits for ancillary services; for example, physiotherapy, dental and optical treatment.

General treatment policies may be offered separately or combined with hospital cover. There are 3 general categories of policies. The classifications are based on the services that are shown as covered on standard information statements.

- Comprehensive cover: must include cover for general dental, major dental (benefit limit must be average or above average for the industry), endodontic, orthodontic (benefit limit must be average or above average for the industry), optical, non-PBS pharmaceuticals, physiotherapy, podiatry and psychology.
- Medium cover: must include cover for general dental, major dental, endodontic *and* any 5 of the following: orthodontic, optical, non-PBS pharmaceuticals, physiotherapy, chiropractic, podiatry, psychology and hearing aids.
- Basic cover: all other policies.

²³ <http://www.privatehealth.gov.au/healthinsurance/howitworks/#general>

*Combined cover*²⁴

Many health funds offer packaged policies that provide cover for both hospital and general treatment services. Some funds have pre-packaged policies, while others allow you to mix and match hospital and general treatment options; for example, you may be able to select a basic hospital cover and a comprehensive general treatment policy to create your own combined package.

The *Private Health Insurance Act 2007* (the Act) and Rules do not define the coverage requirements for general treatment where a Medicare benefit is not payable. Instead, both coverage and benefit amounts for general treatment, including natural therapies, is a commercial decision made by the insurer.

Not all private health funds and private health insurance policies are eligible for the Australian Government Rebate. They are only available if you have a complying health insurance policy with a registered health fund or insurer.

Not all private health insurers offer natural therapy cover; further, they often have limits on benefits, products and annual limits on the amount that may be claimed.

The *Private Health Insurance (Accreditation) Rules 2013* (the Rules) enable private health insurers to pay benefits for natural therapies from their general treatment ancillary tables. Private health insurers are required to determine that a health-care provider meets the requirements of the Rules prior to paying private health insurance benefits for the provider's services. Health funds have developed recognition requirements to ensure that services supplied to members comply with the minimum standards set out in the Rules.

The Act allows private health funds to legitimately set standards enforcing membership of a professional association, education standards and currency of all eligibility criteria, such as first aid and insurance.

It is up to the insurer to determine how a health-care service provider's compliance with the Rules is evidenced, as well as for what services they pay benefits. The decision is primarily

²⁴ <http://www.privatehealth.gov.au/healthinsurance/howitworks/#general>

based on whether the services provide value for money in terms of cost outlays and health outcomes for their members.

Private Health Insurance Administration Council (PHIAC) quarterly data from June 2007 to June 2014 shows an increase in the services and benefits regarding therapies (Figure 2).

