YOGA FOR PREVENTING AND TREATING HEALTH CONDITIONS

EVIDENCE EVALUATION REPORT

prepared by **HT**ANALYSTS

for

National Health and Medical Research Council

NHMRC | Natural Therapies Working Committee Canberra ACT 2601

OCTOBER 2023

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Dates

This evidence evaluation report and accompanying technical reports received approval from the NHMRC Natural Therapies Working Committee (NTWC) on 04 Dec 2023.

The protocol for the evidence evaluation received approval from the NHMRC NTWC on 25 May 2020 (PROSPERO: CRD42020200084).

History

NHMRC has been engaged by the Department of Health and Aged Care (formally Department of Health; Department) to update the evidence underpinning the *2015 Review of the Australian Government Rebate on Natural Therapies for Private Health Insurance* (2015 Review) (1). The natural therapies to be reviewed are Alexander technique, aromatherapy, Bowen therapy, Buteyko, Feldenkrais, homeopathy, iridology, kinesiology, naturopathy, Pilates, reflexology, Rolfing, shiatsu, tai chi, western herbal medicine and yoga. These therapies are among those excluded from the private health insurance rebate as of 1 April 2019.

To support NHMRC in their evidence review, Health Technology Analysts (**HT**ANALYSTS) was engaged to conduct a systematic review of the evidence of clinical effectiveness of yoga. Eligible studies received from the Department's public call for evidence, the Natural Therapies Review Expert Advisory Panel (NTREAP) and the NTWC were also included in the evidence evaluation.

This evidence evaluation report has been developed by **HT**ANALYSTS in conjunction with NHMRC, NTWC, and NTREAP. It describes the main body of evidence related to the effect of yoga for preventing and treating health conditions. Supplementary data are provided in Appendices A to H. All associated materials have been developed in a robust and transparent manner in accordance with relevant best practice standards (2-5).

Funding

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Membership and other details of the Panel and Committee can be found at:

https://www.health.gov.au/committees-and-groups/natural-therapies-review-expert-advisory-panel

https://www.nhmrc.gov.au/about-us/leadership-and-governance/committees/natural-therapies-workingcommittee

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List of abbreviations

BRISA	Regional Base of Health Technology Assessment Reports of the Americas
CINAHL	Cumulative Index to Nursing and Allied Health Literature
COMET	Core Outcome Measures in Effectiveness Trials
GRADE	Grading of Recommendations Assessment, Development and Evaluation
ITT	Intent-to-treat
NHMRC	National Health and Medical Research Council
NRSI	Nonrandomised study of an intervention
NTREAP	Natural Therapies Review Expert Advisory Panel
NTWC	Natural Therapies Working Committee
OR	Odds ratios
РАНО	Pan American Health Organization
PICO	Population, Intervention, Comparator, Outcome
PP	Per protocol
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomised controlled trial
RoB	Risk of bias
RR	Risk ratios
SR	Systematic review
SD	Standard deviation
TIDIER	Template for Intervention Description and Replication

Plain language summary

What was the aim of this review?

The aim of this review was to identify eligible studies and assess whether they demonstrate that yoga is effective in preventing and/or treating certain injuries, diseases, medical conditions or pre-clinical conditions relevant to the Australian population. Yoga is a traditional Indian discipline that promotes a healthy mind and body, and healthy breathing through physical postures or poses (asanas), controlled breathing (pranayama) and meditation (dhyana). This review is targeted for the Australian Government Department of Health and Aged Care (Department) to assist in their Natural Therapies Review, which was designed to determine whether certain natural therapies, including yoga, have enough evidence of effectiveness to be considered re-eligible for private health insurance rebates. This review was not designed to be a complete review of all studies published for yoga, nor is it intended to inform decisions about whether an individual or practitioner should use yoga.

Key messages

For the populations (or conditions) assessed, yoga appears to provide people with some benefit for some of the included conditions and outcomes, when compared with people who do not practise yoga. The evidence assessed in this review was rated as moderate to low certainty. The results of this review are consistent with other systematic reviews of yoga in the populations considered in this review, published up to January 2023.

What was studied in this review?

This review identified studies using a planned literature search, with no limit on publication date. To ensure the review was manageable, the review only assessed studies for certain conditions or groups of people. These priority conditions and groups were decided based on Australian survey information and by seeking expert advice about the reasons why people in Australia commonly practise yoga and about the types of conditions seen by yoga teachers. Included studies needed to compare the results of people who practised yoga to a group of people who did not. Assessment of cost effectiveness, safety and studies of healthy populations were not included in this review.

Studies published in languages other than English were listed, but not included in the assessment. Studies that compared yoga with another intervention (active comparator) were listed, but not included in the main analysis because different studies used different comparators and outcome measures, which did not meet the criteria planned in the protocol.

Studies were assessed using the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) framework. GRADE is a method to assess how confident (or certain) systematic review authors can be that the results reported (estimates of effect) in studies are accurate. The assessment made by the reviewer is then described as either:

- high certainty meaning the authors have a lot of confidence that the true effect is similar to the estimated effect,
- moderate certainty meaning that the true effect is probably close to the estimated effect,
- low certainty meaning the true effect may be markedly different from the estimated effect,
- very low certainty meaning the true effect is probably markedly different from the estimated effect. Reviewers' confidence was so limited that interpretation was not provided.

What studies did we identify in the review?

Using a planned approach, 7111 citations from 11 databases were collected and examined, including 153 studies submitted by the public via the Department's public call for evidence.

Out of 7111 citations identified, <u>95 studies</u> covering 15 prioritised conditions, were assessed in the evidence evaluation and are included in the results. The 15 prioritised conditions were combined and listed below under 11 groupings. Yoga exercises reported in eligible studies were generally consistent with how yoga is practised in Australia, inclusive of poses, controlled breathing and meditation; although some yoga programs were specifically designed for a certain condition, and were focused on laughter, breathing or meditative techniques. Most studies evaluated group yoga classes that were 45 to 90 minutes long, with outcomes evaluated at the beginning and at the end of treatment. However, in some studies the yoga was practised by the individual at home (after some initial instruction). Sessions varied from one to 5 sessions per week and programs typically lasted between 6 weeks and 6 months. No program continued for more than 6 months, but some studies followed patients for an additional 6 months with encouragement to maintain their practice at home. The treatment provider was specified in about 60% of studies and tended to be experienced yoga instructors trained or certified in a particular yoga style (e.g. hatha, vinyasa, lyengar).

At the time of the literature search, a further 160 studies had been presented at conferences, but data were incomplete, 33 studies were not in English, 14 studies could not be retrieved, and 9 studies were published after the search date. In addition, 308 studies had been registered but were not complete at the time of the search. Of these ongoing studies not yet published, 32 were in conditions included in synthesis in this review and were listed as complete or unknown (i.e. might be complete) suggesting that they might have provided data. The lack of publication of these results may indicate they did not show a positive effect of yoga over control (potential publication bias).

What were the main results of the review?

The evidence provides moderate to low certainty that practising yoga is more effective than not practising yoga for some conditions considered critical or important in this review. The evidence also provides moderate to low certainty that yoga has little (to no) benefit for some of the conditions assessed in this review. There are some conditions and outcomes assessed in this review where the effect of yoga is uncertain (very low certainty) or unknown.

The evidence provides moderate certainty that yoga probably:

- reduces systolic (15 RCTs, 1230 participants) and diastolic (13 RCTs, 1090 participants) blood pressure in people with hypertensive heart disease
- improves emotional wellbeing in people with anxiety (2 RCTs, 131 participants)
- reduces symptoms of depression in people with depression (10 RCTs, 434 participants)
- improves health-related quality of life in people with low back pain (4 RCTs, 590 participants).

The evidence provides low certainty that yoga may:

- improve quality of life (3 RCTs, 172 participants), perceived stress (6 RCTs, 401 participants) and emotional wellbeing (2 RCTs, 159 participants) in people with elevated perceived stress
- reduce pain intensity (10 RCTs, 1101 participants) and pain medication use (5 RCTs, 465 participants) in people with low back pain
- reduce stress (1 RCT, 101 participants) in people with anxiety
- improve quality of life (1 RCT, 56 participants), stress (1 RCT, 50 participants), life satisfaction (1 RCT, 40 participants) and self-compassion (1 RCT, 46 participants) in people with depression
- improve emotional wellbeing (1 RCT, 65 participants), reduce headache frequency (4 RCTs, 590 participants) and reduce the number of acute "rescue" pills taken in addition to preventative medication (1 RCT, 65 participants) in people with headache disorders
- improve health-related quality of life (6 RCTs, 826 participants) in people with asthma
- improve health-related quality of life (1 RCT, 53 participants), improve pain acceptance (1 RCT, 53 participants) and reduce fatigue (1 RCT, 53 participants) in people with fibromyalgia
- improve pain (1 RCT, 20 participants) and reduce fear of movement because of pain (1 RCT, 20 participants) in people with mechanical neck pain.

The evidence provides low certainty that yoga may have little (to no) effect on:

- life satisfaction (2 RCTs, 178 participants), fatigue (1 RCT, 37 participants) or sleep quality (3 RCTs, 179 participants) in people with elevated perceived stress
- physical (5 RCTs, 710 participants) or emotional functioning (4 RCTs, 642 participants) in people with low back pain
- health-related quality of life (1 RCT, 56 participants), psychological distress (1 RCT, 50 participants), emotional function (1 RCT, 50 participants) or perceived stress (2 RCTs, 72 participants) in people with depression
- health-related quality of life (3 RCTs, 139 participants), emotional functioning (2 RCTs, 111 participants) or mobility (2 RCTs, 92 participants) in people with chronic pain conditions
- physical functioning, pain, stiffness, tenderness or morning tiredness in people with fibromyalgia (1 RCT, 53 participants)
- perceived stress (3 RCTs, 245 participants) or health-related quality of life (2 RCT, 221 participants) in people with hypertensive heart disease
- pulmonary function (6 RCTs, 680 participants) in people with asthma
- improving pain or physical functioning in people with frozen shoulder (1 RCT, 72 participants).

Implications for health policy and research

This review assesses the evidence for certain conditions and groups of people to inform the Australian Government about health policy decisions for private health insurance rebates. The review does not cover all the reasons that people practise yoga, or the reasons practitioners prescribe yoga and is not intended to inform individual choices about practising yoga. This review listed, but did not assess yoga versus other interventions, so no comment can be made on whether yoga is better or worse than other exercises or other interventions. Studies published in a language other than English were listed, but not included in the assessment. It is not known if including these studies would have affected the overall results but could have increased the certainty of evidence across some outcomes.

The results of this review indicate that yoga may improve some of the conditions and outcomes prioritised in this review and not others. Several of the studies assessed in this review focussed on the effect of yoga in people who received treatment for 12 weeks or less (range 6 weeks to 6 months), so it is difficult to be confident about the effects of yoga in people who continue to practise yoga for more than 12 weeks. This review did not assess whether the effects of yoga continue once people stop practising yoga.

Future research could be improved by undertaking more studies of yoga versus control (no intervention, or inactive comparator); by including outcomes that are considered critical or important for decision-making. Future decision making would be improved by clearer reporting or publishing of the results.

How up to date is this review?

Searches were conducted from the earliest date included in the databases until 30 July 2020. Studies published after this date are not included in this review. A search for recent systematic reviews was conducted up to January 2023 and results of this review were compared (where applicable) for completeness.

Executive summary

Background

Yoga is practised for a range of reasons and is intended to benefit physical health and psychological wellbeing. Practising yoga is claimed to improve health outcomes for a variety of clinical and pre-clinical conditions, including problems associated with chronic pain (e.g. low back pain), conditions related to mental health (e.g. anxiety) and chronic health conditions (e.g. heart disease). Yoga is a traditional Indian discipline that incorporates various philosophies to promote a healthy mind, body and healthy breathing. At its core are a set of principles and practices that are characterised by physical postures or poses (asanas), controlled breathing (pranayama) and meditation (dhyana). Yogic lifestyle, nutrition advice, philosophical and spiritual studies may also be included. In Australia, yoga is usually performed with a mat or cushions on the floor with sessions that typically range from 45 to 90 minutes in length. In some settings, yoga may be practised seated on chairs or in a room with an elevated temperature or humidity. In general, yoga postures, movements and stretches are performed after introductory breathing exercises and/or relaxation, then ending with relaxation and/or meditation exercises. Sometimes yoga sessions will focus entirely on meditation practices, and other times yoga may concentrate on breathing exercises or sacred sounds (mantras). Yoga is often practised as a form of group exercise with the teaching style dependent on the expertise of the instructor. Individuals may also practise yoga at home, whilst viewing or listening to professional videos or other multimedia, without direct supervision.

In 2015, an overview of systematic reviews conducted for the Australian Government found the health effects of yoga as a health service, were uncertain due to the lack of studies for some clinical conditions, and inadequate reporting of information in the included systematic reviews (primary studies included in the eligible systematic reviews). This systematic review has targeted analysis to primary studies assessing the effectiveness of yoga delivered for injury, disease, medical condition or primary prevention in individuals at-risk.

Objectives

The objective of this review was to evaluate the effectiveness of yoga in individuals with a described injury, disease, medical condition, or pre-clinical condition (including primary prevention) in at-risk individuals, on outcomes that align with the reasons why people commonly practise yoga in Australia. This information will be used by the Australian Government in deciding whether to reinclude yoga as eligible for private health insurance rebates, after yoga was excluded in 2019. This review was not designed to assess all the reasons that people practise yoga, or the reasons practitioners prescribe yoga and was not intended to inform individual choices about practising yoga.

Search methods

Literature searches were conducted in EMBASE, MEDLINE, EMCARE, PsycINFO, AMED, CINAHL, SPORTDiscus, CENTRAL, PEDro, PUBMED and PAHO VHL to identify relevant studies published from database inception to 30 July 2020. The public was also invited by the Department of Health and Aged Care to submit references for published research evidence. There were no limits on language of publication or date of publication in the search.

Selection criteria

Randomised controlled trials that examined yoga compared to control (or another intervention, where applicable) were eligible, including quasi-randomised studies, cluster-randomised and crossover trials. Any exercise activity named as yoga that was delivered by an instructor to an individual or group of individuals, or yoga that was self-practised was eligible for inclusion. There were no limits on intensity, duration of practice or mode of delivery. Studies that examined yoga delivered as an adjunct to another therapy were also eligible for inclusion provided that both groups received the other therapy.

The search included studies of people of any age with any injury, disease, medical condition or pre-clinical condition. Studies examining yoga for individual at-risk participants, but not studies assessing at-risk populations in general, were also eligible for inclusion.

The search was not restricted by comparators, however the main comparator of interest was yoga versus control (including no intervention, waitlist, or usual care, if considered inactive). The secondary comparator of interest was yoga versus other comparator (including usual care or control, if considered active). Outcomes were not part of the eligibility criteria and were not included in the search terms but were prioritised as described below. Studies were not excluded based on country of origin, however studies published in a language other than English were not translated and were not included in the synthesis but were listed in an inventory for completeness.

Data collection and analysis

To ensure the review was most relevant to the Australian population, populations were prioritised without knowledge of potential studies to ensure unbiased prioritisation. In determining the priority conditions for inclusion in the analysis and synthesis of the review, the National Health and Medical Research Council (NHMRC) Natural Therapies Working Committee (NTWC) were guided by relevant patient or practitioner reported Australian survey data (where available) and expert advice from the Department's Natural Therapies Review Expert Advisory Panel (NTREAP). Prioritisation was conducted after initial searching and screening process, but before data extraction.

After population prioritisation a blinded outcome prioritisation process was undertaken by NTWC (with input from NTREAP). The outcome prioritisation process was developed based on published core outcome sets and systematic reviews in the priority populations, after the included studies were identified. As part of the process NTWC (with advice from NTREAP) was asked to specify up to seven 'critical' or 'important' outcome domains for inclusion in the analysis and synthesis of the review. Where a study did not report a prioritised outcome for that population or condition, this was noted as an evidence gap in the review. For outcome domains, the NTWC applied the GRADE scoring of 0 (of limited importance for decision making) to 9 (critical for decision making). Harms and cost-effectiveness measures were out of scope.

For each included study, data collection was performed by two researchers: the first collected data using data extraction forms and the second checked the forms for completeness and accuracy. Risk of bias of the eligible studies was conducted using the RoB 2 tool, the revised Cochrane risk of bias tool for randomised trials.

In the data analysis and synthesis for each prioritised population, the overall certainty of evidence for a maximum of seven critical or important outcomes were reported in GRADE summary of findings tables, with corresponding evidence statements assigned to each outcome based on a pre-specified list of statements. Data for reported outcomes at 'end of treatment' were assessed against a threshold such as minimal clinically important differences (MCID) or minimal important difference (MID) (where available). In instances where MCID were unavailable, effect estimates were assessed using ranges of (1) small (Mean difference [MD] <10% of the scale) (2) moderate (MD between 10% to 20% of the scale), or (3) large (MD more than 20% of the scale). If the effect was quantified using a standardised mean difference (SMD), we used Cohen's guidance for interpreting the magnitude of the SMD, where 0.2 represents a small difference, 0.5 is moderate, and 0.8 is large.

Main results

A total of <u>520 studies</u> were identified as eligible for inclusion in this review. Of these, 147 studies covering 15 conditions (grouped under 11 headings) were considered in the evidence evaluation and are included in the results. For the synthesis 95 studies covering 15 (grouped under 11 headings) prioritised conditions compared yoga exercises with inactive control (no intervention, waitlist or usual care). Results for studies of prioritised conditions with active comparators are presented in Appendix F2, but not in the synthesis, as the wide range of comparators and outcomes did not allow for synthesis as planned in the protocol.

At the time of the search, an additional 216 studies were <u>awaiting classification</u> and an additional 308 studies were recorded as <u>ongoing</u> (registered but not published at the time of the search). Of the studies awaiting classification, 160 were conference abstracts, 33 were not published in English and 14 studies were not able to be retrieved and therefore not assessed. The remaining 9 studies were published after the search date. Of the ongoing studies, at the time of search 22 studies were listed as not yet recruiting participants, 80 studies were listed as recruiting participants, 27 studies were listed as recruited participants but not collected data, 109 studies were listed as complete but data were not yet available and 16 studies was unknown. Results for approximately 32 of the ongoing studies, that were complete but not yet available for full text review, may have been eligible for inclusion for conditions prioritised in this review, and may have reported on some of the outcomes considered critical or important by NTWC. The lack of publication of these results may indicate they did not show a positive effect of yoga over control (potential publication bias).

Evidence was available under all 11 headings for all 15 prioritised conditions. Summary of findings tables were restricted to outcomes rated as critical and important by NTWC, study results for outcomes not considered critical or important were not included in the synthesis.