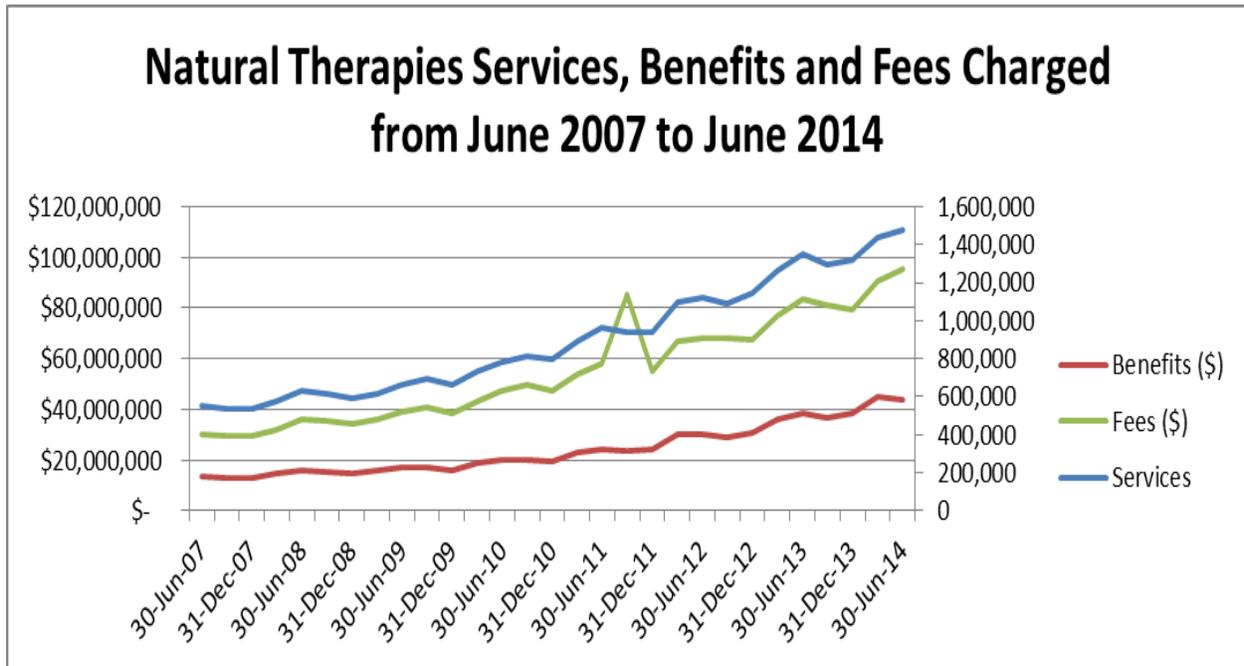


Figure 2. Natural therapies services, benefits and fees charged from June 2007 quarter to June 2014 quarter

Table 10. List of health funds registered under the *Private Health Insurance Act 2007*²⁵

Title	ATO ID	Type	States
ACA Health Benefits Fund	ACA	Restricted	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
ahm Health Insurance	AHM	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Australian Unity Health Limited	AUF	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Bupa Australia Pty Ltd	BUP	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
CBHS Health Fund Limited	CBH	Restricted	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
CDH Benefits Fund	CDH	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Central West Health Cover	CWH	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
CUA Health Limited	CPS	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Defence Health Limited	AHB	Restricted	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Doctors' Health Fund	AMA	Restricted	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
GMF Health	GMF	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
GMHBA Limited	GMH	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Grand United Corporate Health	FAI	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
HBF Health Limited	HBF	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
HCF	HCF	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Health Care Insurance Limited	HCI	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Health Insurance Fund of Australia Limited	HIF	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Health Partners	SPS	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
health.com.au	HEA	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Latrobe Health Services	LHS	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Medibank Private Limited	MBP	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Mildura District Hospital Fund Ltd	MDH	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
National Health Benefits Australia Pty Ltd (onemedifund)	OMF	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Navy Health Ltd	NHB	Restricted	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
NIB Health Funds Ltd.	NIB	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Peoplecare Health Insurance	LHM	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Phoenix Health Fund Limited	PWA	Restricted	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Police Health	SPE	Restricted	Qld, SA, Tas., WA, NT
Queensland Country Health Fund Ltd	QCH	Open	Qld
Railway and Transport Health Fund Limited	RTE	Restricted	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Reserve Bank Health Society Ltd	RBH	Restricted	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
St.Lukes Health	SLM	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Teachers Health Fund	NTF	Restricted	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Transport Health Pty Ltd	TFS	Restricted	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
TUH	QTU	Restricted	ACT, NSW, Qld, SA, Tas., Vic., WA, NT
Westfund Limited	WFD	Open	ACT, NSW, Qld, SA, Tas., Vic., WA, NT

²⁵ <http://www.privatehealth.gov.au/dynamic/healthfundlist.aspx>

REFERENCES

- American Association of Naturopathic Physicians 2011. House of Delegates position paper: definition of naturopathic medicine. [Online] Available at: <http://www.naturopathic.org/content.asp?contentid=59>.
- Ang JY et al. 2012. A randomized placebo-controlled trial of massage therapy on the immune system of preterm infants. *Pediatrics* (130):e1549–e1558.
- Australian Association of Massage Therapists 2013a. Massage Modalities. [Online] Available at: <http://aamt.com.au/about-massage/massage-modalities/#content>. [Accessed 2013].
- Australian Association of Massage Therapists 2013b. Submission to review PHIR for natural therapies. Presented to the Chief Medical Officer, Department of Health and Ageing, Melbourne: Australian Association of Massage Therapists.
- Australian Bureau of Statistics 2013. Participation in sport and physical recreation survey (data from 2005–06; 2009–10; and 2011–12). [Online] Available at: <http://www.abs.gov.au/ausstats/abs@.nsf/mf/4177.0>. [Accessed 6 September 2013].
- Australian Pilates Method Association 2013a. Australian Pilates Method Association web page. [Online] Available at: <http://www.australianPilates.asn.au/>.
- Australian School of Traditional Thai Massage 2013. ATTSM. [Online] Available at: <http://www.healthtraditions.com.au/course-details/massage.htm>. [Accessed 20 July 2013].
- Australian Society of Teachers of the Alexander Technique 2014. AUSTAT training. [Online] Available at: www.alexandertechniqueinstitute.com.au/course_outline.html. [Accessed 6 February 2014].
- Australian Traditional Medicine Society 2013. Website: modalities/sport therapies. [Online] Available at: <http://www.atms.com.au>. [Accessed 27 May 2013].
- Balbuena JM, Cabradilla JM, Quiambao JL & Siasoco MB 2012. Efficacy of yoga in improving clinical outcomes among patients with asthma: a meta-analysis. *Philippine Journal of Chest Diseases* (15):1.

- Bamigboye AA & Smyth MD, R 2007. Interventions for varicose veins and leg oedema in pregnancy. *Cochrane Database of Systematic Reviews* (Issue 1).
- Bauer BA et al. 2010. Effect of massage therapy on pain, anxiety, and tension after cardiac surgery: a randomized study. *Complementary Therapies in Clinical Practice* (16):70–75.
- Beaglehole R, Bonita R & Kjellstrom T 1998. *Basic epidemiology*. Geneva: World Health Organization.
- Becker LA & Oxman AD 2011. Chapter 22: 'Overviews of reviews'. In JPT Higgins & S Green (eds). *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0* [updated March 2011]. The Cochrane Collaboration. [Online]. Available at: <http://handbook.cochrane.org/>.
- Beckner WM & Berman B 2003. *Complementary therapies on the Internet*. St Louis, Missouri, USA: Churchill Livingstone.
- Braun LA et al. 2012. Massage therapy for cardiac surgery patients: a randomized trial. *Journal of Thoracic and Cardiovascular Surgery* (144):1453–1459.
- Buchanan PA 2012. The Feldenkrais Method of somatic education. Chapter in 'A Compendium Essays on Alternative Therapies'. [Online] Available at: <http://www.intechopen.com/books/a-compedium-of-essays-on-alternative-therapy>.
- Burgess J et al 2011. Systematic review of the effectiveness of breathing retraining in asthma management. *Expert Review of Respiratory Medicine* (5):789–807.
- Burns EE et al. 2000. An investigation into the use of aromatherapy in intrapartum midwifery practice. *Journal of Alternative and Complementary Medicines* (6):141–147.
- Burns E et al. 2007. Aromatherapy in childbirth: a pilot randomised controlled trial. *British Journal of Obstetrics and Gynaecology* (7)114:838–844 .
- Campbell TG, Hoffmann T & Glasziou PP 2011. Buteyko breathing for asthma (protocol). *Cochrane Database of Systematic Reviews*, 2011 (Issue 6).
- Chen S, Lin W, Lins S & Chang H 2011. Cancer nursing care: a systematic review of yoga intervention [Chinese]. *Journal of Nursing & Healthcare Research* (7):151–160.

- Chinn J, Trujillo D, Kegerreis S & Worrell T 1994. Effect of a Feldenkrais Intervention on symptomatic subjects performing a functional reach. *Isokinetics and Exercise Science* (4):131–136.
- Cochrane Collaboration 2011. *Cochrane Handbook for Systematic Reviews of Interventions*. [Online] Available at: <http://www.cochrane.org>.
- Cooley K et al. 2009. Naturopathic care for anxiety: a randomized controlled trial. *PLoS One* (4):e6628.
- Costa LO et al. 2012. Pilates for low-back pain (protocol). *Cochrane Database of Systematic Reviews* 2012 (Issue 12).
- Cottingham J, Porges S & Richmond K 1988. Shifts in pelvic inclination angle and parasympathetic tone produced by Rolfing soft tissue manipulation. *Physical Therapy* (68):1364–1370.
- Courtney R 2008. Strengths, weaknesses and possibilities of the Buteyko Breathing Method. *Biofeedback* (36):59–63.
- Cramer H, Lauche R, Haller H & Dobos G 2013a. A systematic review and meta-analysis of yoga for low back pain. *The Clinical Journal of Pain* (29):450–460.
- Cramer H, Krucoff C & Dobos G 2013b. Adverse events associated with yoga: a systematic review of published case reports and case series. *PloS one* 2013;8 (10):e75515.
- Cramer H, Lauche R, Langhorst J & Dobos G 2013c. Yoga for depression: a systematic review and meta-analysis. *Depression and Anxiety* (30):1068–1083.
- Cramer H et al. 2013d. Yoga for schizophrenia: a systematic review and meta-analysis. *BMC Psychiatry* (13):32.
- da Silva ACL & Mannrich G 2009. Pilates on rehabilitation: a systematic review [Portuguese]. *Fisioterapia em Movimento* (22):449–455.
- da Silva TL, Ravindran LN, & Ravindran AV. 2009. Yoga in the treatment of mood and anxiety disorders: a review. *Asian Journal of Psychiatry* 2009; 2(1):6-16. Epub 2009/03/01.