All included studies examined yoga exercises delivered in a manner that was applicable to the Australian context, inclusive of poses, controlled breathing and meditation; although some yoga programs were specifically designed for a certain condition, and were focused on laughter, breathing or meditative techniques. Most studies evaluated group yoga classes that were 45 to 90 minutes in duration, with outcomes evaluated at the beginning and at the end of treatment. In some studies, yoga was practised by the individual at home (after some initial instruction). Sessions varied from one to 5 sessions per week and programs typically lasted between 6 weeks and 6 months. No program continued for more than 6 months, but some studies followed patients for an additional 6 months with encouragement to maintain their practice at home. The treatment provider was specified in about 60% of studies and tended to be experienced yoga instructors trained or certified in a particular yoga style (e.g. hatha, vinyasa, lyengar).

Studies were assessed using the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) framework. GRADE combines information to assess overall how certain systematic review authors can be that the estimates of the effect (reported across a study/s for each critical or important outcome) are correct. High certainty means the authors have a lot of confidence that the true effect is similar to the estimated effect. Moderate certainty means that the true effect is probably close to the estimated effect. Low certainty means the true effect might be markedly different from the estimated effect. Very low certainty means the true effect is probably markedly different from the estimated effect.

This review evaluated 15 prioritised conditions, grouped under 11 headings for which there was evidence about the effect of yoga on an outcome considered critical or important by NTWC. The evidence provides:

- moderate certainty that yoga probably results in:
 - a large reduction in systolic (15 RCTs, 1230 participants) and diastolic (13 RCTs, 1090 participants)
 blood pressure in people with hypertensive heart disease
 - a moderate improvement in emotional wellbeing in people with anxiety (2 RCTs, 131 participants)
 - a moderate reduction in symptoms of depression in people with depression (10 RCTs, 434 participants)
 - a slight improvement in health-related quality of life in people with low back pain (4 RCTs, 590 participants)
- low certainty that yoga may result in:
 - o a large improvement in self-compassion (1 RCT, 46 participants) in people with depression
 - a large improvement in emotional wellbeing (1 RCT, 65 participants) and a large reduction in headache frequency (4 RCTs, 317 participants) in people with headache disorders
 - a large improvement in health-related quality of life (6 RCTs, 826 participants) in people with asthma

- a large reduction in pain and reduced kinesophobia (1 RCT, 20 participants) in people with neck pain
- a moderate improvement in quality of life (3 RCTs, 172 participants), perceived stress (6 RCTs, 401 participants) and emotional wellbeing (2 RCTs, 159 participants) in people with elevated perceived stress
- a moderate improvement in life satisfaction (1 RCT, 40 participants), quality of life (1 RCT, 56 participants) and perceived stress (2 RCTs, 62 participants) in people with depression
- a moderate reduction in pain medication use (5 RCTs, 465 participants) in people with low back pain
- a moderate reduction in the number of acute "rescue" pills taken in addition to preventative medication (1 RCT, 65 participants) in people with headache disorders
- o a slight improvement in pain acceptance in people with fibromyalgia (1 RCTs, 83 participants)
- o a slight reduction in pain intensity (10 RCTs, 1101 participants) in people with low back pain
- o a slight reduction in perceived stress (1 RCT, 101 participants) in people with anxiety
- a slight improvement in quality of life (1 RCT, 53 participants) and a slight reduction in fatigue (1 RCT, 53 participants) in people with fibromyalgia.
- low certainty that yoga may result in little (to no) change in:
 - life satisfaction (2 RCTs, 178 participants), fatigue (1 RCT, 37 participants) or sleep quality (3 RCTs, 179 participants) in people with elevated perceived stress
 - physical (5 RCTs, 710 participants) or emotional functioning (4 RCTs, 642 participants) in people with low back pain
 - shoulder pain (1 RCT, 72 participants) or physical function (1RCT, 72 participants) in people with frozen shoulder
 - psychological distress (1 RCT, 50 participants) or emotional function (1 RCT, 50 participants) in people with depression
 - health-related quality of life (3 RCTs, 139 participants, non-fibromyalgia), emotional functioning (2 RCTs, 111 participants) or mobility (2 RCTs, 92 participants) in people with chronic pain conditions
 - physical functioning, pain, stiffness, tenderness or morning tiredness in people with fibromyalgia (1 RCT, 53 participants)
 - perceived stress (3 RCTs, 245 participants) or health-related quality of life (2 RCT, 221 participants) in people with hypertensive heart disease
 - o pulmonary function (6 RCTs, 680 participants) in people with asthma.

The evidence provides very low certainty of the effect of yoga versus inactive control (no intervention, waitlist or usual care) for 20 out of the 88 critical or important outcomes prioritised for analysis in this review.

Of the 88 outcomes prioritised as critical or important in this review, there were no studies found reporting on 23 of those outcomes and therefore the effect of yoga on these outcomes is unknown.

A summary of harms of yoga is not possible, as it was out of scope of this review to assess adverse outcomes related to the practice of yoga.

Limitations

This review is limited to analysis of conditions prioritised by NTWC, who were guided by relevant patient and/or practitioner reported Australian survey data (where available) and expert advice from NTREAP during the prioritisation process, therefore this report may not cover all the reasons people practise yoga. Given the large number of studies identified across a diverse range of conditions, and as agreed *a priori*, the evidence synthesis was limited to 15 priority conditions, grouped under 11 headings.

The outcomes assessed in this review were limited to those deemed critical or important by NTWC for each priority condition. Most conditions had evidence available for 4 or more critical or important outcomes.

A large number of studies remained ongoing or were unpublished at the time of the search. Results of these studies may (or may not) support the use of yoga. It is therefore unknown whether the results of these studies would impact the overall conclusions of this review.

Given the wide variety of active comparators, outcomes and conditions, an examination of the effectiveness of yoga compared with other forms of exercise or other interventions was not conducted.

Conclusions

The evidence provides moderate to low certainty that practising yoga is more effective than not practising yoga for many of the prioritised conditions and outcomes assessed in this review where evidence was available. However, the evidence also provides moderate to very low certainty that yoga has little (to no) benefit for some of the prioritised conditions and outcomes assessed in this review. For some of the prioritised outcomes there was no evidence available.

The results of this review are generally consistent with systematic reviews of yoga published up until January 2023, which conclude that whilst there is promising evidence for yoga to improve outcomes for some health conditions, there remains an absence of high certainty evidence that practising yoga is more effective than not practising yoga. Larger studies and more research on identified high priority conditions and outcomes would be helpful in reaching a definitive conclusion on the effectiveness of yoga for preventing and treating health conditions.

1 Background

In 2015, a review of yoga found low certainty evidence that yoga improves symptoms in people with depression and no clear evidence demonstrating its efficacy in treating any other clinical condition (6, 7). The 2015 review was underpinned by an overview of systematic reviews (SRs) that focused solely on yoga and were published in the English language between 2008 and December 2013. Randomised controlled trials (RCTs) that were reported within included SRs and assessed yoga delivered to treat any clinical condition were eligible, with outcomes selected according to predefined criteria. In this 2020 update, the evidence review was built upon the 2015 review but was not limited by publication date and a broader range of study types were eligible for inclusion (inclusive of quasi-randomised studies). This review also includes studies that assess yoga delivered to at-risk populations for primary prevention. Similar to the 2015 review, eligible comparisons include yoga versus inactive control and yoga versus other interventions. Studies not published in the English language were not translated but were listed in an evidence inventory for completeness, databases in languages other than English were not searched.

1.1 Description of the condition

Yoga is practised for a range of reasons and is intended to benefit physical health and psychological wellbeing. A 2012 survey of Australians practising yoga found that one in 5 did so for a specific health or medical reason (8). Practising yoga is claimed to improve health outcomes for a variety of clinical and preclinical conditions, including: symptoms associated with chronic pain and disability, such as osteoarthritis and rheumatoid arthritis (9, 10); mental health disorders, such as anxiety and depression (11, 12); chronic health conditions, such as diabetes and heart disease (13, 14); respiratory conditions, such as asthma (15) and chronic obstructive pulmonary disease (16); neurological conditions, such as epilepsy (17) and multiple sclerosis (18), as well as providing symptomatic relief in people with cancer (19). Yoga is also practiced by women to manage health conditions or symptoms associated with menstruation, childbirth, and menopause (20, 21).

Given the breadth of the review and variety of potential conditions for which yoga is used, a concise description of each prioritised population (or condition) is provided before each result (Section 4 Results).

Yoga can be practised in a range of settings (see Description of the intervention) and as such this review was not limited by setting.

1.2 Description of the intervention

Yoga is a traditional Indian discipline, incorporating various philosophies and spiritual practices (22). Current forms of yoga practice include many branches and various styles, but at its core are a set of principles and practices designed to promote health and wellbeing through the integration of body, breathing and mind (23, 24). In this regard, almost all forms of yoga are characterised by one or more of physical postures or poses (asanas), controlled breathing (pranayama) and meditation (dhyana) (23, 25, 26), delivered in accordance with yoga models of health, such as the *pancamaya kosha* (dimensions of the human system) and *guna* (fundamental forces of nature) (24). Yoga practice can also be expanded to include *asana* relaxation, *mudra* (energetic gestures and seals), *banda* (energy locks), *mantra* (sacred sounds), *bhavana* (imagery), and *sankalpa* (affirmation/intention). Yogic lifestyle and nutrition advice and education in yoga philosophy may also be delivered in accordance with a yoga educational framework (24).

Yoga can be practised at any time and in any location. It does not require specialist facilities or dedicated clothing and can be practised by anyone, regardless of age or level of fitness. Yoga can also be performed seated on chairs or on a mat or cushions on the floor. In some settings, yoga may be practised in a room with an elevated temperature or humidity. In Australia, yoga is often practised as a form of group exercise with the teaching style dependent on the expertise of the instructor. In addition, individualised yoga sessions may occur in a one-to-one setting. Individuals may also practise yoga at home, whilst viewing or listening to professional videos or other multimedia, without direct supervision.

Yoga sessions typically range from 45 to 90 minutes in length, with the structure of the session dependent on size and setting (gymnasium, yoga centre, home-based). Typically, a yoga class includes an introduction involving breathing exercises and/or relaxation, followed by a physical warm-up. Yoga postures, movements and stretches are then performed, followed by relaxation and/or meditation (27). Sometimes yoga sessions will focus entirely on meditation, commencing with introductory breathing exercises, relaxation, and inspirational readings, followed by mental focusing and meditation practices, and ending with a final return to outward focus and brief discussion (27).

While the training and accreditation of yoga instructors in Australia varies, Yoga Australia - the peak national body for registration and representation of yoga teachers in Australia - requires more than 350 hours of yoga teacher training to become a fully registered member of the association. However, those with at least 200 hours of training can acquire a provisional membership, which enables them to teach yoga.

1.3 How the intervention might work

The physical benefits of yoga are thought to be related to the regular practise of aerobic exercise, which improves heart function and enhances muscle flexibility, strength, balance and endurance (25, 26). In patients with pain conditions, it is postulated that yoga may stimulate physiological changes that lessen the feeling of pain through decreases in the activity of the sympathetic nervous system (28), reductions in inflammatory (29) and stress markers (30), and increases in flexibility and strength (31).

The breathing and posture techniques of yoga are thought to improve quality of life by influencing neurotransmitters that increase cognition, sleep and attention (32-34) and decrease negative symptoms such as depression and anxiety (35, 36). Other potential mechanisms for improved physical and mental well-being through practice of yoga are thought to be derived from practising controlled breathing or meditation exercises, and through the facilitation of motor learning to improve body awareness (25, 26, 37).

1.4 Why it is important to do this review?

In Australia, natural therapies, including yoga, are most often used in conjunction with conventional medicine and other strategies for maintaining good health and wellness. Yoga is also a popular form of exercise in Australia, with a 2013-14 survey estimating that approximately 320,000 Australians participated in yoga annually (38). Some people use yoga to manage health. To enable consumers, health care providers and policy makers to make informed decisions about care, the Australian Government will use this review to assist in deciding whether to reinclude yoga as eligible for private health insurance rebates.

The 2015 review identified 59 systematic reviews containing evidence from 111 unique RCTs involving 11 to 313 participants across 31 clinical conditions and concluded that, compared with control, there was low certainty evidence that yoga improves symptoms in people with depression compared with control. There was also very low certainty evidence to suggest that yoga may have some beneficial health effects in a limited number of conditions for a limited number of outcomes including people with cancer, insomnia, neurological, musculoskeletal, cardiovascular, mental health, endocrine, respiratory, renal and metabolic conditions, pregnant women in labour, smoking cessation rates in adults, children with health complications and menopausal women.

Compared to other comparators, the 2015 review concluded that there is very low certainty evidence that yoga may have beneficial effects relative to active comparators on selected outcomes in people with cancer, insomnia, neurological, musculoskeletal, cardiovascular, mental health and respiratory conditions, smoking cessation rates in adults, children with health complications and menopausal women.

Overall, the health effects of yoga were considered uncertain (6), due to the lack of studies for some clinical conditions, and inadequate reporting of information in the reviews and potentially in the primary studies. The reviewers noted that the body of evidence from RCTs was typically compromised by deficiencies in study design, noting uncertainty surrounding the magnitude of the effects and their relevance in clinical practice.

2 Objectives

To conduct a systematic review of RCTs to evaluate the effectiveness of yoga in individuals with a described injury, disease, medical condition, or pre-clinical condition.

The intent was to evaluate the evidence representative of the populations (or conditions) commonly seen by yoga instructors in Australia, the intervention(s) commonly used by the instructor, and outcomes that align with the reasons why patients use yoga and/or instructors administer yoga.

Table 1 lists the conditions identified and considered in this review and specifies whether studies were identified that assessed yoga versus the primary (inactive) or secondary (active) comparator. A prespecified prioritisation process aimed at making best use of the available evidence is described in **Appendix A6**.

Populations in order of priority are listed below:

- 1. Elevated perceived stress (including prevention of mental illness in at-risk populations)
- 2. Low back pain
- 3. Anxiety
- 4. Neck pain with or without shoulder pain
- 5. Depression
- 6. Insomnia and sleep disorders
- 7. Headache (incl tension, migraine)
- 8. Post-traumatic stress disorder
- 9. Chronic pain
- 10. Hypertension
- 11. Asthma
- 12. Pregnancy/post-partum
- 13. Menopausal symptoms (including peri- and post-menopausal women)
- 14. Joint pain (osteoarthritis, rheumatoid arthritis, etc.)
- 15. Premenstrual syndrome
- 16. Cancer
- 17. Gastrointestinal conditions (e.g. irritable bowel syndrome)
- 18. Obesity and overweight
- 19. Metabolic syndrome
- 20. Osteoporosis
- 21. Obsessive compulsive disorder

We planned to review the first 15 populations, but the volume of evidence meant it was not feasible to do so. As such, the top 11 populations were included in the evidence synthesis, with joint pain (condition 14) also being added into the chronic pain condition as agreed by NTWC. Studies in priority conditions not yet assessed (pregnancy, menopause) and studies in lower priority conditions (conditions 15 to 21) are listed in the evidence inventory, along with studies that met criteria for active comparators.

3 Methods

Methods reported in this systematic review are based on that described in the *Cochrane Handbook for Systematic Reviews of Interventions* (39) and relevant sections in the Joanna Briggs Institute Reviewer's manual (40). Covidence (www.covidence.org), a web-based platform for producing SRs, was used for screening citations and recording decisions made. Covidence is compatible with EndNote and Microsoft Excel, which were used for managing citations and data extraction, respectively. Where appropriate, RevMan (41) was used for the main analyses and GRADEpro GDT software (www.gradepro.org) was used to record decisions and derive an overall assessment of the certainty of evidence for each outcome guided by GRADE methodology (5).

Eligible studies were assigned to an appropriate *International Classification of Disease* (ICD-11) category based on the primary clinical condition reported in the study, such that each study only contributed data to one population (see Appendix A5.4). Populations and up to seven critical or important outcomes were prioritised to inform the data synthesis for the systematic review on the effects of yoga for preventing and treating health conditions. Throughout the population and outcome prioritisation exercise, NTWC remained blinded to the screening results (i.e. number of studies identified) and characteristics of included studies (e.g. study design, size, quality) to prevent any influence on decision-making (see Appendix A6). For prioritised conditions, risk of bias was assessed, appropriate data was extracted into data extraction tables, and the results summarised into appropriate categories according to identified populations, conditions and comparators.

Summary of Findings tables were developed for studies which compared yoga to control (main comparison) and which reported on outcomes rated as critical or important by NTWC. Summary of Findings tables included up to seven critical and important outcomes prioritised by NTWC who were guided by the GRADE framework (see Appendix A6.2 and Appendix B4).

The final approved review protocol was registered on the international prospective register of SRs (PROSPERO: CRD42020200084).

Further details on the methods and approach used to conduct the evidence evaluation are provided in Appendix A and Appendix B of the Technical Report, which outline the following:

- Appendix Al search methods
- Appendix A2 search strategy
- Appendix A3 search results
- Appendix A4 study selection criteria
- Appendix A5 selection of studies (inclusion decisions)
- Appendix A6 refining the research questions
- Appendix A7 summary screening results
- Appendix B1 risk of bias process
- Appendix B2 data extraction process
- Appendix B3 data analysis and synthesis
- Appendix B4 evidence statements

4 Results

4.1 Description of studies

4.1.1 Flow of studies

The literature was searched around 30 July 2020 to identify relevant studies published from database inception to the literature search date. The results of the literature search and the application of the study selection criteria are provided in Appendix A1 – A5 and Appendix C1 and C2.

A PRISMA flow diagram summarising the search and screening results is provided in Figure 1. The PRISMA flow diagram shows the number of studies at each stage of the search and screening process, including: the initial search, studies considered irrelevant based on the title and/or abstract, studies found not to be relevant when reviewed at full text, studies that met the eligibility criteria for inclusion in the review and the number of studies that were considered in the analysis for prioritised conditions.

The search retrieved 1049 citations corresponding to 519 studies that were eligible for inclusion. One additional study (not retrieved in the search) was identified and included from the Department's public call for evidence (see <u>Included studies</u>) the remaining studies provided from the Department's call were already identified in the search (see Appendix C2). A further 216 studies are <u>awaiting classification</u> and 308 studies recorded as <u>ongoing</u>.

4.1.2 Excluded studies

There were 1587 citations screened at full text that were excluded for not meeting the prespecified eligibility criteria. Of these, 688 studied an intervention out of scope (unable to assess yoga independent of other interventions), 347 had a study design out of scope (e.g. systematic review or non-randomised study), 303 studied a population out of scope (e.g. healthy population not at risk), 206 were of a publication type out of scope (e.g. opinion piece), 29 had a comparator out of scope (e.g. studies comparing different forms of yoga) and 14 citations were of clinical trials that had been withdrawn.

Citation details of the excluded studies can be found in Appendix C1. Note that some studies may have been out of scope for more than one reason, but only one reason is listed for each.