Dalal K et al. 2010. Efficacy of reflexology in managing chronic pain and difficulty in lower limb movement involving intractable epilepsy. Kharagpur, India, ICSMB.

Deeks JJ, Higgins PT & Altman DG 2011. Chapter 9 'Analysis and undertaking meta-analysis'. In JPT Higgins & Green (eds) Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0. [Online] Available at: www.cochrane-handbook.org.

Dennis JA & Cates CJ 2012. Alexander technique for chronic asthma. Cochrane Database of Systematic Reviews (Issue 9).

Department of Veterans' Affairs 2010. Alternative therapies and Department of Veterans' Affairs Gold and White Card arrangements literature review. Canberra Australia: Department of Veterans' Affairs.

Dolation M, Hasanpour A & Montazeri S 2011. The effect of reflexology on pain intensity and duration of labor on primiparas. Iranian Red Crescent Medical Journal (13):475–479.

Dwan K et al. 2011. Comparison of protocols and registry entries to published reports for randomised controlled trials. Cochrane Database of Systematic Reviews 2011 (Issue 1).

Ernst E 2000. Iridology: not useful and potentially harmful. Archives of Ophthalmology (118):120–121.

Ernst E 2007. Herbal medicine: buy one, get two free. Postgraduate Medical Journal (83):615–616.

Ernst E & Canter PH 2005. The Feldenkrais Method: a systematic review of randomised clinical trials. Physikalische Medizin Rehabilitationsmedizin Kurortmedizin (15)3:151–156.

Ernst E, Pittler M & Wider B 2006. The desktop guide to complementary and alternative medicine: an evidence-based approach. Philadelphia, PA, USA: Mosby Elsevier.

European Shiatsu Federation 2013. About the ESF. [Online] Available at: <http://www.shiatsufederation.ed/about-shiatsu.html>. [Accessed 20 July 2013].

Finnegan J, Molassiotis A, Richardson A & Ream E 2013. A systematic review of complementary and alternative medicine interventions for the management of cancer-related fatigue. Integrative Cancer Therapies (12):276–290.

- Furlan AD et al. 2010. Complementary and alternative therapies for back pain II. Evidence Report/Technology Assessment (194):1–764.
- Gayeski ME & Brüggemann OM 2010. Non-pharmacological approach to pain relief during labor as hard-light care technology: a systematic review. *Texto & Contexto Enfermagem* (19):774–782.
- Gillespie DL et al. 2009. Interventions for preventing falls in older people living in the community. *Cochrane Database of Systematic Reviews* 2009 (Issue 2).
- Grabia S & Ernst E 2003. Homeopathic aggravations: a systematic review of randomised, placebo-controlled clinical trials. *Homeopathy* (92):92–98.
- Hall A, Maher C, Latimer J & Ferreira M 2009a. The effectiveness of Tai Chi for chronic musculoskeletal pain conditions: a systematic review and meta-analysis. *Arthritis & Rheumatism* (61):717–724.
- Hall S, Lewith G, Brien S & Little P 2008. A review of the literature in applied and specialised kinesiology. *Forsch Komplementarmed* (15):40–46.
- Hansen C & Taylor-Piliae RE 2011. What is Bowenwork? A systematic review. *The Journal of Alternative and Complementary Medicine* (7):1001–1006.
- Hartmann KE et al. 2009. Treatment of overactive bladder in women. Evidence Report/Technology Assessment (187):1–120.
- Herman PM, Poindexter BL, Witt CM & Eisenberg DM 2012. Are complementary therapies and integrative care cost-effective? A systematic review of economic evaluations. *BMJ Open* 2012 (2):e001046.
- Herman PM, Szczurko O, Cooley K & Mills EJ 2008. Cost-effectiveness of naturopathic care for chronic low back pain. *Alternative Therapies in Health and Medicine* (14):32–39.
- Higgins JPT, Altman DG & Sterne JAC 2011. Chapter 8: 'Assessing risk of bias in included studies'. JPT Higgins JPT & S Green (eds). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011]. The Cochrane Collaboration. [Online] Available at: www.cochrane-handbook.org.