4.1.3 Studies awaiting classification

Studies that could not be retrieved or that met the inclusion criteria but contained insufficient or inadequate data for inclusion are listed in the *Citation details of studies awaiting classification* table (see Appendix C4). This includes 160 conference abstracts with incomplete information about the study (Appendix C4.1), 33 studies published in languages other than English that are possible eligible for inclusion (pending translation into English; Appendix C4.2), 14 studies for which publications were not able to be retrieved (Appendix C4.3) and 9 studies that were published after the literature search date (Appendix C4.5). There were also 6 studies that were unable to be translated or interpreted at the title/abstract stage (Appendix C4.4).

Among the 216 studies awaiting classification, 71 were conducted in a priority population^a, with 45 of those comparing yoga with an inactive control^b (no intervention, waitlist or usual care). The studies appeared to be comparable to those included in the evidence synthesis in terms of sample size, study duration and outcomes measured. Among those published in a language other than English, many were from similar (non-English) countries (i.e. India, Iran, Brazil, China, Japan, Germany) to those identified and included in the review.

^a 8 studies were in a language other than English.

^b 6 studies were in a language other than English.

4.1.4 Ongoing studies

Ongoing studies that do not have published results are listed in the *Characteristics of ongoing studies* table (see Appendix C5). Of the 308 ongoing studies, there were 22 studies listed as 'not yet recruiting', 80 studies listed as 'recruiting,' 10 studies that listed as 'active but not recruiting' and 17 studies listed as completed recruitment. A further 109 studies were listed as complete, but the study data were not yet available, and 16 studies had completed data synthesis, but results were not yet published. The status of 54 studies is unknown.

Among the 308 ongoing studies, 74 were conducted in a priority population and 32 were also listed as complete or unknown (i.e. might be complete) suggesting that they might have provided data. The ongoing studies appeared to be comparable to those included in the evidence synthesis in terms of sample size, study duration and outcomes measured. Many ongoing studies were found on Clinical trial registries of countries corresponding those identified and included in the review (i.e. India, Iran, Brazil, China).

4.1.5 Included studies

There were 520 studies (401 RCTs, 119 quasi RCTs) identified as eligible for inclusion in the review (see Figure 1). After prioritisation of the populations (or conditions) considered most relevant to the practise of yoga in Australia (see Appendix A6.1), 147 studies (118 RCTs, 29 quasi RCTs) were considered in the evidence evaluation (qualitative synthesis).

An overview of the conditions identified and included in this review is provided in provided in Table 1.

For the main comparison of yoga versus inactive control (no intervention, waitlist or usual care, if considered inactive), 95 studies were considered for quantitative synthesis. Those that included NTWC prioritised critical and important outcome domains and measures, were included in the final analysis. The prioritised outcome domains are highlighted in a blue box in Appendix FI. Yoga versus other active comparators are included in qualitative descriptions in the report, and results are listed in Appendix F2.

There were 373 studies that met the eligibility criteria for the review but were not included in the evidence evaluation. This is because they were either conducted in populations (or conditions) not prioritised by NTWC for analysis or synthesis (250 studies^c) or were conducted in populations that were of lower priority (123 studies^d). These studies are listed in an inventory titled *Citation details of studies from low and non-priority populations* (Appendix C3, Table C.3).

Appendix D provides detailed descriptions of the included studies, including an overview of the PICO criteria, a summary of the risk of bias assessment and results of the data synthesis for the main comparison. Descriptions of the included studies can be found in the *'Characteristics of included studies'* table (see Appendix F).

^{° 166} studies comparing yoga with control (no intervention, waitlist or usual care)

^d 82 studies comparing yoga with control (no intervention, waitlist or usual care)



Figure 1 Literature screening results: Yoga, randomised controlled trials

ICD-11	Population	N	Included as a priority population^	Included in main comparison			
01 Certai	n infectious and parasitic diseases						
	People living with HIV	5	No				
	Pulmonary tuberculosis	1	No				
02 Neopl	02 Neoplasms						
	Breast cancer (survivors)	20	Low				
	Breast cancer (undergoing treatment)	17	Low				
	Cancer, other (survivors)#	6	Low				
	Cancer, other (undergoing treatment) ##	9	Low				
03 Disea	ses of the blood or blood-forming organs		I	1			
	Sickle cell disease	1	No				
05 Endoo	crine, nutritional and metabolic diseases						
	Diabetes	27	No				
	Metabolic syndrome	10	Low				
	Obesity	11	Low				
	Polycystic ovary syndrome	2	No				
	Prediabetes	5	No				
06 Menta	al and behavioural disorders						
	Anxiety disorder (or symptoms of anxiety)	7	Yes	Yes			
	Depressive disorders (major depression, bipolar, postpartum) or symptoms of depression	20	Yes	Yes			
	Feeding-eating disorders	5	No				
	Neurocognitive	4	No				
	Neurodevelopmental	6	No				
	Obsessive-compulsive disorder	2	Low				
	Post-traumatic stress disorder	11	Yes	Yes			
	Psychiatric disorders	2	No				
	Schizophrenia and related	14	No				
	Substance abuse, rehabilitation	19	No				
07 Sleep	-wake disorders			1			
	Insomnia	3	Yes	Yes			
	Restless leg syndrome	2	No				
08 Disea	ses of the nervous system						
	Carpal tunnel syndrome	2	No				
	Chronic fatigue syndrome	1	No				
	Duchenne muscular dystrophy	1	No				
	Epilepsy	3	No				
	Guillain-Barre syndrome	1	No				
	Headache disorders	6	Yes	Yes			
	Multiple sclerosis	15	No				
	Parkinson's Disease	6	No				
	Stroke recovery	5	No				
09 Disea	ses of the visual system						
	Disorders of refraction and accommodation	2	No				
	Visual impairment	2	No				
10 Diseas	ses of the ear or mastoid process						
	Tinnitus	2	No				

Table 1 List of conditions and population groups identified and considered in this review

ICD-11	Population	Ν	Included as a priority population^	Included in main comparison
11 Disea	ses of the circulatory system		1	
	Cardiac arrhythmias (paroxysmal atrial fibrillation)	2	No	
	Cardiac rehabilitation	7	No	
	Heart disease	4	No	
	Heart failure	4	No	
	Hypertension	24	Yes	Yes
12 Disea	ses of the respiratory system		1	1
	Asthma	17	Yes	Yes
	Chronic obstructive pulmonary disease	10	No	
	Obstructive pulmonary disease (COPD or asthma)	1	No	
	Upper respiratory tract disorders	2	No	
13 Disea	ses of the digestive system			
	Functional gastrointestinal disorders	9	Low	
	Haemorrhoids (rehabilitation after surgery)	1	No	
	Inflammatory bowel disease	2	No	
	Pancreatitis	1	No	
	Periodontal disease	2	No	
15 Disea	ses of the musculoskeletal system or connective tissue			
	Deforming dorsopathies (kyphosis)	1	No	
	Frozen shoulder (adhesive capsulitis)	1	Yes	Yes [†]
	Inflammatory arthropathies	6	Yes	Yes‡
	Osteoarthritis	9	Yes	Yes‡
	Osteoporosis (with fracture)	1	No	
	Sarcopenia	1	No	
16 Disea	ses of the genitourinary system			
	Chronic kidney disease (on haemodialysis)	3	No	
	Dysfunctional uterine bleeding	1	No	
	Endometriosis	1	No	
	Female infertility (women undergoing IVF)	1	No	
	Fibroadenosis (benign breast disease)	1	No	
	Menstrual irregularities, mixed	4	No	
	Pelvic organ prolapse	1	No	
	Pelvic pain associated with genital organs or menstrual cycle	6	No	
	Premenstrual tension syndrome (with pelvic pain)	2	Yes*	No
	Premature ejaculation	1	No	
	Urinary incontinence	3	No	
18 Pregi	nancy, childbirth or the puerperium			
	Postpartum mothers	2	Yes*	No
	Pregnant women	25	Yes*	No
21 Symp	toms, signs or clinical finding, not elsewhere classified			
	Abnormalities of breathing (snoring, apnoea)	1	No	
	Aggressive behaviour (counterproductive work behaviour)	1	No	
	Chronic pain	4	Yes	Yes‡
	Emotional eating	1	No	
	Low back pain	22	Yes	Yes
	Menopausal symptoms or complaint	9	Yes*	No
	Neck pain (chronic)	5	Yes	Yes [†]
22 Iniur	v. poisoning or certain other consequences of external causes		I	I

ICD-11	Population	N	Included as a priority population^	Included in main comparison
	Burns (circumferential burn of chest)	1	No	
	Fractures (simple)	1	No	
	Hip fracture (elderly)	1	No	
	Injured workers (paraplegia, acquired limb amputations)	1	No	
	Spinal cord injury	2	No	
	Traumatic brain injury	1	No	
24 Facto	rs influencing health status or contact with health services			·
	Employment conditions, workers with elevated perceived stress or with burnout	5	Yes	Yes**
	Employment conditions, workers with musculoskeletal disorders of upper limbs (associated with overuse)	1	No	
	Employment conditions, workers with and without back pain	1	No	
	Social-cultural conditions, adults or students with elevated perceived stress (or seeking treatment)	7	Yes	Yes**
25 Preve	ntion		-	
	04 Diabetes, type 2	2	No	
	06 Aggression	1	No	
	06 Attention deficit & hyperactivity	1	No	
	06 Feeding-eating disorders (body dissatisfaction)	1	No	
	06 Substance abuse	1	No	
	11 Heart disease	2	No	
	21 Age-related decline, older adults	29	No	
	21 Falls, older adults	7	No	
	21 Menopausal symptoms and complaints	1	No	
Grand to	tal	520	185	95

Abbreviations: COPD, chronic obstructive pulmonary disease; HIV, human immunodeficiency virus; ICD-11, International Classification of Diseases for Mortality and Morbidity Statistics (ICD-11 MMS) 11th Revision; IVF, in vitro fertilisation.

inclusive of colorectal cancer, head and neck cancers, and myeloproliferative neoplasms

inclusive of gliomas, lymphomas and non-small cell lung cancer

† grouped as one condition Neck and/or shoulder pain

‡ combined as one condition Chronic pain – but with a separate Summary of Findings Table for Fibromyalgia.

* Due to the volume of evidence, and as agreed *a priori*, this population was not included in the evidence synthesis.

** combined in synthesis as one condition Stress

^ Studies marked as low priority were not included in the evidence synthesis.

4.2 Anxiety

4.2.1 Description of the condition

Anxiety is the most common mental health condition in Australia and the 6th largest contributor to burden of disease, with one in 4 people experiencing anxiety at some stage in their life (42, 43). While it is normal to feel anxious or stressed in certain situations, those with an anxiety disorder experience these symptoms more frequently and persistently without an obvious cause. Feelings of anxiety can impact quality of life and day-to-day functioning (42) and can also have significant direct and indirect economic consequences (44). It is not uncommon for anxiety disorders to become chronic, with the 12-month prevalence rate estimated at 17% and a lifetime prevalence rate of close to 25% (45).

There are different types of anxiety presenting with different symptoms, including generalised anxiety disorder, social anxiety, specific phobias, and panic disorders. Each type of anxiety disorder has its own features, however there are some common symptoms including excessive fear or worrying, panic attacks, racing heart, tightening of the chest, shortness of breath, and avoidance of situations that cause anxiety.

Treatments for anxiety focus on controlling symptoms to minimise their impact on daily life. This can include psychological treatments such as Cognitive Behavioural Therapy, medical treatments such as antidepressants, or an anxiety management strategy (42). A shift towards natural and holistic forms of therapy to assist pharmacological approaches or act as an alternative in a variety of anxiety-related conditions has seen increasing support from scientific evidence, clinical experience, and community attitudes. Meditation in the treatment of stress and related disorders is one such therapy that has the expectation of cognitive-behavioural benefits. This in turn can be extended to meditative forms of exercise such as Yoga and Tai Chi (46).

4.2.2 Description of studies

Eight citations (47-54) corresponding to 5 RCTs (Armat 2020, Bazzano 2018, de Manincor 2016, Parthasarathy 2014, Shaikh 2013) and 2 quasi RCTs (Gupta 2013, Han 2015) were identified in the literature. There were 4 <u>ongoing studies</u>, and 7 <u>studies awaiting classification</u> including one study published in a language other than English (55) and one study published after the literature search date (56, 57). No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D1.1.1.

All studies were carried out at single centres in either Australia (de Manincor 2016), China (Han 2015), India, (Gupta 2013, Parthasarathy 2014, Shaikh 2013), Iran (Armat 2020) or the United States (Bazzano 2018). Sample sizes ranged from 12 to 107 participants (total 353 participants), with 3 studies enrolling adults with a diagnosed anxiety disorder (Gupta 2013, Han 2015, Parthasarathy 2014), 2 studies enrolling adults (Shaikh 2013) or children (Bazzano 2018) with symptoms of anxiety, and 2 studies enrolling adults with symptoms of anxiety and/or depression (Armat 2020, de Manincor 2016).

Three studies (Armat 2020, de Manincor 2016, Parthasarathy 2014) compared yoga with no intervention or a waitlist control. Parthasarathy 2014 also included a third study group, being an integrated yoga module. In one study (Han 2015) participants received either yoga, auricular plaster therapy^e, or a combination of both interventions. The remaining 3 studies compared yoga with another intervention. Bazzano 2018 compared yoga with usual care that included counselling lead by the school social worker. Gupta 2013 compared yoga with naturopathy and Shaikh 2013 compared yoga with daily relaxation exercises.

Yoga sessions were typically 30 to 75 minutes in duration, with frequency ranging from twice per day to less than once per week.

Results for yoga versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see 4.2.4.1). Results of studies that compared yoga with another comparator are presented in Appendix F2.

^e Vaccaria seeds attached to medicine tape applied with pressure on selected ear acupoints.

4.2.3 Risk of bias - per item

The risk of bias for each item in the included RCTs for anxiety is presented in Figure 2. Details are provided in Appendix D1.1.2.

No studies were judged to be at overall low risk of bias.

Figure 2 Risk of bias summary: review author's judgements about each risk of bias item for each included study – Anxiety



4.2.4 Main comparison (vs control)

Three RCTs (Armat 2020, de Manincor 2016, Parthasarathy 2014) and one quasi RCT (Han 2015) comparing yoga with no intervention, usual care or waitlist control in people with anxiety or with symptoms of anxiety were eligible for this comparison and contributed data to 4 outcomes considered critical or important for this review.

There were 3 studies awaiting classification (152 participants) and one ongoing study^f (total 60 participants) that compared yoga with inactive control that could have contributed data to anxiety, life-satisfaction and quality of life outcomes (see Appendix C6). There are also 3 ongoing studies (total 529 participants) that had either completed recruitment or were still recruiting participants (see Appendix C5).

^f completed with results not available

4.2.4.1 Summary of findings and evidence statements

Yoga compared to control (no intervention, waitlist or usual care) for anxiety

Patient or population: Anxiety

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated absolute effects* (95% CI)		Relative	Nº of	Certainty of		
Outcomes	Risk with control	Risk with yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statement	
Anxiety symptoms assessed with: HAM-D, BAI, DASS- 21 (anxiety) (higher is worse) follow-up: range 6 to 12 weeks	-	SMD 1.14 SD lower ** (2.41 lower to 0.13 higher)	-	193 (3 RCTs) †	⊕○○○ VERY LOW a,b,c,d	The evidence is very uncertain about the effect of yoga on anxiety symptoms in people with anxiety.	
Quality of life – not reported	-	-	-	-	-	No studies found. The effect of yoga on health- related quality of life in people with anxiety is unknown.	
Perceived stress assessed with: DASS-21 (stress) (higher is worse) Scale from: 0 to 42 follow-up: 6 weeks	The mean DASS-21 score was 20.67	MD 4.12 points lower (7.54 lower to 0.7 lower)	-	101 (1 RCT)	⊕⊕⊖⊖ LOW ^{e,f,g}	Yoga may result in a slight reduction in distress in people with anxiety. ***	
Emotional function assessed with: SF- 12 MCS, Quality of Life Inventory-74 MCS (higher is better) follow-up: range 6 to 12 weeks	-	SMD 0.66 SD higher ** (0.3 higher to 1.01 higher)	-	131 (2 RCTs)	⊕⊕⊕O MODERATE _{e,h}	Yoga probably improves emotional functioning in people with anxiety.	
Physical function assessed with: SF- 12 PCS, Quality of Life Inventory-74 PCS (higher is better) follow-up: range 6 to 12 weeks	-	SMD 0.84 SD higher ** (1.32 lower to 3.0 higher)	-	131 (2 RCTs)	⊕OOO VERY LOW b,c,e,h	The evidence is very uncertain about the effect of yoga on physical functioning in people with anxiety.	
Sleep quality - not reported	-	-	-	-	-	No studies found. The effect of yoga on sleep quality in people with anxiety is unknown.	

Yoga compared to control (no intervention, waitlist or usual care) for anxiety

Patient or population: Anxiety

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	olute effects*	Deletive	NI0 - F	Certainty of		
Outcomes	Risk with control	Risk with yoga	effect (95% CI)	nª or participants (studies)	tne evidence (GRADE)	Evidence statement	
Life satisfaction - not reported	-	-	-	-	-	No studies found. The effect of yoga on life satisfaction in people with anxiety is unknown.	

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

** As a rule of thumb, an SMD of 0.2 is considered a small difference, 0.5 is medium, and 0.8 is large difference (58).

*** Effect estimates were considered on 3 levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).

+ Data from one RCT reporting an effect in favour of yoga was not included in the meta-analysis for this outcome (number of participants in the intervention/comparator groups not available).

BAI: Beck anxiety inventory; CI: confidence interval; DASS: depression, anxiety, stress scale; HAM-A: Hamilton Anxiety Rating Scale; MCS: mental component score; MD: mean difference; PCS: physical component score; SMD: standardised mean difference

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. No serious risk of bias. One RCT contributing over 30% of the data was judged at high risk of bias. In a sensitivity analysis examining the impact of this RCT, the size of the effect estimate decreased, but no change to the direction. Certainty of evidence not downgraded.

b. No serious inconsistency. Point estimates vary and confidence intervals of some studies do not overlap. The magnitude of statistical

heterogeneity was high (I² > 90%) but may be explained by variances in study PICOs. Certainty of evidence not downgraded.

c. Serious imprecision. Wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded.
 d. Publication bias suspected. Three studies awaiting classification and one ongoing study that could have contributed data to this outcome. There is a strong suspicion of non-reporting of results likely to be related to *p* value, direction, or magnitude of effect. Certainty of evidence downgraded.

e. Studies had some concerns but no serious risk of bias. Certainty of evidence not downgraded.

f. Serious imprecision. One study with wide confidence intervals contributing data. Certainty of evidence downgraded.

g. Publication bias suspected. One study (71 participants) that was complete but did not have published results could have contributed data to this outcome. There is a strong suspicion that non-reporting of results is likely to be related to *p* value, direction, or magnitude of effect. Certainty of evidence downgraded.

h. Publication bias suspected. One study (60 participants) that was complete but did not have published results could have contributed data to this outcome. There is a strong suspicion that non-reporting of results is likely to be related to *p* value, direction, or magnitude of effect. Certainty of evidence downgraded.

4.2.4.2 Forest plots

Outcome results related to anxiety symptoms in people with anxiety are presented in Figure 3.

Outcome results related to perceived stress in people with anxiety are presented in Figure 4. Outcome results related to emotional functioning in people with anxiety are presented in Figure 5. Outcome results related to physical functioning in people with anxiety are presented in Figure 6.

Figure 3 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Anxiety - anxiety symptoms

	Yoga			Control			9	Std. Mean Difference	Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI	
1.1.1 Hamilton Anxiety Rating Scale										
Han 2015 (1) Subtotal (95% CI)	12.2	4.11	15 15	15.19	3.99	15 15	32.2% 32.2%	-0.72 [-1.46, 0.02] - 0.72 [-1.46, 0.02]	•	
Heterogeneity: Not applicable										
Test for overall effect: Z = 1.90 (P = 0.06)										
1.1.2 Beck Anxiety Inventory										
Armat 2020 (2)	3.83	2.183	31	15	6.098	31	32.9%	-2.41 [-3.07, -1.75]		
Subtotal (95% CI)			31			31	32.9%	-2.41 [-3.07, -1.75]	\bullet	
Heterogeneity: Not applicable										
Test for overall effect: Z = 7.12 (P < 0.00001)										
1.1.3 Depression, Anxi	ety and S	Stress S	Scale -	anxiety	1					
de Manincor 2016	9.62	6.97	47	12.53	9.65	54	34.9%	-0.34 [-0.73, 0.05]		
Subtotal (95% CI)			47			54	34.9%	-0.34 [-0.73, 0.05]	•	
Heterogeneity: Not appl	icable									
Test for overall effect: Z	= 1.69 (P	9 = 0.09)							
1.1.4 Taylor Manifest A	nxiety S	cale								
Parthasarathy 2014 (3)	17.4	0	0	19.13	0	0		Not estimable		
Subtotal (95% CI)			0			0		Not estimable		
Heterogeneity: Not appl	icable									
Test for overall effect: N	ot applica	able								
T (1 (059) (01)						400	100.001			
Total (95% CI)			93			100	100.0%	-1.14 [-2.41, 0.13]		
Heterogeneity: Tau ² = 1.16; Chi ² = 27.79, df = 2 (P < 0.00001); l ² = 93%									-4 -2 0 2 4	
Test for overall effect: Z = 1.76 (P = 0.08)								Favours yoga Favours control		
Test for subgroup differences: Chi ² = 27.79, df = 2 (P < 0.00001), l ² = 92.8%										
Footnotes										

(1) Yoga + auricular plaster therapy vs. auricular plaster therapy

(2) Laughter yoga vs control(waitlist)

(3) Study reports a significant (p<0.05) post-test difference in favour yoga but does not report sample size or standard deviation.

Figure 4 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Anxiety - perceived stress



Figure 5 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Anxiety – emotional function ^

	Yoga			Control			ę	Std. Mean Difference		Std. Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI		IV, Random, 95% CI		
1.3.2 SF-12 Mental Component Summary Score												
de Manincor 2016	-34.06	7.28	47	-29.59	7.61	54	78.1%	-0.59 [-0.99, -0.19]				
Subtotal (95% CI)			47			54	78.1%	-0.59 [-0.99, -0.19]		\bullet		
Heterogeneity: Not app	licable											
Test for overall effect: 2	Z = 2.92	(P = 0	.004)									
1.3.4 Generic Quality of Life Inventory-74 Mental Component Summary Score												
Han 2015	-74.81	6.49	15	-68.92	6.57	15	21.9%	-0.88 [-1.63, -0.12]				
Subtotal (95% CI)			15			15	21.9%	-0.88 [-1.63, -0.12]				
Heterogeneity: Not app	licable											
Test for overall effect: 2	<u>Z</u> = 2.28	(P = 0	.02)									
1.3.5 Outcome not reported, probably because it was not measured												
Armat 2020	0	0	0	0	0	0		Not estimable				
Parthasarathy 2014	0	0	0	0	0	0		Not estimable				
Subtotal (95% CI)			0			0		Not estimable				
Heterogeneity: Not app	licable											
Test for overall effect: I	Not appli	cable										
Total (95% CI)			62			69	100.0%	-0.66 [-1.01, -0.30]		\bullet		
Heterogeneity: Tau² = 0.00; Chi² = 0.42, df = 1 (P = 0.52); l² = 0%								+		+		
Test for overall effect: Z = 3.64 (P = 0.0003)								-4	-2 U Z	4		
Test for subgroup differ	rences: (Chi² = (0.42, df	[;] = 1 (P =	= 0.52)	, l² = 0%	6					

Note: ^ Values inverted for consistency in direction of effect. Original scale reported in GRADE table.
Figure 6 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Anxiety – physical function ^

	Yoga Control					5	Std. Mean Difference	Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	IV, Random, 95% Cl
1.4.1 SF-12 Physical	Compon	ent Sı	ummar	y Score					
de Manincor 2016	-49.37	8.01	47	-51.03	6.72	54	51.7%	0.22 [-0.17, 0.62]	
Subtotal (95% CI)			47			54	51.7%	0.22 [-0.17, 0.62]	•
Heterogeneity: Not app	plicable								
Test for overall effect:	Z = 1.12	(P = 0	.26)						
1.4.3 Generic Quality	of Life I	nvento	ory-74	Physica	l Com	ponent	Summary	y Score	
Han 2015	-74.91	5.87	15	-62.33	6.47	15	48.3%	-1.98 [-2.88, -1.09]	— — —
Subtotal (95% CI)			15			15	48.3%	-1.98 [-2.88, -1.09]	\bullet
Heterogeneity: Not app	olicable								
Test for overall effect:	Z = 4.34	(P < 0	.0001)						
1.4.5 Outcome not re	ported, p	orobak	oly bec	ause it v	was no	ot meas	sured		
Armat 2020	0	0	0	0	0	0		Not estimable	
Parthasarathy 2014	0	0	0	0	0	0		Not estimable	
Subtotal (95% CI)			0			0		Not estimable	
Heterogeneity: Not app	plicable								
Test for overall effect:	Not appli	cable							
Total (95% CI)			62			69	100.0%	-0.84 [-3.00, 1.32]	
Heterogeneity: Tau ² =	2.31; Ch	i² = 19	.56, df :	= 1 (P <	0.000)1); l² =	95%		
Test for overall effect:	Z = 0.76	(P = 0	.45)						-4 -2 0 2 4 Favours Yoga Favours control
Test for subgroup diffe	erences: (Chi² = '	19.56, (df = 1 (P	< 0.00)001), l ^a	² = 94.9%		

Note: ^ Values inverted for consistency in direction of effect. Original scale reported in GRADE table.

4.3 Depression

4.3.1 Description of the condition

Depression is a highly prevalent mood disorder having the third highest burden of all diseases in Australia (59), affecting 1 in every 16 Australians (60) and more than 300 million people worldwide (61). Depression is characterised by intense feeling of sadness that impact one's physical and mental health for extended periods of time. Those experiencing depression will often report symptoms of low mood, loss of interest or pleasure in most activities, sleep disturbances, changes in appetite or unintentional changes of weight, decreased energy, either slowed or agitated movement, decreased concentration and, in some cases, feelings of guilt, worthlessness and thought of suicide (62). Depressive symptoms can become chronic, leading to substantial impairment in an individual's ability to function in everyday life (63).

There are several different types of depressive disorders that are characterised by the specific symptoms experienced by the person, as well as the severity of the symptoms - either mild, moderate, or severe. Major depressive disorder is the most commonly diagnosed depressive disorder in Australia, however, several other types including bipolar disorder, cyclothymic disorder, dysthymic disorder and seasonal affective disorder are also recognised with the Australian healthcare context (64). A variety of social, psychological, and biological factors contribute to depression. In particular, people who have experienced adverse life events are at higher risk of developing depression. In Australia, females are more likely to be diagnosed (60).

There are many known and effective treatments for depression that are highly dependent on the severity and pattern of depressive episodes. Traditional treatments offered by health-care providers include psychological treatments such as behavioural activation, cognitive behavioural therapy and interpersonal psychotherapy, and/or antidepressant medication (61). In additional to traditional therapy, prevention programmes and alternative treatments have been shown to reduce depression. Alternative interventions such as yoga, mindfulness, relaxation and breathing exercises are becoming increasingly population worldwide (65).

4.3.2 Description of studies

There were 25 citations (30, 65-88) corresponding to 13 RCTS (Bressington 2019, Buttner 2015, Chu 2017, Falsafi 2016, Kinser 2013, Kumar 2019b, Prathikanti 2017, Ravindran 2020, Sharma 2015a, Tolahunase 2018a, Tolahunase 2018b, Uebelacker 2017, Weinstock 2016) and 7 quasi RCTs (Janakiramaiah 2000, Sarubin 2014, Shahidi 2011, Sharma 2005, Wahbeh 2019, Whiddon 2011, Woolery 2004) identified in the literature search. There were 9 <u>ongoing studies</u> and 3 <u>studies awaiting classification</u> (89-91). No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D1.2.1.

Twelve studies were carried out at single centres, with 7 of these being provided through a hospital setting in Germany (Sarubin 2014), Hong Kong (Bressington 2019), India (Janakiramaiah 2000, Kumar 2019b, Sharma 2015a) or the United States (Ravindran 2020, Uebelacker 2017) and 5 being conducted in via outpatient or counselling centres across India (Sharma 2005, Tolahunase 2018a, Tolahunase 2018b) or the United States (Falsafi 2016, Prathikanti 2017). Eight studies enrolled participants from the community in Iran (Shahidi 2011), Taiwan (Chu 2017) or the United States (Buttner, 2015, Kinser 2013, Wahbeh 2019, Weinstock 2016, Whiddon 2011, Woolery 2004).

Fourteen studies (Bressington 2019, Falsafi 2016, Janakiramaiah 2000, Kinser 2013, Kumar 2019b, Prathikanti 2017, Ravindran 2020, Sarubin 2015, Sharma 2005, Sharma 2015a, Tolahunase 2018a, Tolahunase 2018b, Uebelacker 2017, Weinstock 2016) included participants diagnosed with a diagnosed mood disorder (e.g. major depression, dysthymia, bipolar, depression and/or anxiety). Five studies (Chu 2017, Shahidi 2011, Wahbeh 2019, Whiddon 2011, Woolery 2004) included participants not clinically diagnosed but had meet an enrolment criteria indicating symptoms of depression, and one study (Buttner 2015) enrolled participants who met criteria indicative of postpartum depression. Sample sizes ranged from 25 to 178 (total 1120).

Twelve studies compared yoga to control, being either no intervention (Falsafi 2016, Kumar 2019b, Shahidi 2011, Tolahunase 2018b), waitlist (Buttner 2015, Sharma 2015, Whiddon 2011) or usual activities/usual care (Bressington 2019, Chu 2017, Sarubin 2014, Sharma 2005, Woolery 2004). Six of these studies (Bressington 2019, Kumar 2019b, Sarubin 2014, Sharma 2005, Sharma 2015, Tolahunase 2018b) permitted participants to continue receiving standard medical care (e.g. antidepressants, counselling). Two other studies included a third treatment arm, being either mindfulness meditation (Falsafi 2016) or physical activity (Shahidi 2011). The inactive control arm of these studies was included in the main evidence synthesis.

Seven studies compared yoga to an active comparator, including a wellness education programme (Kinser 2013, Prathikanti 2017, Ravindran 2020, Uebelacker 2017), pharmacotherapy (Janakiramaiah 2000, Tolahunase 2018a), electroconvulsive therapy (Janakiramaiah 2000), a self-help book (Weinstock 2016) or a 2-day retreat (Wahbeh 2019), with Ravindran 2020 and Uebelacker 2017 allowing participants to continue with standard medical care (e.g. antidepressants, mood stabilisers).

The type of yoga practised varied from hatha or vinyasa yoga (inclusive of pranayamas, asanas and meditation) to yoga programs specifically designed for depression that focused on laughter, breathing or meditative techniques. Yoga sessions typically ranged from 30 to 90 minutes in duration, with frequency ranging from twice per day (at home or group practice several times per week) to once per week.

Results for yoga versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see 4.3.4.1). Results of studies that compared yoga with another comparator are presented in Appendix F2.

4.3.3 Risk of bias - per item

The risk of bias for each item in the included RCTs for depression (or symptoms of depression) is presented in Figure 7. Details are provided in Appendix D1.2.2.

No studies were judged to be at overall low risk of bias.

			P	lisk of bia	us domair	IS				
		D1	D2	D3	D4	D5	Overall			
	Bressington 2019	-	+	-	-	-	-			
	Buttner 2015	+	+	+	-	-	-			
	Chu 2017	-	+	-	-	-	-			
	Falsafi 2016	-	+	-	-	-	-			
	Janakiramaiah 2000	-	+	+	-	-	-			
	Kinser 2013	-	X	-	-	-	X			
	Kumar 2019	-	X	X	-	-	X			
	Prathikanti 2017	+	+	-	-	-	-			
	Ravindran 2020	+	-	X	-	-	X			
Лрг	Sarubin 2014	-	X	-	-	-	X			
Sti	Shahidi 2011	-	+	-	-	-	-			
	Sharma 2005	-	+	+	-	-	-			
	Sharma 2015	-	+	-	-	-	-			
	Tolahunase 2018b	+	+	-	-	-	-			
	Tolahunase 2018a	+	+	X	-	-	X			
	Uebelacker 2017	+	+	+	-	-	-			
	Wahbeh 2019	-	+	+	-	-	-			
	Weinstock 2016	-	+	-	-	-	-			
	Whiddon 2011	X	+	+	-	-	X			
	Woolery 2004	-	+	-	-	-	-			
		Domains:				Judgem	ent			
		D1: Bias a D2: Bias d	arising from due to devia	n the rando ations from	mization pro intended ir	ocess nterventi dis	įh			
		D3: Bias o	due to miss	ing outcom	ne data.	- So	me concerns			
	D4: Bias in measurement of the outcome. D5: Bias in selection of the reported result.									

Figure 7 Risk of bias summary: review author's judgements about each risk of bias item for each included study – Depression

4.3.4 Main comparison (vs control)

Twelve studies comparing yoga with control (no intervention, waitlist or usual care) in people with depression (diagnosed or with symptoms) were eligible for this comparison and contributed data to 6 outcomes considered critical or important for this review (Bressington 2019, Buttner 2015, Chu 2017, Falsafi 2016, Kumar 2019b, Sarubin 2014, Shahidi 2011, Sharma 2005, Sharma 2015a, Tolahunase 2018b, Whiddon 2011, Woolery 2004).

There were 3 studies awaiting classification (155 participants) and 5 ongoing studies⁹ (503 participants) that could have contributed data to this comparison for the outcomes of HRQoL, depression, perceived stress, and self-esteem (see Appendix C6).

^g completed with results not available or unknown status

4.3.4.1 Summary of findings and evidence statements

Yoga compared to control for Depression

Patient or population: Depression

Setting: Community

Intervention: Yoga

Comparison: control (no intervention, waitlist or usual care)

	Anticipated ab effects* (95% C	osolute CI)	Delative	Nº of	Certainty of	
Outcomes	Risk with control	Risk with yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statement
Quality of life assessed with: SF-36 (higher is better) Scale from: 0 to 100 follow-up: 8 weeks	The mean SF- 36 score was 63.18	MD 12.01 higher (4.67 higher to 19.35 higher)	-	56 (1 RCT)	⊕⊕⊖⊖ LOW ^{a,b}	Yoga may increase quality of life in people with depression.***
Life satisfaction assessed with: SWLS (higher is better) Scale from: 5 to 35 follow-up: mean 10 sessions	The mean life satisfaction score was 20	MD 5.9 higher (9.22 higher to 2.58 higher)	-	40 (1 RCT)	⊕⊕⊖⊖ Low ^{a,b}	Yoga may improve life satisfaction in people with depression.***
Symptoms of depression assessed with: HAM- D, BDI, DASS-21, MADRS or GDS (higher is worse) follow-up: range 25 days to 12 weeks	-	SMD 0.76 SD lower ** (1.07 lower to 0.46 lower)	-	434 (10 RCTs) †	⊕⊕⊕⊖ MODERATE _{c,d}	Yoga probably reduces symptoms of depression in people with depression.
Psychological distress – DASS-21 (stress) (higher is worse) Scale from: 0 to 42 follow-up: 4 weeks	The mean DASS-2 (stress) score was 25.11	MD 1.08 higher (3.17 lower to 5.33 higher)	-	50 (1 RCT)	⊕⊕⊖⊖ Low ^{a,b}	Yoga may result in little to no difference in psychological distress in people with depression.
Emotional function assessed with: SF-12 (mental) (higher is better) Scale from: 0 to 100 follow-up: 4 weeks	The mean SF- 12 (mental) score was 34.25	MD 0.32 lower (4.94 lower to 4.30 higher)	-	50 (1 RCT) ‡	⊕⊕⊖⊖ Low ^{a,b}	Yoga may result in little to no difference in emotional function in people with depression. ***
Perceived stress assessed with: PSS or SSI (higher is worse) follow-up: range 8 to 12 weeks	-	SMD 0.54 SD lower ** (1.06 lower to 0.02 lower)	-	72 (2 RCTs)	⊕⊕⊖⊖ LOW ^{e,f,g}	Yoga may reduce perceived stress in people with depression.
Self-compassion assessed with: Self- compassion scale (higher is better) follow-up: mean 8 weeks	-	SMD 0.83 SD lower ** (1.44 lower to 0.23 lower)	-	46 (1 RCT)	⊕⊕⊖⊖ LOW ^{a,b}	Yoga may result in a large increase in self- compassion in people with depression.

Yoga compared to control for Depression

Patient or population: Depression

Setting: Community

Intervention: Yoga

Comparison: control (no intervention, waitlist or usual care)

	Anticipated ab effects* (95% C	osolute CI)	Relative	N ⁰ of	Certainty of	
Outcomes	Risk with control	Risk with yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statement

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

** As a rule of thumb, an SMD of 0.2 represents a small difference, 0.5 is moderate, and 0.8 is a large difference (58).

*** Effect estimates were considered on 3 levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).

† Data from two studies (79 participants) not able to be included in the meta-analysis.