Hipmair G et al. 2012. Efficacy of Bowen therapy in postoperative pain management: a single blinded (randomized) controlled trial. [Online] Available at: <http://www.therapy-training.com/research/bowen-pain-research.html>.

Holland AE, Hill CJ, Jones AY & McDonald CF 2012. Breathing exercises for chronic obstructive pulmonary disease. *The Cochrane Database of Systematic Reviews* 2012 (Issue 10).

Hollinghurst S et al. 2008. Randomised controlled trial of Alexander technique lessons, exercise, and massage (ATEAM) for chronic and recurrent back pain: economic evaluation. *BMJ* (337):a2656.

Howe TE et al. 2011. Exercise for improving balance in older people. *The Cochrane database of systematic reviews* 2011 (Issue 11).

Ives J & Shelley G 1998. The Feldenkrais method in rehabilitation a review. *Work* (11):75–90.

Ju H et al. 2009. The management of acute/subacute soft tissue injuries to the low back: evidence update and recommendations for clinical practice, Adelaide: Workcover SA.

Kay TM et al. 2012. Exercises for mechanical neck disorders. *Cochrane Database of Systematic Reviews* 2012 (Issue 8).

Kim JH, Park MK & Oh MR 2013. Meta-analysis of complementary and alternative intervention on menstrual distress [Korean]. *Korean Journal of Women Health Nursing* (19):23–35.

Kong EH, Evans LK & Guevara JP 2009. Nonpharmacological intervention for agitation in dementia: a systematic review and meta-analysis. *Aging and Mental Health* (13):512–520.

Lee MS, Choi J, Posadzki P & Ernst E 2012b. Aromatherapy for health care: an overview of systematic reviews. *Maturitas* (71):257–260.

Lee MS & Ernst E 2009. Qigong for movement disorders: A systematic review, *Movement Disorders*, pp. 24 (2), 301-303.

Lee MS et al. 2009. Yoga for menopausal symptoms: a systematic review. *Menopause* (16):602–608.

- Li CY et al. 2011. Li C. Randomised controlled trial of the effectiveness of using foot reflexology to improve quality of sleep amongst Taiwanese postpartum women. *Midwifery* (27):181–186.
- Lin KY et al. 2011. Effects of yoga on psychological health, quality of life, and physical health of patients with cancer: a meta-analysis. *Evidence-Based Complementary and Alternative Medicine* 2011.
- Lin V et al. 2009. The practice and regulatory requirements of naturopathy and western herbal medicine in Australia. *Risk Management and Healthcare Policy* (2):21–33.
- Little P et al. 2008. Randomised controlled trial of Alexander technique lessons, exercise, and massage (ATEAM) for chronic and recurrent back pain. *British Medical Journal* (337):a884.
- Long AF 2008. The effectiveness of shiatsu: findings from a cross-European, prospective observational study. *Journal of Alternative & Complementary Medicine* (14):921–930.
- Lundblad I, Elert J & Gerdle B 1999. Randomized controlled trial of physiotherapy and Feldenkrais interventions in female workers with neck-shoulder complaints. *Journal of Occupational Rehabilitation* (9)179–194.
- Mackawan S et al. 2007. Effects of traditional Thai massage versus joint mobilization on substance P and pain perception, in patients with non-specific low back pain. *Journal of Bodywork and Movement Therapies* (11):9–16.
- Marr M, Baker J, Lambon N & Perry J 2011. The effects of the Bowen technique on hamstring flexibility over time: a randomised controlled trial. *Journal of Bodywork and Movement Therapies* (15):281–290.
- Marr M, Lambon N & Baker J 2008. Effects of the Bowen technique on flexibility levels: implications for fascial plasticity. *Journal of Body Work and Movement Therapy* (12):388.
- McGowan J 2003. Health education in asthma management: does the Buteyko Institute method make a difference? *Thorax* (58):iii–28.
- Merriam Webster Online Dictionary 2013. Merriam-Webster Online Dictionary. [Online] Available at: <http://www.merriam-webster.com/dictionary/kinesiology>.