- [‡] Data from one study (28 participants) not reported by the study authors however the outcome is mentioned in-text. Data not available for inclusion in the meta-analysis.
- BDI: Beck depression inventory; CI: confidence interval; DASS-21: 21-item depression, anxiety, stress scale; HAM-D: Hamilton depression rating scale; MADRS: Montgomery-Asberg depression rating scale; MD: mean difference; SMD: standardised mean difference; SSI: Student-life stress inventory; SWLS: Satisfaction with life scale

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

- a. Serious imprecision. One study contributing data. Wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded.
- b. Publication bias suspected. Evidence is limited to one small trial. There is a strong suspicion of non-reporting of results likely to be related to the p value, direction or magnitude of effect. Certainty of evidence downgraded.
- c. Three studies contributing ~10% of the data were at high risk of bias not considered to seriously influence the results. Certainty of evidence not downgraded.
- d. Publication bias suspected. Visual inspection of the funnel plot suggests that poor methodological quality may have led to exaggerated results in smaller studies, and that smaller studies without statistically significant results may be unpublished. Six studies (553 participants) that could have contributed data to this outcome. There is a strong suspicion of non-reporting of results likely to be related to p-value, direction, or magnitude of effect. Certainty of evidence downgraded.
- e. Serious imprecision. Wide confidence intervals (upper and lower bounds overlap with both large and with no important difference). Certainty of evidence downgraded.
- f. Publication bias suspected. Evidence is limited to two small trials. There is a strong suspicion of non-reporting of results likely to be related to the p value, direction or magnitude of effect. Certainty of evidence downgraded.
- g. No serious indirectness. The available evidence is in women but could be sensibly applied to the broader population. Certainty of evidence not downgraded.

4.3.4.2 Forest plots

Outcome results related to HRQoL in people with depression are presented in Figure 8.

Outcome results related to life satisfaction in people with depression are presented in Figure 9.

Outcome results related to symptoms of depression in people with depression are presented in Figure 10.

Outcome results related to psychological distress in people with depression are presented in Figure 11.

Outcome results related to emotional function in people with depression are presented in Figure 12.

Outcome results related to stress in people with depression are presented in Figure 13

Outcome results related to self-compassion in people with depression are presented in Figure 14.

Figure 8 Forest plot of comparison: Yoga vs control (no intervention, waitlist or usual care): Depression – health-related quality of life^



Test for subgroup differences: Not applicable

Note: ^ Values inverted for consistency in direction of effect. Original scale reported in GRADE table.

Figure 9 Forest plot of comparison: Yoga vs control (no intervention, waitlist or usual care): Depression – life satisfaction^

		Yoga Control		Mean Difference		Mean Difference				
Study or Sul	bgroup M	ean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
2.2.1 Diener	life satisfact	ion s	cale							
Shahidi 2011 Subtotal (95	-2 % CI)	25.9	5.6	20 20	-20	5.1	20 20	100.0% 100.0%	-5.90 [-9.22, -2.58] - 5.90 [-9.22, -2.58]	-
Heterogeneit	y: Not applica	ble								
Test for over	all effect: Z =	3.48	(P = (0.0005)					
Total (95% C	:1)			20			20	100.0%	-5.90 [-9.22, -2.58]	
Heterogeneit	y: Not applica	ble								-20 -10 0 10 20
Test for over	all effect: Z =	3.48	(P = (0.0005)					Favours voga Favours control
Test for subg	roup differend	ces: N	lot ap	pplicab	le					, , , , , , , , , , , , , , , , , , , ,

Note: ^ Values inverted for consistency in direction of effect. Original scale reported in GRADE table.

Depression – symptoms of depression Std. Mean Difference Control Std. Mean Difference Yoga IV, Random, 95% CI Study or Subgroup Mean SD Total Mean SD Total Weight IV, Random, 95% CI 2.3.1 Hamilton Depression Rating Scale Buttner 2015 12.0% -0.46 [-0.99. 0.08] 5.87 6.03 27 8.52 5.43 29 4.26 Sharma 2005 8.27 4.37 15 11.53 15 8.9% -0.74 [-1.48, 0.01] Sharma 2015 (1) -9.77 6.8505 0.5 6.4779 12 7.1% 13 -1.49 [-2.39, -0.58] 31 Not estimable

27.9%

-0.80 [-1.36, -0.24]

Figure 10 Forest plot of comparison: Yoga vs control (no intervention, waitlist or usual care):

87

Sarubin 2014	0	0	22	0	0
Subtotal (95% CI)			77		
Heterogeneity: Tau ² = 0.1	1; Chi² =	3.72, d	f = 2 (P	= 0.16);	l² = 46%
Test for overall effect: Z =	2.81 (P	= 0.005)		

Tolahunase 2018b 11.7% 17.34 6.4 29 23.66 5.52 29 -1.04 [-1.59, -0.49] 23 21.2 23 Falsafi 2016 9.1 5 10.9 10.1% -1.40 [-2.05, -0.75] Chu 2017 9.51 13 21.15 11.28 13 16.85 8.4% -0.40 [-1.18, 0.38] Woolery 2004 3.9 4.66 10 4.32 13 6.6% 11 -1.53 [-2.49, -0.57] Whiddon 2011 (2) 0 12 0 14 Not estimable 0 0 Subtotal (95% CI) 92 36.8% 87 -1.08 [-1.53, -0.63] Heterogeneity: Tau² = 0.08; Chi² = 4.76, df = 3 (P = 0.19); I² = 37% Test for overall effect: Z = 4.74 (P < 0.00001) 2.3.3 Depression, Anxiety and Stress Scale Bressington 2019 23.1 9.6396 23 24.07 9.2492 27 11.6% -0.10 [-0.66, 0.46] Subtotal (95% CI) 23 27 11.6% -0.10 [-0.66, 0.46] Heterogeneity: Not applicable Test for overall effect: Z = 0.36 (P = 0.72)

2.3.4 Montgomery-Asber Depression Scale

2.3.2 Beck Depression Inventory

Kumar 2019 (3)	-24.43	7.78	40	-21.7	7.35	40	13.5%	-0.36 [-0.80, 0.08]
Subtotal (95% CI)			40			40	13.5%	-0.36 [-0.80, 0.08]
Heterogeneity: Not a	pplicable							
Test for overall effec	t: Z = 1.58 (F	o = 0.11)						

6.1

20

20

10.2%

10.2%

-0.78 [-1.43, -0.14]

-0.78 [-1.43, -0.14]

-0.76 [-1.07, -0.46]

-2

-4

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Favours yoga Favours control

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4

2.3.5 Geriatric Depression Scale Shahidi 2011 10 6.9 20 15.2 Subtotal (95% CI) 20 Heterogeneity: Not applicable

Test for overall effect: Z = 2.38 (P = 0.02)

266 100.0% Total (95% CI) 247 Heterogeneity: Tau² = 0.13; Chi² = 19.99, df = 9 (P = 0.02); l² = 55% Test for overall effect: Z = 4.93 (P < 0.00001) Test for subgroup differences: $Chi^2 = 9.41$, df = 4 (P = 0.05), l² = 57.5%

Footnotes

(1) Change from baseline

(2) Individual treatment group scores not reported. Point estimate favours yoga

(3) Change from baseline

Figure 11 Forest plot of comparison: Yoga vs control (no intervention, waitlist or usual care): Depression – psychological distress

	Yoga Control				Mean Difference	Mean Difference		
Study or Subgroup	Mean S	D Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	CI IV, Random, 95% CI
2.4.3 Depression, An	xiety and Stre	ss Scale -	- Stress	s subsca	ale			
Bressington 2019 Subtotal (95% CI)	26.19 8.392	7 23 23	25.11	6.6511	27 27	100.0% 100.0%	1.08 [-3.17, 5.33] 1.08 [-3.17, 5.33]	
Heterogeneity: Not app Test for overall effect:	olicable Z = 0.50 (P = 0	.62)						
Total (95% CI) Heterogeneity: Not app Test for overall effect: Test for subgroup diffe	olicable Z = 0.50 (P = 0 rences: Not ap	23 .62) plicable			27	100.0%	1.08 [-3.17, 5.33]	-10 -5 0 5 10 Favours yoga Favours control

Figure 12 Forest plot of comparison: Yoga vs control (no intervention, waitlist or usual care): Depression – emotional function^

		Yoga		(Control			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
2.7.1 SF-12 (mental)									
Bressington 2019 (1) Subtotal (95% Cl)	-33.93	9.3519	23 23	-34.25	6.8589	27 27	100.0% 100.0%	0.32 [-4.30, 4.94] 0.32 [-4.30, 4.94]	
Heterogeneity: Not appl	licable								
Test for overall effect: Z	2 = 0.14 (P = 0.89)						
2.7.2 Profile of Mood S	States								
Woolery 2004 (2) Subtotal (95% CI)	0	0	13 13	0	0	15 15		Not estimable Not estimable	
Heterogeneity: Not appl	licable								
Test for overall effect: N	lot applic	able							
Total (95% CI)			36			42	100.0%	0.32 [-4.30, 4.94]	
Heterogeneity: Not appl	licable							_	
Test for overall effect: Z	2 = 0.14 (P = 0.89)						-4 -2 U 2 4 Eavours voga Eavours control
Test for subgroup differ	ences: N	lot applic	able						Favours yoga Favours control
Footnotes									

(1) Significant difference favouring control at baseline

(2) Profile of Mood States is mentioned in-text as an outcome, but not reported in the results

Note: ^ Values for SF-12 mental score inverted for consistency in direction of effect. Original scale reported in GRADE table.

Figure 13 Forest plot of comparison: Yoga vs control (no intervention, waitlist or usual care): Depression – perceived stress

	`	Yoga Control				5	Std. Mean Difference	Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	IV, Random, 95% CI
2.5.1 Perceived stres	s scale								
Chu 2017 Subtotal (95% CI)	27.62	9.91	13 13	29.62	8.53	13 13	39.7% 39.7%	-0.21 [-0.98, 0.56] - 0.21 [-0.98, 0.56]	
Heterogeneity: Not ap	plicable								
Test for overall effect:	Z = 0.53	(P = 0).59)						
2.5.2 Study-life stress	s invent	ory							
Falsafi 2016 Subtotal (95% CI)	1.7	0.6	23 23	2.2	0.7	23 23	60.3% 60.3%	-0.75 [-1.35, -0.15] - 0.75 [-1.35, -0.15]	•
Heterogeneity: Not ap	plicable								
Test for overall effect:	Z = 2.46	(P = 0).01)						
Total (95% CI)			36			36	100.0%	-0.54 [-1.06, -0.02]	•
Heterogeneity: Tau ² =	0.02; Cł	ni² = 1.	19, df =	= 1 (P =	0.27);	l² = 16º	%		
Test for overall effect: Z = 2.02 (P = 0.04)									-Z -I U I Z
Test for subgroup diffe	erences:	Chi² =	1.19, d	lf = 1 (P	= 0.27	7), ² = ′	16.1%		i avouis yoga i avouis contiol

Figure 14 Forest plot of comparison: Yoga vs control (no intervention, waitlist or usual care): Depression – self-compassion^

	Y	Yoga Control				I		Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
2.6.1 Self-compassion	n scale								
Falsafi 2016 Subtotal (95% CI)	-3	0.6	23 23	-2.4	0.8	23 23	100.0% 100.0%	-0.83 [-1.44, -0.23] - 0.83 [-1.44, -0.23]	
Heterogeneity: Not app Test for overall effect: 2	olicable Z = 2.70	(P =	0.007)						
Total (95% CI) Heterogeneity: Not app	blicable	,	23			23	100.0%	-0.83 [-1.44, -0.23]	-4 -2 0 2 4
Test for overall effect:	∠ = 2.70	(P =	0.007)	.1.					Favours yoga Favours control

Test for subgroup differences: Not applicable

Note: A Values inverted for consistency in direction of effect. Original scale reported in GRADE table.

4.4 Post-traumatic stress disorder

4.4.1 Description of the condition

Post-traumatic stress disorder (PTSD) occurs from exposure to traumatic events such as war, assault, kidnap, terrorist attacks, torture, natural disasters or severe motor vehicle accidents, resulting in psychological distress and trauma (92). Psychological symptoms of distress usually settle in the days to weeks following the traumatic event. However, a minority of people have persisting symptoms and develop acute stress disorder or PTSD. Symptoms of PTSD for more than one month are characterised by intrusive thoughts or feelings related to the traumatic event, persistent avoidance of stimuli associated with the traumatic event, negative thoughts or feelings, and marked alterations in reactivity and arousal (e.g. irritability, aggression, difficulty concentrating (92, 93). Individuals with PTSD may commonly have comorbid problems, substance use, major depression, or somatic complaints (92).

In Australia, 2.4 million Australian adults experience high to severe psychological distress (94). An estimated 12% of Australians experience PTSD in their life (lifetime prevalence), with women being at almost twice the risk of men (15.8% and 8.6%, respectively) (94).

Effective treatments for PTSD include counselling, meditation or a combination of both (93). Psychotherapy treatments for PTSD include trauma-focused cognitive behaviour therapy (TF-CBT) (92). Treatment recommendations may include exercise and physical therapies, with complementary alternative treatments recommended by Australian guidelines, including acupuncture, Taoism, and Yoga (92).

4.4.2 Description of studies

Seventeen citations (95-111) corresponding to 9 RCTs (Davis 2020, Huberty 2018, Jindani 2015, Martin 2015, Quinones 2015, Reddy 2013, Reinhardt 2018, Seppala 2014, Telles 2010) and 2 quasi RCTs (Culver 2015, Van Der Kolk 2014) were identified in the literature search. There were 7 <u>ongoing studies</u> and 3 <u>studies awaiting</u> <u>classification</u> including 2 studies published after the literature search date (112-114). No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D1.3.1.

All studies were carried out at single centres in a variety of countries including Canada (Jindani 2015), Colombia (Quinones 2015), India (Telles 2010) and the United States (Culver 2015, Davis 2020, Huberty 2018, Martin 2015, Reddy 2013, Reinhardt 2018, Seppala 2014, Van Der Kolk 2014). Participant ages ranged between 18 and 65 years in all studies except one (Culver 2015) that enrolled children aged between 7 and 17 years. Sample sizes ranged from 21 to 212 participants (total 727).

Participants were enrolled based on several criteria. Three studies (Davis 2020, Reinhardt 2018, Van der Kolk 2014) included participants with confirmed PTSD diagnosis, with Van der Kolk 2014 enrolling participants with treatment resistant PTSD and a prior 3 months of treatment. Four studies (Jindani 2015, Martin 2015, Quinones 2015, Reddy 2013) enrolled participants based on scores received in a range of PTSD-related tests including the PTSD Checklist (PCL-17), the PTSD Symptom Scale-Interview (PSS-I) and the Primary Care PTSD screen (PC-PTSD). Four studies included participants based on life experience such as those in orphanages (Culver 2015), veterans (Seppala 2014), flood survivors (Telles 2010), and women who had experienced a stillbirth in the last 6 to 24 weeks and achieved a minimum score on the Impact of Events Scale (Huberty 2018).

There were 7 studies that compared yoga exercises (with and without equipment) with an inactive control, being either no intervention (Martin 2015, Reinhardt 2018), waitlist (Jindani 2015, Seppala 2014, Telles 2010) or usual care/activities (Quinones 2015, Reddy 2013). Four studies compared yoga with an active comparator including: physical activity (Culver 2015, Huberty 2018), lifestyle modification (Davis 2020) and wellness education program (Van Der Kolk 2014).

In most studies, a typical yoga session was between 45 and 90 minutes in duration; however, one study (Seppala 2014) had sessions run for 3 hours. Program intensity was predominantly one to 2 sessions a week. Two studies required yoga sessions be performed daily for a week (Seppala 2014, Telles 2010). Program durations included one week (Seppala 2014, Telles 2010), 8 weeks (Culver 2015, Jindani 2015), 10 weeks (Van Der Kolk 2014, Reinhardt 2018), 12 weeks (Huberty 2018, Martin 2015, Quinones 2015), and 16 weeks (Davis 2020). In one study (Reddy 2014) the treatment program options were 6 weeks or 12 weeks, depending on participant preference.

Results for yoga versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see Section 4.4.4.1) and Appendix F2. Results of the RCTs comparing yoga with an active comparator are presented in Appendix F2.

4.4.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 15. Details are provided in Appendix D1.3.2. No studies were judged to be at overall low risk of bias.

Figure 15 Risk of bias summary: review author's judgements about each risk of bias item for each included RCT – Post-traumatic stress disorder



4.4.4 Main comparison (vs control)

Seven RCTs comparing yoga with control (no intervention, usual care, waitlist) in people with PTSD were eligible for this comparison, 4 of which contributed data relevant to 5 outcomes considered critical or important for this review (Jindani 2015, Reddy 2013, Seppala 2014, Telles 2010). The other 3 RCTS (Martin 2015, Quinones 2015, Reinhardt 2018) did not measure or report data for the specified outcomes.

There were no studies awaiting classification and 5 ongoing studies^h (total 252 participants) that compared yoga with inactive control in people with PTSD that could have contributed data to several outcomes (see Appendix C6). An additional 2 studies (total 276 participants) were still recruiting participants (see Appendix C5).

^h completed but results were not available or unknown status

4.4.4.1 Summary of findings and evidence statements

Yoga compared to control for post-traumatic stress disorder

Patient or population: post-traumatic stress disorder

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abso (95% CI)	olute effects*	Delative	Nº of	Certainty of	
Outcomes	Risk with control	Risk with yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statement
Symptoms of anxiety assessed with: DASS-21 (anxiety), MASQ, STAI, VAS. follow-up: range 7 days to 8 weeks	-	SMD 0.32 SD lower ** (0.68 lower to 0.05 higher)	-	118 (4 RCTs)	⊕○○○ VERY LOW _{a,b,c}	The evidence is very uncertain about the effect of yoga on anxiety in people with PTSD.
Perceived stress assessed with: PSS (higher is worse) Scale from: 0 to 40 follow-up: mean 8 weeks	The mean perceived stress score was 21.6	MD 9.2 lower (13.83 lower to 4.57 lower)	-	50 (1 RCT)	⊕OOO VERY LOW c,d,e	The evidence is very uncertain about the effect of yoga on perceived stress in people with PTSD. ***
Emotional function assessed with: Resilience scale (higher is better) Scale from: 25 to 175 follow-up: mean 8 weeks	The mean RS score was 112.4	MD 13.6 lower (26.86 lower to 0.34 lower)	-	50 (1 RCT)	⊕OOO VERY LOW c,d,e	The evidence is very uncertain about the effect of yoga on emotional function in people with PTSD. ***
Quality of life - not reported	-	-	-	-	-	No studies found. The effect of yoga on quality of life in people with PTSD is unknown.
Physical functioning / mobility - not reported	-	-	-	-	-	No studies found. The effect of yoga on physical functioning/ mobility in people with PTSD is unknown.
Symptoms of depression assessed with: DASS-21 or CES-D (higher is worse) follow-up: mean 8 weeks	-	SMD 0.14 SD lower ** (0.6 lower to 0.31 higher)	-	76 (2 RCTs)	⊕○○○ VERY LOW _{b,c,f}	The evidence is very uncertain about the effect of yoga on depression in people with PTSD.

Yoga compared to control for post-traumatic stress disorder

Patient or population: post-traumatic stress disorder

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	olute effects*	Pelative	Nº of	Certainty of		
Outcomes	Risk with control	Risk with yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statement	
Sleep quality assessed with: ISI (higher is worse) Scale from: 0 to 28 follow-up: 8 weeks	The mean ISI score was 16.4	SMD 0.90 SD lower ** (1.49 lower to 0.31 lower)	-	50 (1 RCT)	⊕OOO VERY LOW c,d,e	The evidence is very uncertain about the effect of yoga on sleep quality in people with PTSD.	