National Center for Complementary and Alternative Medicine 2013. Tai Chi: an introduction [Internet]. [Online] Available at: <http://nccam.nih.gov/health/taichi/introduction.htm> [Accessed 5 November 2013]. [Accessed 5 November 2013].

Ng KCW & Cohen M 2011. The effectiveness of massage therapy: a summary of evidence-based research. RMIT University report for Australian Association of Massage Therapists, Melbourne: Australian Association of Massage Therapists.

Ng SM et al. 2012. Tai Chi exercise for patients with heart disease: a systematic review of controlled clinical trials. *Alternative Therapies in Health & Medicine* (18):16–22.

NHMRC (National Health & Medical Research Council) 2000. How to review the evidence: systematic identification and review of the scientific literature. Canberra: National Health and Medical Research Council.

NHMRC 2009. NHMRC levels of evidence and grades for recommendations for developers of guidelines. Canberra: National Health and Medical Research Council.

Oberg EB et al. 2013. Estimated effects of wholesystem: a systematic review. San Diego: [manuscript draft].

O'Connor E et al. 2012. Breathing exercises and/or retraining techniques in the treatment of asthma: comparative effectiveness. 71 ed. Rockville MD: Agency for Healthcare Research and Quality (US).

Padiha RQ, Riera R & Atallah AN 2011. Homeopathic plumbum metallicum for lead poisoning: a randomized clinical trial. *Homeopathy* (100)116–121.

Patel K et al. 2012. Massage for mechanical neck disorders. *Cochrane Data Base of Systematic Reviews* 2012 (Issue 9).

Perry R, Hunt K & Ernst E 2011. Nutritional supplements and other complementary medicines for infantile colic: a systematic review. *Pediatrics* (127):720–733.

Pilates Alliance of Australia 2013. Frequently asked questions: Pilates Alliance Australasia. [Online] Available at: [Available at: http://www.pilatesalliance.net/find/faq/](http://www.pilatesalliance.net/find/faq/).

Robinson N, Lorence A & Liao X 2011. The evidence for Shiatsu: a systematic review of Shiatsu and acupuncture. *BMC complementary and alternative medicine* (11):88.

Savigny P et al. 2009. *Low back pain: early management of persistent non-specific low back pain*. London: National Collaborating Centre for Primary Care and Royal College of General Practitioners.

Seely D et al. 2013. Naturopathic medicine for the prevention of cardiovascular disease: a randomized clinical trial. *Canadian Medical Association journal = journal de l'Association medicale canadienne* (185):e409–e416.

Seers K et al. 2008. A randomised controlled trial to assess the effectiveness of a single session of nurse-administered massage for short-term relief of chronic non-malignant pain. *BMC Nursing* (7):10.

Sharma S & Sharma N 2012. Long-term evaluation of homeopathy on post-treatment impairment of pulmonary tuberculosis. *BMC Complementary and Alternative medicine* (12)suppl1:223.

Sharma S, Sharma N & Sharma R 2012. Accelerating the healing of bone fracture using homeopathy: a prospective, randomized double-blind controlled study. *BMC Complementary and Alternative Medicine* (12)Suppl 1):061.

Shea BJ et al. 2007. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. *BMC Medical Research Methodology* (7):10.

Sherrington C, Lord SR & Close J 2008a. *Best practice recommendations for physical activity to prevent falls in older adults*. Sydney: The Sax Institute.

Sherrington C et al. 2008b. Effective exercise for the prevention of falls: a systematic review and meta-analysis. *Journal of the American Geriatric Society* (56):2234–2243.

Shiatsu Therapy Association of Australia 2013. Public submission to the Private Health Insurance Rebate review. [Online] Available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/phi-natural-therapies-submissions>.

Shneerson C et al. 2013. The effect of complementary and alternative medicine on the quality of life of cancer survivors: a systematic review and meta-analyses. *Complementary Therapies in Medicine* (21):417–429.

Siebenwirth J et al. 2009. Effectiveness of a classical homeopathic treatment in atopic eczema. A randomised placebo-controlled double-blind clinical trial. *Forschende Komplementarmedizin* (16):315–323.

Singer SR et al. 2010. Traumeel S for pain relief following hallux valgus surgery: a randomized controlled trial. *BMC Clinical Pharmacol* (10):9.