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

** As a rule of thumb, an SMD of 0.2 is considered a small difference, 0.5 is medium, and 0.8 is large difference (58).

- *** Effect estimates were considered on 3 levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).
- CI: confidence interval; BDI-II: Beck depression inventory; CES-D: Center for Epidemiological Studies depression scale; DASS: Depression, Anxiety and Stress Scale; ISI: insomnia severity index; MASQ: Mood and anxiety symptoms questionnaire; MD: mean difference; PSS: Perceived stress scale; SMD: standardised mean difference; STAI: state-trait anxiety inventory; VAS: visual analogue scale

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. Serious risk of bias. One study contributing ~42% of data was at high risk of bias. Meta-analysis results were not robust against a sensitivity analysis involving removal of studies at high risk of bias. Certainty of evidence downgraded.

b. Serious imprecision. Wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded.

c. Publication bias suspected. Four ongoing studies (252 participants) that could have contributed data to this outcome. There is a strong suspicion of non-reporting of results likely to be related to the p value, direction or magnitude of effect. Certainty of evidence downgraded.

d. Serious risk of bias. One study contributing 100% of the data was at high risk of bias. Certainty of evidence downgraded.

e. Serious imprecision. Wide confidence intervals (upper and lower bounds overlap with both a large and small important difference). Certainty of evidence downgraded.

f. Serious risk of bias. One study contributing ~65% of data was at high risk of bias. Certainty of evidence downgraded.

4.4.4.2 Forest plots

Outcome results related to anxiety in people with PTSD are presented in Figure 16.

Outcome results related to perceived stress in people with PTSD are presented in Figure 17.

Outcome results related to emotional function in people with PTSD are presented in Figure 18.

Outcome results related to depression in people with PTSD are presented in Figure 19.

Outcome results related to sleep in people with PTSD are presented in Figure 20.

Figure 16 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): PTSD – anxiety

	Yoga Control				5	Std. Mean Difference	Std. Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
1.1.1 Depression, An	xiety and	d Stres	s Scal	e (DASS	S 21-D)				
Jindani 2015	5.7	4.3	29	7.8	5.5	21	41.9%	-0.43 [-1.00, 0.14]	
Subtotal (95% CI)			29			21	41.9%	-0.43 [-1.00, 0.14]	\bullet
Heterogeneity: Not ap	plicable								
Test for overall effect: Z = 1.47 (P = 0.14)									
1.1.2 Mood and anxiety symptoms questionnaire (MASQ)									
Seppala 2014	101.4	26.6	10	121.4	19.4	10	16.0%	-0.82 [-1.74, 0.10]	_
Subtotal (95% CI)			10			10	16.0%	-0.82 [-1.74, 0.10]	
Heterogeneity: Not ap	plicable								
Test for overall effect:	Z = 1.75	(P = 0.	08)						
1.1.3 State-trait anxie	ety inven	tory							
Reddy 2013 (1)	42	16.84	14	40.7	13.61	12	22.8%	0.08 [-0.69, 0.85]	
Subtotal (95% CI)			14			12	22.8%	0.08 [-0.69, 0.85]	•
Heterogeneity: Not ap	plicable								
Test for overall effect:	Z = 0.21	(P = 0.	84)						
1.1.4 Visual analogu	e scale								
Telles 2010	4.49	2.64	11	4.88	3.15	11	19.3%	-0.13 [-0.97, 0.71]	_
Subtotal (95% CI)			11			11	19.3%	-0.13 [-0.97, 0.71]	
Heterogeneity: Not ap	plicable								
Test for overall effect:	Z = 0.30	(P = 0.	76)						
Total (95% CI)			64			54	100.0%	-0.32 [-0.68, 0.05]	•
Heterogeneity: Tau ² =	0.00; Ch	i² = 2.5	2, df =	3 (P = 0	.47); l ²	= 0%			
Test for overall effect:	Z = 1.69	(P = 0.	, 09)	- (-	,,				-4 -2 0 2 4
Test for subgroup diffe	erences:	Chi² = 2	52, df	= 3 (P =	= 0.47),	l² = 0%			Favours yoga Favours control
Footnotes									
(1) state subscore.									

Figure 17 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): PTSD – perceived stress

	Yoga Control				Mean Difference	Mear	Mean Difference				
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% C	IV, Ra	ndom, 95% Cl	
1.2.1 Perceived stress	s scale										
Jindani 2015 Subtotal (95% CI)	12.4	11.4	29 29	21.6	4.8	21 21	100.0% 1 00.0%	-9.20 [-13.83, -4.57] -9.20 [-13.83, -4.57]			
Heterogeneity: Not app	licable										
Test for overall effect: Z	Z = 3.90	(P < (0.0001)								
1.2.2 outcome not rep	orted										
Reddy 2013	0	0	14	0	0	12		Not estimable			
Seppala 2014	0	0	10	0	0	10		Not estimable			
Telles 2010	0	0	11	0	0	11		Not estimable			
Subtotal (95% CI)			35			33		Not estimable			
Heterogeneity: Not app Test for overall effect: N	olicable Not appl	icable									
Total (95% CI)			64			54	100.0%	-9.20 [-13.83, -4.57]			
Heterogeneity: Not app	licable										<u> </u>
Test for overall effect: 2	Z = 3.90	(P < 0	0.0001)						-20 -10 Eovouro vo	U 10	20
Test for subgroup differ	rences:	Not ap	plicabl	е					Favours yo	ya Favours control	

Figure 18 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): PTSD – emotional function^

	Yoga Control				Mean Difference			ifference				
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% C	l	IV, Rand	om, 95% Cl	
1.3.1 Resilience scale												
Jindani 2015 Subtotal (95% CI)	-124.7	23.2	29 29	-111.1	23.9	21 21	100.0% 100.0%	-13.60 [-26.86, -0.34] -13.60 [-26.86, -0.34]			-	
Heterogeneity: Not app	licable											
Test for overall effect: Z	2 = 2.01	(P = 0	.04)									
1.3.2 outcome not rep	orted											
Reddy 2013	0	0	14	0	0	12		Not estimable				
Seppala 2014	0	0	10	0	0	10		Not estimable				
Telles 2010	0	0	11	0	0	11		Not estimable				
Subtotal (95% CI)			35			33		Not estimable				
Heterogeneity: Not app	licable											
Test for overall effect: N	lot appli	cable										
Total (95% CI)			64			54	100.0%	-13.60 [-26.860.34]			-	
Heterogeneity: Not and	licable		• •			• ·	,.		+		+	+
Test for overall offect: 7	7 - 201	(D – 0	04)						-50	-25	0 25	50
Test for subgroup differ	. – 2.011	(F - 0	.04) aliaahla							Favours yoga	Favours control	
i est for subgroup differ	ences: N	vot ap	plicable									

Note: ^ Values inverted for consistency in direction of effect. Original scale reported in GRADE table.

Figure 19 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): PTSD – depression

	١	′oga		c	ontrol		5	Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
1.4.1 Depression, An	xiety and	Stres	s Scal	e (DASS	S 21-D)				
Jindani 2015	6	4.3	29	7.2	5.1	21	65.2%	-0.25 [-0.82, 0.31]	
Subtotal (95% CI)			29			21	65.2%	-0.25 [-0.82, 0.31]	
Heterogeneity: Not app	olicable								
Test for overall effect:	Z = 0.88 ((P = 0.3	38)						
1.4.2 Center for Epide	emiologio	cal Stu	idies- I	Depress	sion sca	ale (CE	S-D)		
Reddy 2013	22.5	15.82	14	21.64	11.21	12	34.8%	0.06 [-0.71, 0.83]	_
Subtotal (95% CI)			14			12	34.8%	0.06 [-0.71, 0.83]	
Heterogeneity: Not app	olicable								
Test for overall effect:	Z = 0.15 ((P = 0.	88)						
1.4.3 outcome not rep	ported								
Seppala 2014	0	0	10	0	0	10		Not estimable	
Telles 2010	0	0	11	0	0	11		Not estimable	
Subtotal (95% CI)			21			21		Not estimable	
Heterogeneity: Not app	plicable								
Test for overall effect:	Not applie	cable							
Total (95% CI)			64			54	100.0%	-0.14 [-0.60, 0.31]	-
Heterogeneity: Tau ² =	0.00; Chi	² = 0.4	1, df =	1 (P = 0	.52); l² :	= 0%		—	
Test for overall effect:	Z = 0.62 (P = 0.	53)						-2 -1 U I Z
Test for subgroup diffe	rences: C	chi² = 0	.41, df	= 1 (P =	= 0.52),	l² = 0%			

Figure 20 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): PTSD – sleep quality

	Expe	erimen	ntal	С	ontrol		:	Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
1.5.1 Insomnia Sever	ity Inde	x (ISI)							
Jindani 2015 Subtotal (95% CI)	10.6	6.7	29 29	16.4	5.8	21 21	100.0% 100.0%	-0.90 [-1.49, -0.31] - 0.90 [-1.49, -0.31]	
Heterogeneity: Not ap	plicable								
Test for overall effect:	Z = 2.99	(P = 0	0.003)						
1.5.2 Visual analogue	e scale								
Telles 2010 Subtotal (95% CI)	3.04	3.44	11 11	4.03	3.91	11 11	100.0% 100.0%	-0.26 [-1.10, 0.58] - 0.26 [-1.10, 0.58]	
Heterogeneity: Not ap	plicable								
Test for overall effect:	Z = 0.60	(P = 0).55)						
1.5.3 outcome not re	ported								
Reddy 2013	0	0	14	0	0	12		Not estimable	
Seppala 2014 Subtotal (95% CI)	0	0	10 24	0	0	10 22		Not estimable Not estimable	
Heterogeneity: Not ap	plicable								
Test for overall effect:	Not appl	licable							
									-++++++
		O L 12							Favours yoga Favours control

Test for subgroup differences: $Chi^2 = 1.50$, df = 1 (P = 0.22), l² = 33.3%

4.5 Insomnia and sleep problems

4.5.1 Description of the condition

Sleep problems are characterised by an inability to fall asleep or a lack of sleep which can cause daytime impairment. Common across the adult population, sleep problems can range in severity from experiencing some sleep disturbances each week to a diagnosis of clinical insomnia (115). Insomnia is a disorder that presents as onset insomnia, which is difficulty initiating sleep, or maintenance insomnia, which is difficulty maintaining sleep through the night or early awakening (116). In short term cases, precipitating factors such as shift work, stressors, or comorbid conditions may trigger insomnia. In other cases, insomnia is paired with hyperarousal which can distort sleep perception or interrupt sleep. Left untreated, maladaptive behaviours like daytime napping or sedative dependence may form alongside neurocognitive responses such as conditioned night-time arousal or cognitive alterations, eventually developing into chronic insomnia. If symptoms of sleeplessness and impaired daytime function occur 3 or more times a week for more than 3 months, patients are considered to have chronic insomnia disorder by ICSD-3 criteria (117).

In Australia, 14.8% of adults are reported to have chronic insomnia and 59.4% report sleep symptoms more than 3 times a week. Women are more likely to report chronic insomnia and daytime consequences than men. In both men and women, the prevalence of chronic insomnia increases with age with adults aged over 75 years reporting the highest rates of chronic insomnia (23.1%). Older people are also significantly more likely to report maintenance insomnia. Despite these significant numbers, less than 1/3 of people seek treatment. Even when treatment is initiated, it can take a relatively heterogenous approach (115).

Current treatment options for insomnia include pharmacological interventions, herbal supplements (such as melatonin or valerian), and cognitive behavioural therapy for insomnia (CBTi). CBT is recommended for first line management for patients with insomnia since improvements can be maintained for up to 3 years and medications are only recommended for short term usage (115, 118). However, CBT can be time consuming (4-8 weeks) and limited by accessibility to clinicians. New evidence has suggests that exercise interventions and mindfulness based interventions can be helpful in improving sleep quality (118).

4.5.2 Description of studies

Three citations (119-121) corresponding to one RCT (Sobana 2013) and 2 quasi RCTs (Afonso 2012, Tapas 2013) were identified in the literature search. There were 5 <u>ongoing studies</u> and 3 <u>studies awaiting classification</u> including 2 conference abstracts (122, 123) and one study published in a language other than English (124). No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D2.1.1.

All studies were conducted in single centre settings, with one study conducted in Brazil (Afonso 2012) and 2 studies conducted in India (Sobana 2013, Tapas 2013). All studies included participants with insomnia, with one study focusing on men (Sobana 2013) and one focusing on postmenopausal women aged between 50 and 65 years (Afonso 2012). The sample size ranged between 30 and 44 (total 114 participants).

Two studies (Sobana 2013, Afonso 2012) compared yoga with control (no intervention). In Afonso 2012, another comparator group (passive stretching sessions) was also included, with all participants also receiving calcium as a co-intervention (500mg ingested daily). One study (Tapas 2013) compared yoga with another intervention, being Sirodhara (an Ayurvedic healing technique).

All studies delivered a yoga intervention that included both postures and breathing, with yoga sessions being between 45 and 90 minutes in duration. Program intensity ranged from twice per week for 16 weeks (Afonso 2012) to daily for 15 days (Tapas 2013) or 8 weeks (Sobana 2013).

Results for yoga versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see Section 4.5.4.1) and Appendix F2. Results of the RCTs comparing yoga with an active comparator are presented in Appendix F2.

4.5.3 Risk of bias – per item

The risk of bias for each item in the included studies is presented in Figure 21. Details are provided in Appendix D2.1.2. No studies were judged to be at overall low risk of bias.

Figure 21 Risk of bias summary: review author's judgements about each risk of bias item for each included RCT – Insomnia



4.5.4 Main comparison (vs control)

One study (Afonso 2012) comparing yoga with control (no intervention) in people with insomnia was eligible for this comparison and contributed data to two outcomes. The other study (Sobana 2013) did not report outcomes or measures considered critical or important for this review.

There were 2 ongoing studies (total 108 participants) that compared yoga with no intervention in people with insomnia that were complete and could have contributed data to two outcomes (see Appendix C6), but data were not available to make any judgements.

4.5.4.1 Summary of findings and evidence statements

Yoga compared to control for Insomnia

Patient or population: Insomnia Setting: Community Intervention: Yoga Comparison: Control (no intervention, waitlist or usual care)

	Anticipated ab (95% CI)	solute effects*	Relative	Nº of	Certainty of	
Outcomes	Risk with control	Risk with yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statement
Sleep quality/ symptom severity assessed with: ISI (higher is worse) Scale from: 0 to 28 follow-up: mean 16 weeks	The mean ISI score was 13.7	MD 4.00 lower (7.33 lower to 0.67 lower)	-	30 (1 RCT)	⊕OOO VERY LOW a,b,c,d	The evidence is very uncertain about the effect of yoga on sleep quality in people with insomnia. **
Daytime functioning - not reported	-	-	-	-	-	No studies found. The effect of yoga on daytime functioning in people with insomnia is unknown.
Fatigue - not reported	-	-	-	-	-	No studies found. The effect of yoga on fatigue in people with insomnia is unknown.

Yoga compared to control for Insomnia

Patient or population: Insomnia

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated ab (95% CI)	solute effects*	Relative	N° of	Certainty of	
Outcomes	Risk with control	Risk with yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statement
Quality of life - not reported	-	-	-	-	-	No studies found. The effect of yoga on quality of life in people with insomnia is unknown.
Stress symptoms assessed with: Stress Symptoms Inventory for Adults (higher is worse) follow-up: mean 16 weeks	The mean SSI (alert) score was 4.1 The mean SSI (resistance) score was 7.2 The mean SSI (exhaustion) score was 7.4	MD 1.50 lower (3.44 lower to 0.44 higher) MD 3.10 lower (5.04 lower to 1.16 lower) MD 2.20 lower (4.69 lower to 0.29 higher)	-	30 (1 RCT)	⊕OOO VERY LOW a,b,c,d	The evidence is very uncertain about the effect of yoga on symptoms of stress in people with insomnia. **

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

** Effect estimates were considered on 3 levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).

CI: confidence interval; MD: mean difference; PSQI: Pittsburgh Sleep Quality Index; SMD: standardised mean difference

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. Serious risk of bias. One study contributing 100% of the data was at high risk of bias. Certainty of evidence downgraded.

- b. Serious imprecision. One study with wide confidence intervals (upper and lower bounds overlap with both a large and small important difference). Certainty of evidence downgraded.
- c. No serious indirectness. The evidence is directly generalisable to the Australian population with some caveats but could be sensibly applied. The available evidence is in postmenopausal females with insomnia and may not be applicable to men or females aged less than 50 years. Certainty of evidence not downgraded.
- d. Publication bias suspected. Two ongoing studies (108 participants) that could have contributed data to this outcome. There is a strong suspicion of non-reporting of results likely to be related to the p value, direction or magnitude of effect. Certainty of evidence downgraded.

4.5.4.2 Forest plots

Outcome results related to sleep quality in people with insomnia are presented in Figure 22.

Outcome results related to stress in people with insomnia are presented in Figure 23.

Figure 22 Forest plot of comparison: Yoga vs control (no intervention): Insomnia – sleep quality

	Yo	oga		Control			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl
3.1.1 Insomnia sever	ity index (0	-28)						
Afonso 2012 Subtotal (95% CI)	9.7 4.6	6476 15 15	13.7	4.6476	15 15	100.0% 100.0%	-4.00 [-7.33, -0.67] - 4.00 [-7.33, -0.67]	
Heterogeneity: Not ap Test for overall effect:	plicable Z = 2.36 (P	= 0.02)						
Total (95% CI) Heterogeneity: Not ap Test for overall effect: Test for subgroup diffe	plicable Z = 2.36 (P erences: Not	15 = 0.02) t applicable			15	100.0%	-4.00 [-7.33, -0.67] –	-10 -5 0 5 10 Favours yoga Favours control

Figure 23 Forest plot of comparison: Yoga vs control (no intervention): Insomnia – stress

	Y	oga			Control			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
3.2.1 Stress Symptor	n Inventor	y for a	dults (alert)					
Afonso 2012	2.6 2	.7111	15	4.1	2.7111	15	100.0%	-1.50 [-3.44, 0.44]	
Subtotal (95% CI)			15			15	100.0%	-1.50 [-3.44, 0.44]	\bullet
Heterogeneity: Not ap	olicable								
Test for overall effect:	Z = 1.52 (F	P = 0.13	3)						
3.2.2 Stress Symptor	n Inventor	y for a	dults (resista	nce))				_
Afonso 2012	4.1 2	.7111	15	7.2	2.7111	15	100.0%	-3.10 [-5.04, -1.16]	
Subtotal (95% CI)			15			15	100.0%	-3.10 [-5.04, -1.16]	\bullet
Heterogeneity: Not ap	olicable								
Test for overall effect:	Z = 3.13 (F	P = 0.00	02)						
3.2.3 Stress Symptor	n Inventor	y for a	dults (exhaus	stion)				_
Afonso 2012	5.2 3	.4857	15	7.4	3.4857	15	100.0%	-2.20 [-4.69, 0.29]	
Subtotal (95% CI)			15			15	100.0%	-2.20 [-4.69, 0.29]	•
Heterogeneity: Not ap	olicable								
Test for overall effect:	Z = 1.73 (F	P = 0.08	8)						
								_	-10 -5 0 5 10
									Favours yoga Favours control

4.6 Headache disorders

4.6.1 Description of the condition

Headache disorders include tension headaches – a dull aching pain throughout the whole head; cluster headaches – piercing pain affecting one side of the head at a time which occur in a series that can last days of weeks at a time; and migraines – a pulsing or throbbing pain from deep within the head that can last up to days at a time and includes other symptoms such as nausea, vomiting, sensitivity to light and sound, and affected vision (125-127). Tension-type headaches can also be accompanied by tightness or tenderness of scalp, neck and shoulder muscles, along with trouble concentrating, depression and anxiety (126). While it is unknown what exactly causes headaches and migraines, episodes are thought to be triggered by diet, stress, sleep and hormonal influences among others (125, 127).

Headache disorders are one of the most common health-related conditions in Australia, imposing a significant burden to individuals, society and the economy (128). International studies show that 36% of men and 42% of women suffer tension-type headaches, which translates to around 7 million Australians (126). For migraines, an estimated 1.4 to 4.9 million people in Australia are affected (127, 129). Onset usually begins in teenage years, with prevalence declining after one's 40s. Women are approximately 3 times more than men to be affected by migraines, being the 14th largest contributor to non-fatal disease burden for women in Australia (43).

Effective management of headaches and migraines includes both acute and preventative treatments to reduce the frequency of attacks. Treatments include pain relief medication, avoiding trigger factors, exercise, and relaxation techniques (125, 127). Non-pharmaceutical treatments include a variety of options including aromatherapy, deep breathing, hypnotherapy, biofeedback, yoga, Tai Chi and neck and shoulder massage (126, 127).

4.6.2 Description of studies

Nine citations (130-138) corresponding to 4 RCTs (John 2007, Kumar 2019a, Naji-Esfahani 2014, Talakad 2013) and 2 quasi RCTs (Latha 1992, Sethi 1981) were identified in the literature. There were 3 <u>ongoing studies</u> and 9 <u>studies awaiting classification</u> (139-147). No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D3.1.1.

All 6 studies were conducted at single centres in India (John 2007, Kumar 2019a, Latha 1992, Sethi 1982, Talakad 2013) or Iran (Naji-Esfahani 2013), with 2 studies (John 2007, Kumar 2019a) enrolling participants attending a hospital/outpatient clinic. Four studies included participants with migraines (John 2007, Kumar 2019a, Talakad 2013), one of which focused on women (Naji-Esfahani 2014). One study included both tension headaches and migraines (Latha 1992), while another focused solely on people with tension headaches (Sethi 1982). The sample sizes ranged between 16 and 160 (total 394 participants).

Five studies examined the effect of yoga compared with control (no intervention) (John 2007, Kumar 2019a, Latha 1992, Naji-Esfahani 2014, Talakad 2013). In one study (John 2007) the control participants received an educational leaflet that outlined self-care strategies that was considered inactive (usual care). In these 5 studies, all participants received standard medical care for their headache disorder, including pharmacotherapy where required. One study (Sethi 1989) compared yoga with another intervention (electromyographic biofeedback sessions).

All studies delivered a yoga intervention that included postures, breathing and relaxation, with yoga sessions being between 30 and 75 minutes in duration. In some studies the duration was not specified. Program intensity ranged from 2 to 5 sessions per week for 6 (Talakad 2013), 10 (Sethi 1981) or 12 weeks (John 2007, Kumar 2019a, Naji-Esfahani 2014), up to daily practice for 4 months (Latha 1992).

Results for yoga versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see Section 4.5.4.1) and Appendix F2. Results of the RCTs comparing yoga with an active comparator are presented in Appendix F2.

4.6.3 Risk of bias - per item

The risk of bias of included studies for headache disorders is summarised in Figure 24. Details are provided in Appendix D3.1.2. No studies were judged to be at overall low risk of bias.

Figure 24 Risk of bias summary: review author's judgements about each risk of bias item for each included RCT – Headache disorders



4.6.4 Main comparison (vs control)

Four RCTs (John 2007, Kumar 2019a, Naji-Esfahani 2014, Talakad 2013) and one quasi-RCT (Latha 1992) comparing yoga with control (no intervention, waitlist or usual care) in people with headache or migraine were eligible for this comparison and contributed data to 6 outcomes.

There were 9 studies awaiting classification (>350 participants) and 2 ongoing studies (98 participants) that could have contributed data to these outcomes (see Appendix C6). Missing results are probably because the p value, magnitude or direction of effect was considered unfavourable by the study investigators.

4.6.4.1 Summary of findings and evidence statements

Yoga compared to control (no intervention, waitlist or usual care) for headache or migraine

Patient or population: Headache disorders Setting: Community Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	solute effects*	Deletive	N0 - 6	Certainty of	
Outcomes	Risk with control	Risk with yoga	effect (95% CI)	№ or participants (studies)	tne evidence (GRADE)	Evidence statement
Pain assessed with: Short- Form MPQ (higher is worse) Scale from: 0 to 45 follow-up: median 12 weeks	The mean pain score was 3.97	MD 2.28 lower (2.54 lower to 2.02 lower)	-	65 (1 RCT)	⊕OOO VERY LOW a,b,c,d	The evidence is very uncertain about the effect of yoga on pain in people with headache disorders. #

Yoga compared to control (no intervention, waitlist or usual care) for headache or migraine

Patient or population: Headache disorders

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	solute effects*	Relative	Nº of	Certainty of	
Outcomes	Risk with control	Risk with yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statement
Headache severity assessed with: VAS (higher is worse) Scale from: 0 to 10 follow-up: range 6 weeks to 12 weeks	The mean severity score ranged from 6.73 to 7.73	MD 2.85 lower (4.81 lower to 0.90 lower)	-	317 (4 RCTs) †	⊕OOO VERY LOW c,d,e,fg	The evidence is very uncertain about the effect of yoga on headache severity in people with headache disorders. **
Headache frequency assessed with: headache days per month (higher is worse) follow-up: range 6 weeks to 12 weeks	The mean frequency ranged from 5.09 to 10.18	MD 3.52 lower (5.14 lower to 1.90 lower)	-	317 (4 RCTs) †	⊕⊕⊖⊖ LOW ^{c,d,e,g}	Yoga may result in a large reduction in headache frequency in people with headache disorders. ***
Headache-specific disability assessed with: HIT-6 (higher is worse) Scale from: 36 to 78 follow-up: range 6 weeks to 12 weeks	The mean HIT- 6 score ranged from 60.8 to 68.6	MD 15.22 lower (32.16 lower to 1.71 higher)	-	252 (3 RCTs)	⊕○○○ VERY LOW c,d,fg,h	The evidence is very uncertain about the effect of yoga on headache-specific disability in people with headache disorders. ##
Emotional function (anxiety) assessed with: HADS (higher is worse) Scale from: 0 to 21 follow-up: median 12 weeks	The mean HADS (anxiety) score was 13.39	MD 8.70 lower (9.47 lower to 7.93 lower)		65 (1 RCT)	⊕⊕⊖⊖ LOW ^{a,c,d}	Yoga may result in a large reduction in anxiety in people with headache disorders. ###
Emotional function (depression) assessed with: HADS (higher is worse) Scale from: 0 to 21 follow-up: median 12 weeks	The mean HADS (depression) score was 13.21	MD 8.87 lower (9.67 lower to 8.07 lower)		65 (1 RCT)	⊕⊕⊖⊖ LOW ^{a,c,d}	Yoga may result in a large reduction in depression in people with headache disorders. ###
Medication use assessed with: Medication Score - number of acute rescue pills taken in addition to preventative medication (higher is worse)	The mean number of rescue pills was range 3.94 to 5.9	MD 2.36 lower (3.03 lower to 1.69 lower)	-	225 (2 RCTs) †	⊕⊕⊖⊖ LOW ^{c,d,g,j}	Yoga may reduce the number of acute rescue pills taken in addition to preventative medication in people with headache disorders.

Yoga compared to control (no intervention, waitlist or usual care) for headache or migraine

Patient or population: Headache disorders

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	solute effects*	Relative		Certainty of	
Outcomes	Risk with control	Risk with yoga	Relative effect (95% Cl)	№ of participants (studies)	the evidence (GRADE)	Evidence statement

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

** Effect estimates were considered on 3 levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).

*** A 50% reduction in the frequency of days with headache or migraine is considered clinically meaningful (148).

**** Any reduction in number of acute rescue pills taken in addition to preventative medication is considered clinically meaningful (148).

The MCID for the SF-MPQ in people with headache or migraine is unknown. An MCID of 5 points has been proposed for people with musculoskeletal or rheumatic pain (149).

The MCID in HIT-6 score in people with headache or migraine is 2.3 (150, 151).

The MCID for the HADS in people with headache or migraine is unknown. An MCID of 1.5 points has been proposed for people with chronic obstructive pulmonary disease.

+ Data is missing from one RCT (20 participants) that reported a significant improvement in the yoga group compared to the control group for this outcome.

CI: confidence interval; HIT: Headache impact test; MD: mean difference; MPQ: McGill Pain Questionnaire; SMD: standardised mean difference; VAS: visual analogue scale

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

- a. Serious risk of bias. One study at high risk of bias contributing 100% of data. Certainty of evidence downgraded.
- b. Serious imprecision. Only one study contributing data. Certainty of evidence downgraded.
- c. Publication bias suspected. Missing data from several studies (~200 participants) that could have contributed data to this outcome. There is a strong suspicion of non-reporting of results likely to be related to the *p* value, direction or magnitude of effect. Certainty of evidence downgraded.
- d. No serious indirectness. The available evidence is in people with migraine. The impact of yoga on pain in people with other headache disorders is unknown but could be sensibly applied. Certainty of evidence not downgraded.
- e. No serious risk of bias. Three out of 4 RCTs contributing almost 75% of the data were at high risk of bias. In a sensitivity analysis examining the impact of these studies, the direction of effect did not materially change. Certainty of evidence not downgraded.
- f. Serious inconsistency. Point estimates vary widely. Confidence intervals of some studies do not overlap. Substantial statistical heterogeneity (l² > 90%) that is unable to be explained. Certainty of evidence downgraded.
- g. Serious imprecision. Wide confidence interval (upper and lower bounds overlap with both a large and small important difference). Certainty of evidence downgraded.
- h. No serious risk of bias. Two out of 3 RCTs contributing 65% of the data were at high risk of bias. In a sensitivity analysis examining the impact of these studies, the direction of effect did not materially change. Certainty of evidence not downgraded.
- j. No serious risk of bias. One out of 2 RCTs contributing 73% of the data was at high risk of bias. In a sensitivity analysis examining the impact of this RCT, the direction of effect did not materially change. Certainty of evidence not downgraded.

4.6.4.2 Forest plots

Outcome results related to pain in people with headache disorders are presented in Figure 25.

Outcome results related to headache severity in people with headache disorders are presented in Figure 26.

Outcome results related to headache frequency in people with headache disorders are presented in Figure 27.

Outcome results related to headache-specific disability in people with headache disorders are presented in Figure 28.

Outcome results related to emotional function in people with headache disorders are presented in Figure 29.

Outcome results related to medication use in people with headache disorders are presented in Figure 30.

Figure 25 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Headache disorders - pain

	١	/oga		С	ontrol			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
2.1.1 McGill Pain Que	stionna	ire							
John 2007 Subtotal (95% CI)	1.69	0.47	32 32	3.97	0.58	33 33	100.0% 100.0%	-2.28 [-2.54, -2.02] -2.28 [-2.54, -2.02]	
Heterogeneity: Not app	licable								
Test for overall effect: 2	Z = 17.4	4 (P <	0.0000	1)					
2.1.2 Outcome not rep	ported,	proba	bly bec	cause it	was r	not me	asured		
Kumar 2019	0	0	80	0	0	80		Not estimable	
Latha 1992	0	0	10	0	0	10		Not estimable	
Naji-Esfahani 2014	0	0	18	0	0	14		Not estimable	
Talakad 2013	0	0	30	0	0	30		Not estimable	
Subtotal (95% CI)			138			134		Not estimable	
Heterogeneity: Not app	licable								
Test for overall effect: I	Not appl	icable							
Total (95% CI)			170			167	100.0%	-2.28 [-2.54, -2.02]	•
Heterogeneity: Not app	licable							-	
Test for overall effect: 2	Z = 17.4	4 (P <	0.0000	1)					
Test for subgroup diffe	rences:	Not ap	plicable	e					Favours yoga Favours control

Figure 26 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Headache disorders - headache severity

	`	Yoga		С	ontrol			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
5.2.1 Visual analogue	e scale (0-10)							
John 2007	4.64	0.72	32	7.62	0.91	33	26.1%	-2.98 [-3.38, -2.58]	•
Kumar 2019a	5.7	2.38	80	6.8	1.81	80	25.7%	-1.10 [-1.76, -0.44]	+
Naji-Esfahani 2014	5.27	2.09	18	6.73	2.41	14	22.5%	-1.46 [-3.05, 0.13]	
Talakad 2013	2.03	1.3	30	7.73	1.2	30	25.7%	-5.70 [-6.33, -5.07]	•
Subtotal (95% CI)			160			157	100.0%	-2.85 [-4.81, -0.90]	\bullet
Heterogeneity: Tau ² =	3.76; Cł	ni² = 1()4.96, c	lf = 3 (P	< 0.00	0001); l	² = 97%		
Test for overall effect:	Z = 2.86	i (P = ().004)						
5.2.2 Measure not rep	orted								
Latha 1992 (1)	-17	0	10	-1	0	10		Not estimable	
Subtotal (95% CI)			10			10		Not estimable	
Heterogeneity: Not app	plicable								
Test for overall effect:	Not appl	licable							
Total (95% CI)			170			167	100.0%	-2.85 [-4.81, -0.90]	\bullet
Heterogeneity: Tau ² =	3.76; Cł	ni² = 1()4.96, c	lf = 3 (P	< 0.00	0001); l	² = 97%	-	
Test for overall effect:	Z = 2.86	i (P = ().004)						-10 -5 0 5 10 Favours voga Favours control
Test for subgroup diffe	erences:	Not ap	plicable	е					i avours yoga i avours control
Footnotes									

(1) Reports significant difference favouring yoga

Figure 27 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Headache disorders - headache frequency

	`	Yoga		С	ontro			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
5.3.2 Headache days pe	er mont	h							
John 2007	4.56	1.79	32	10.18	2.14	33	26.1%	-5.62 [-6.58, -4.66]	+
Kumar 2019a	4.7	3.68	80	6.8	2.98	80	25.7%	-2.10 [-3.14, -1.06]	
Naji-Esfahani 2014 (1)	2.27	1.49	18	5.09	2.98	14	21.8%	-2.82 [-4.53, -1.11]	
Talakad 2013	1.8	1.5	30	5.2	2.1	30	26.3%	-3.40 [-4.32, -2.48]	*
Subtotal (95% CI)			160			157	100.0%	-3.52 [-5.14, -1.90]	\blacklozenge
Heterogeneity: Tau ² = 2.3	36; Chi ²	= 25.9	9, df =	3 (P < 0	0.0000	1); ² =	88%		
Test for overall effect: Z	= 4.27 (F	- < 0.0	001)						
5.3.3 Measure not repo	rted								
Latha 1992	-8	0	10	0	0	10		Not estimable	
Subtotal (95% CI)			10			10		Not estimable	
Heterogeneity: Not applie	cable								
Test for overall effect: No	ot applic	able							
Total (95% CI)			170			167	100.0%	-3.52 [-5.14, -1.90]	\bullet
Heterogeneity: Tau ² = 2.3	36; Chi²	= 25.9	9, df =	3 (P < 0	0.0000	1); ² =	88%	_	
Test for overall effect: Z	= 4.27 (F	- < 0.0	001)						-10 -5 0 5 10 Eavours voga Eavours control
Test for subgroup differe	nces: N	ot appl	icable						
Footnotes									

(1) Assumed to be headache days per month.