Smith AL, Kolt GS & Mcconville JC 2001. The effect of the Feldenkrais method on pain and anxiety in people experiencing chronic low back pain. *New Zealand Journal of Physiotherapy* (29):6–14.

Smith CA, Collins CT & Crowther CA 2011. Aromatherapy for pain management in labour. *Cochrane Database of Systematic Reviews* 2011 (Issue 7).

Smith CA, Levett KM, Collins CT & Jones L 2012. Massage, reflexology and other manual methods for pain management in labour. *Cochrane Database of Systematic Reviews* 2012 (Issue 2).

Stallibrass C, Sissons P & Chalmers C 2002. Randomized controlled trial of the Alexander technique for idiopathic Parkinson's disease. *Clinical Rehabilitation* (16):695–708.

Stephens J et al. 2001. Use of awareness through movement improves balance and balance confidence in people with multiple sclerosis: a randomized controlled study. *Neurology Report* (25)39–49.

Strauch R 1996. An overview of the Feldenkrais method. [Online] Available at: http://www.somatic.com/articles/feldenkrais_overview.pdf.

Szczurko O et al. 2007. Naturopathic care for chronic low back: a randomized trial. *PLoS One* (2):e919.

Szczurko O et al. 2009. Naturopathic treatment of rotator cuff tendinitis among Canadian postal workers; a randomised controlled trial. *Arthritis and Rheumatism* (61):1037–1045.

- Teixeira MZ 2009. Effectiveness of individualized homeopathic treatment in perennial allergic rhinitis (PAR). *International Journal of High Dilution Research* (8):141–143.
- TRACsa 2008. Clinical guidelines for best practice management of acute and chronic whiplash-associated disorders. Adelaide: TRACsa.
- UMMC (University of Maryland Medical Centre) 2013. Yoga. [Online] Available at: <http://umm.edu/health/medical/altmed/treatment/yoga>. [Accessed 7 May 2013].
- Vakilian K, Atarha M, Bekhradi R & Chaman R 2011. Healing advantages of lavender essential oil during episiotomy recovery: a clinical trial. *Complementary Therapies in Clinical Practice* (17):50–53.
- Verhagen AP et al. 2009. Ergonomic and physiotherapeutic interventions for treating work-related complaints of the arm, neck or shoulder in adults. *Cochrane Database of Systematic Reviews* (Issue 3).
- Vickers AP, Ledwith F & Gibbens A 1999. The impact of the Alexander Technique on chronic mechanical low back pain. Kendal, UK 1-19: Westmorland General Hospital.
- Vrantsidis F et al. 2009. Getting Grounded Gracefully: effectiveness and acceptability of Feldenkrais in improving balance. *Journal of Aging and Physical Activity* (17):57–76.
- Wang MY et al. 2008. The efficacy of reflexology: systematic review. *Journal of Advanced Nursing* (62):512–520.
- Wardle J, Steel A & Adams J 2012. A review of tensions and risks in naturopathic education and training in Australia: a need for regulation. *Journal of Alternative and Complementary Medicine* (18):363–370.
- Weinberg R & Hunt V 1979. Effects of structural integration on state-trait anxiety. *Journal of clinical psychology* (35):319–322.
- Wells C, Kolt GS & Bialocerkowski A 2012. Defining Pilates exercise: A systematic review. *Complementary Therapies in Medicine* (20):253–262.
- Wentworth LJ et al. 2009. Massage therapy reduces tension, anxiety, and pain in patients awaiting invasive cardiovascular procedures. *Progress in Cardiovascular Nursing* (24):155–161.

Wolf S et al. 1996. Reducing frailty and falls in older persons: an investigation of Tai Chi and computerised balance training. Atlanta FICSIT Group. Frailty and injuries: Cooperative Studies of Intervention Techniques. *Journal of the American Geriatrics Society* (44):489–497.

Woodman JP & Moore NR 2012. Evidence for the effectiveness of Alexander Technique lessons in medical and health-related conditions: a systematic review. *International Journal of Clinical Practice* (66)98–112.

Yeung WF et al. 2012. Acupressure, reflexology, and auricular acupressure for insomnia: A systematic review of randomized controlled trials. *Sleep Medicine* (13):971–84.

Zhang J, Yang KH, Tian JH & Wang CM 2012. Effects of yoga on psychologic function and quality of life in women with breast cancer: a meta-analysis of randomized controlled trials. *Journal of Alternative and Complementary Medicine* (18):994–1002.