Figure 28 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Headache disorders - headache-specific disability

		Yoga		С	ontrol			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
2.4.1 HIT-6									
Kumar 2019	53.7	11.01	80	60.8	8.87	80	33.4%	-7.10 [-10.20, -4.00]	
Naji-Esfahani 2014	55.7	8.15	18	64.36	5.85	14	32.9%	-8.66 [-13.51, -3.81]	
Talakad 2013 Subtotal (95% CI)	38.9	2.2	30 128	68.6	4.6	30 124	33.7% 100.0%	-29.70 [-31.52, -27.88] -15.22 [-32.16, 1.71]	
Heterogeneity: Tau ² = 2	220.84;	Chi ² = 1	185.94,	df = 2 (P < 0.0	00001);	l² = 99%		
Test for overall effect: 2	Z = 1.76	(P = 0.	08)						
2.4.2 Outcome not rep John 2007 (1)	ported 0	0	32 10	0	0	33 10		Not estimable	
Subtotal (95% CI)	0	Ŭ	42	0	Ŭ	43		Not estimable	
Heterogeneity: Not app Test for overall effect: I	olicable Not appl	licable							
Total (95% CI)			170			167	100.0%	-15.22 [-32.16, 1.71]	
Heterogeneity: Tau ² = 2	220.84;	Chi ² = 1	185.94,	df = 2 (P < 0.0	00001);	l² = 99%	-	
Test for overall effect: 2	Z = 1.76	(P = 0.	08)						-20 -10 0 10 20
Test for subgroup diffe	rences:	Not app	licable						Tavours yoga Favours control
Footnotes									

(1) Study did not report the outcome, and it is unclear whether it was measured

(2) Study did not report the outcome, probably because it was not measured

Figure 29 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Headache disorders - emotional function

	۲	Yoga		С	ontrol			Mean Difference		Mean I	Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI		IV, Rano	dom, 95% Cl	
2.5.1 Hospital anxiety	/ and de	press	ion (ar	nxiety)								
John 2007	4.69	1.42	32	13.39	1.73	33	100.0%	-8.70 [-9.47, -7.93]				
Subtotal (95% CI)			32			33	100.0%	-8.70 [-9.47, -7.93]	•			
Heterogeneity: Not ap	plicable											
Test for overall effect:	Z = 22.1	9 (P <	0.0000)1)								
2.5.2 Hospital anxiety	/ and de	press	ion (de	pressi	on)							
John 2007	4.34	1.33	32	13.21	1.92	33	100.0%	-8.87 [-9.67, -8.07]				
Subtotal (95% CI)			32			33	100.0%	-8.87 [-9.67, -8.07]	•			
Heterogeneity: Not ap	plicable											
Test for overall effect:	Z = 21.7	1 (P <	0.0000)1)								
2.5.3 Outcome not re	ported,	proba	bly be	cause i	t was i	not mea	asured					
Kumar 2019	0	0	80	0	0	80		Not estimable				
Latha 1992	0	0	10	0	0	10		Not estimable				
Naji-Esfahani 2014	0	0	18	0	0	14		Not estimable				
Talakad 2013	0	0	30	0	0	30		Not estimable				
Subtotal (95% CI)			138			134		Not estimable				
Heterogeneity: Not ap	plicable											
Test for overall effect:	Not appli	icable										
										i.		
									-10	-5	0 5	10
		.								Favours yog	a Favours c	ontrol
l est for subgroup diffe	erences:	Chi ² =	0.09, c	it = 1 (P	= 0.76	5), I² = ()%					

Figure 30 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Headache disorders – number of acute rescue pills taken in addition to preventative medication

	`	Yoga		С	ontrol			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl
5.6.1 Medication sco	re								
John 2007	1.37	1.01	32	3.94	0.97	33	73.1%	-2.57 [-3.05, -2.09]	
Kumar 2019	4.1	4.48	80	5.9	2.59	80	26.9%	-1.80 [-2.93, -0.67]	_
Subtotal (95% CI)			112			113	100.0%	-2.36 [-3.03, -1.69]	\bullet
Heterogeneity: Tau ² =	0.10; Cł	ni² = 1.	50, df =	= 1 (P =	0.22);	² = 330	%		
Test for overall effect:	Z = 6.92	(P < 0	0.00001	1)					
5.6.2 Measure not rep	oorted								
Latha 1992 (1)	0	0	10	0	0	10		Not estimable	
Subtotal (95% CI)			10			10		Not estimable	
Heterogeneity: Not ap	plicable								
Test for overall effect:	Not appl	licable							
5.6.3 Outcome not re	ported,	proba	bly be	cause it	t was I	not me	asured		
Naji-Esfahani 2014	0	0	18	0	0	14		Not estimable	
Talakad 2013	0	0	30	0	0	30		Not estimable	
Subtotal (95% CI)			48			44		Not estimable	
Heterogeneity: Not ap	plicable								
Test for overall effect:	Not appl	licable							
									•
Total (95% CI)			170			167	100.0%	-2.36 [-3.03, -1.69]	\bullet
Heterogeneity: Tau ² =	0.10; Ch	ni² = 1.	50, df =	= 1 (P =	0.22);	² = 33 ⁰	%	-	
Test for overall effect:	Z = 6.92	(P < 0	0.00001	1)					Favours voga Favours control
Test for subgroup diffe	erences:	Not ap	plicabl	е					
Footnotes									

(1) Authors indicate a reduction in analgaesic use in the yoga group and increased use in the control group but data was not reported.

4.7 Hypertensive heart disease

4.7.1 Description of the condition

Elevated blood pressure is a significant contributor to global burden of cardiovascular disease and mortality (152). Approximately 1 in 3 Australians over 18 years have high blood pressure, 23% of which are uncontrolled (BP remains above 140/90 mmHg whether or not a person is taking medication) (153). As an independent risk factor for stroke, heart failure, chronic kidney disease and premature death, uncontrolled hypertension poses a significant burden to Australia's health care system (154). Structural changes to the left atrium, responsible for regulating left ventricular functioning during systole and diastole, can occur as an adaptive process in response to prolonged elevated blood pressure. This may lead to reduced functioning and myocardium fibrosis (155).

Different categories and grades are used to assist in the diagnosis and management of BP (154). In adults, normal BP is defined as systolic 120-129 mmHg and diastolic 80-84 mmHg, whereas an optimal blood pressure is 120/80 mmHg. High to normal BP is classified as systolic 130-139 mmHg and diastolic 85-89 mmHg. Hypertension is classified into 3 grades as follows:

- grade 1 (mild) hypertension is systolic 140-159 mmHg / diastolic 90-99 mmHg
- grade 2 (moderate) hypertension is systolic 160-179 mmHg / diastolic 100-109 mmHg
- grade 3 (severe) hypertension is ≥ 180/110 mmHg

Appropriately controlling, managing and reducing hypertension is imperative to reducing CVD burden. Studies have demonstrated the benefits of regular exercise on cardiovascular health, with regular physical activities and progressive resistance exercises demonstrated to reduce blood pressure (156, 157) and improve cardiovascular function in those with cardiovascular disease (e.g. heart failure) (157, 158). However, there is insufficient evidence regarding the frequency, intensity, time, and duration of physical activity to influence the associations between physical activity and BP (157). The National Heart Foundation of Australia Guidelines recommend regular physical exercise, including muscle strengthening activities at least 2 days a week to aid in the management and reduction of blood pressure (154).

4.7.2 Description of the studies

Thirty citations (159-188) corresponding to 24 RCTs (Ankolekar 2019, Cohen 2011, Cohen 2013, Cramer 2018, Ghati 2020, Hagins 2014, McCaffrey 2005, Misra 2019, Mourya 2009, Murugesan 2000, Patil 2014, Punita 2016, Pushpanathan 2015, Saptharishi 2009, Shetty 2017, Sieverdes 2014, Sriloy 2015, Sujatha 2014, Thanalakshmi 2020, Thiyagarajan 2015, Tolbanos Roche 2014, Tolbanos Roche 2017, Wolff 2016, Yadav 2012) were identified in the literature search. There were 10 <u>ongoing studies</u> and 10 <u>studies awaiting classification</u> (189-198), all of which were published as conference abstracts. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D4.1.1.

The studies were predominantly carried out in single care settings in a variety of countries including India (Ankolekar 2019, Ghati 2020, Mourya 2009, Murugesan 2000, Patil 2014, Punita 2016, Pushpanathan 2015, Shetty 2017, Sriloy 2015, Thanalakshmi 2020, Thiyagarajan 2015, Yadav 2012), Spain (Tolbanos Roche 2014, Tolbanos Roche 2017) and the United States (Cohen 2011, Cohen 2013, Hagins 2014, Misra 2019, Sieverdes 2014). Four studies recruited participants from local community or multiple care settings in Germany (Cramer 2018), India (Saptharishi 2009, Sujatha 2014), Thailand (McCaffrey 2005) and Sweden (Wolff 2016).

Participants were included based on variety of hypertension criteria. Ten studies (Cramer 2018, Misra 2019, Murugesan 2000, Punita 2016, Pushpanathan 2015, Sriloy 2015, Thanalakshmi 2020, Tolbanos Roche 2014, Tolbanos Roche 2017, Yadav 2012) included participants with hypertension at any stage (SBP > 140 mmHg; DBP > 90 mmHg). In Misra 2019, the participants had uncontrolled hypertension, despite pharmacological treatment and in Murugesan 2000, participants were nonmedicated. Five studies included participants with grade 1 or grade 2 hypertension (defined in 4 studies as SBP 140 to 180 mmHg; DBP: 90 to 110 mmHg [Ghati 2020, McCaffrey 2005, Mourya 2009, Patil 2014] and in one study as SBP 140 to 169 mmHg; DBP: 90 to 109 mmHg [Sujatha 2014]). Eight studies included participants who had either prehypertension (SBP: 120 to 139 mmHg; DBP: 80 to 89 mmHg) or grade 1 hypertension (SBP: 140 to 159 mmHg; DBP: 90 to 99 mmHg) or both. In one study (Sieverdes 2014) the sample population was pre- or normotensive.

Participants in all but 2 studies were aged between 18 and 70 years. Patil 2014 enrolled participants aged 60 to 80 years and Sieverdes 2014 enrolled adolescents aged 11 to 13 years. The sample size ranges from 31 to 238 (total 1959 participants).

There were 17 studies that compared yoga with an inactive control, being either no intervention (Ankolekar 2019, Cohen 2013, McCaffrey 2005, Misra 2019, Mourya 2009, Murugesan 2000, Punita 2016, Pushpanathan 2015, Saptharishi 2009, Sujatha 2014, Thanalakshmi 2020, Thiyagarajan 2015, Tolbanos Roche 2014, Tolbanos Roche 2017), waitlist (Cramer 2018, Shetty 2017) or usual care (Wolff 2016). Four of these studies also included another intervention group being an education program with walking (Cohen 2013), anti-hypertensive medication (Murugesan 2000), walking or diet-modification (Saptharishi 2009) and Himalayan Tradition mediation or breathing exercises (Tolbanos Roche 2017).

A further 7 studies compared yoga with an active comparator being either a behavioural modification program (Cohen 2011a), low-intensity physical activity such as walking (Hagins 2014, Patil 2014), acupuncture (Sriloy 2015), or attention control such as breathing, reading or music classes (Ghati 2020, Sieverdes 2014, Yadav 2012).

In 9 studies the yoga program included asana and pranayamas (with or without meditation), with a typical yoga session being between 30 and 90 minutes in duration. There were 8 studies (Ghati 2020, Misra 2019, Mourya 2009, Shetty 2017, Sriloy 2015, Thanalakshmi 2020, Yadav 2012, Wolff 2016) that focused on breathing, with sessions that lasted just 10 to 15 minutes. Treatment intensity predominantly ranged from one to 5 sessions a week. Outliers had 6 sessions a week (Ankolekar 2019, Patil 2014), daily (Shetty 2017, Thanalakshmi 2020) or twice daily (Mourya 2009, Murugesan 2000, Wolff 2016). Treatment program durations included one off sessions (Ghati 2020, Sriloy 2015, Yadav 2012), 1 month (Shetty 2017, Thanalakshmi 2020), 6 weeks (Misra 2019), 8 weeks, 11 weeks (Murugesan 2000), 12 weeks and 24 weeks (Ankolekar 2019, Cohen 2013).

Results for yoga versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see Section 4.7.4.1) and Appendix F2. Results of the RCTs comparing yoga with an active comparator are presented in Appendix F2.

4.7.3 Risk of bias - per item

The risk of bias for each item in the included RCTs for hypertensive heart disease are presented in Figure 31. Details are provided in Appendix D4.1.2.

No studies were judged to be at overall low risk of bias.

				Risk of bia	s domains						
		D1	D2	D3	D4	D5	Overall				
	Ankolekar 2019	-	+	X	-	-	×				
	Cohen 2011a	-	X	X	-	-	×				
	Cohen 2013	+	×	X	-	-	×				
	Cramer-2018	+	+	+	+	-	-				
	Ghati 2020	+	+	+	+	-	-				
	Hagins 2014	+	+	-	+	-	-				
	McCaffrey 2005	-	+	+	+	-	-				
	Misra 2019	+	X	-	+	-	X				
	Mourya 2009	-	+	+	+	-	-				
	Murugesan 2000	-	-	X	+	-	X				
	Patil 2014	-	+	+	+	-	-				
Лрг	Punita 2016	+	-	+	+	-	-				
Sti	Pushpanathan 2015	+	+	+	+	-	-				
	Saptharishi 2009	+	+	X	+	-	×				
	Shetty 2017	-	-	+	+	-	-				
	Sieverdes 2014	-	+	+	+	-	-				
	Sriloy 2015	+	+	+	+	-	-				
	Sujatha 2014	-	+	+	-	-	-				
	Thanalakshmi 2020	+	+	+	+	-	-				
	Thiyagarajan 2015	+	X	+	+	-	×				
	Tolbanos Roche 2014	X	-	-	-	-	×				
	Tolbanos Roche 2017	X	X	X	-	-	X				
	Wolff 2016	+	+	+	-	-	-				
	Yadav 2012	-	+	+	+	-	-				
		Domains:	ning from the	randomizatio	Judge	Judgement					
		D1: Blas ari	e to deviation	n. 🗙 H	High						
		D3: Bias du	e to missing of measurement	- :	Some concerns						
	D4: Bias in measurement of the outcome.										

Figure 31 Risk of bias summary: review author's judgements about each risk of bias item for each included study – Hypertension

4.7.4 Main comparison (vs control)

Seventeen RCTs comparing yoga with control (no intervention, waitlist or usual care) in people with preand/or primary hypertension were eligible for this comparison and contributed data relevant to four outcomes considered critical or important for this review (Ankolekar 2019, Cohen 2013, Cramer 2018, McCaffrey 2005, Misra 2019, Mourya 2009, Murugesan 2000, Punita 2016, Pushpanathan 2015, Saptharishi 2009, Shetty 2017, Sujatha 2014, Thanalakshmi 2020, Thiyagarajan 2015, Tolbanos Roche 2014, Tolbanos Roche 2017, Wolff 2016). There were 5 studies awaiting classification (total 270 participants) and 5 ongoing studies (total 533 participants) that could have contributed data to these outcomes (see Appendix C6). Nonreporting of results is possibly because the *p* value, magnitude or direction of effect was considered unfavourable by the study investigators.

4.7.4.1 Summary of findings and evidence statements

Yoga compared to control for hypertensive heart disease

Patient or population: Hypertensive heart disease

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	olute effects*	Delative	Nº of	Certainty of		
Outcomes	Risk with control	Risk with Yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statements	
Cardiovascular disease risk assessed with: SBP (closer to 120 mmHg is best) follow-up: range 30 days to 24 weeks	The mean SBP was range 123 to 161.89 mmHg	MD 7.95 mmHg lower (12.31 lower to 3.59 lower)	-	1230 (15 RCTs) †	⊕⊕⊕⊖ MODERATE a,b,c,d	Yoga probably results in a large reduction in cardiovascular disease risk (SBP) in people with hypertension. #	
Cardiovascular disease risk assessed with: DBP (closer to 80 mmHg is best) follow-up: range 30 days to 24 weeks	The mean DBP was range 78.3 to 107.1 mmHg	MD 5.61 mmHg lower (8.69 lower to 2.54 lower)	-	1090 (13 RCTs) †	⊕⊕⊕⊖ MODERATE _{b,c,d,e}	Yoga probably results in a large reduction cardiovascular disease risk (DBP) in people with hypertension. #	
Fitness / exercise capacity - not reported	-	-	-	-	-	No studies found. The effect of yoga on fitness / exercise capacity in people with hypertension is unknown.	
Physical function / mobility - not reported	-	-	-	-	-	No studies found. The effect of yoga on physical function in people with hypertension is unknown.	
Perceived stress assessed with: PSS- 10 (higher is worse) Scale from: 0 to 40 follow-up: range 8 weeks to 12 weeks	The mean stress score was 21.2	MD 1.75 lower (4.89 lower to 1.38 higher)	-	245 (3 RCTs) ⁺⁺	⊕⊕⊖⊖ Low ^{fg}	Yoga may result in little to no difference in perceived stress in people with hypertension. ##	
Quality of life assessed with: SF- 36 or WHOQOL- BREF (higher is best) follow-up: 12 weeks	No important dif studies of people hypertensive hea range -0.39 SD la higher) **	ference in 2 with art disease (SMD ower to 0.06 SD	-	221 (2 RCTs) ⁺⁺⁺	⊕⊕⊖⊖ Low ^{g,h}	Yoga may result in little to no difference in quality of life in people with hypertension.	

Yoga compared to control for hypertensive heart disease

Patient or population: Hypertensive heart disease

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	olute effects*	Relative	Nº of	Certainty of	
Dutcomes Risk with control Risk with		Risk with Yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statements
Anxiety assessed with: HADS, BAI, STAI (state) follow-up: range 2 months to 12 weeks		SMD 0.33 SD lower ** (1.07 lower to 0.41 higher)	-	485 (4 RCTs)	⊕OOO VERY LOW b,f,g,h	The evidence is very uncertain about the effect of yoga on anxiety in people with hypertension.
Medication use - not reported	-	-	-	-	-	No studies found. The effect of yoga on medication use in people with hypertension is unknown.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

** As a rule of thumb, an SMD of 0.2 represents a small difference, 0.5 is moderate, and 0.8 is a large difference (58).

*** Effect estimates were considered on 3 levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).

A reduction of 2 mmHg or more is clinically important (199).

Estimated MCID of between 2.19 and 2.66 points among undergraduate students with elevated stress (200).

- + Two studies (total 100 participants) reporting a decrease in SBP and DBP in the yoga group were not included in the meta-analysis (data not able to be extracted).
- ++ One study (total 241 participants) reporting an effect favouring the yoga group when compared to control was not included in the meta-analysis (data not able to be extracted).
- +++ Data from 1 study not included here. One study (101 participants) reported an effect favouring the yoga group when compared to control but the measure used was not specified.

CI: confidence interval; BAI: Beck anxiety inventory; DBP: Diastolic blood pressure; HADS: Hospital anxiety and depression inventory; MCS: mental component score; MD: mean difference; PCS: physical component score: PSS: Perceived Stress scale; SBP: Systolic blood pressure; SMD: standardised mean difference; STAI: state-trait anxiety inventory

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

- a. No serious risk of bias. Eight studies contributing ~50% of data were at high risk of bias. In a sensitivity analysis the direction and size of the effect estimate did not materially change. Certainty of evidence not downgraded.
- b. No serious inconsistency. Point estimates vary and the confidence intervals of some studies do not overlap. Substantial statistical heterogeneity (I² > 90%) may be explained by variances in the study PICOs. Certainty of evidence not downgraded.

- c. Publication bias suspected. Missing data from several studies (>500 participants) that could have contributed data to this outcome. There is a strong suspicion of non-reporting of results likely related to the *p* value, direction or magnitude of effect. Certainty of evidence downgraded.
- d. No serious indirectness. The available evidence includes studies that focused on yogic breathing, which may not be representative of yoga as practised in Australia but could be sensibly applied. Certainty of evidence not downgraded.
- e. No serious risk of bias. Seven studies contributing ~50% of data were at high risk of bias. In a sensitivity analysis the effect estimate did not substantially change. Certainty of evidence not downgraded.
- f. No serious risk of bias. One study contributing ~20% of data was at high risk of bias. In a sensitivity analysis the effect estimate did not substantially change. Certainty of evidence not downgraded.
- g. Publication bias suspected. Missing data from several studies (~200 participants) that could have contributed data to this outcome. There is a strong suspicion of non-reporting of results likely related to the *p* value, direction or magnitude of effect. Certainty of evidence downgraded.
- h. Serious imprecision. Wide confidence intervals (upper and lower bounds overlap with both important and no important difference). Certainty of the evidence downgraded.

4.7.4.2 Forest plots

Outcome results related to cardiovascular disease risk in people with hypertension are presented in Figure 32 (SBP) and Figure 33 (DBP).

Outcome results related to perceived stress in people with hypertension are presented in Figure 34.

Outcome results related to quality of life in people with hypertension are presented in Figure 35.

Outcome results related to anxiety in people with hypertension are presented in Figure 36.

Figure 32 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Hypertension – systolic blood pressure

	,	Yoga		С	ontrol			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
6.1.1 prehypertension (or	grade 1)								
Ankolekar 2019	127.75	6.582	51	134.48	6.635	51	7.6%	-6.73 [-9.29, -4.17]	
Cohen 2013 (1)	130	17	46	130.6	16	48	6.6%	-0.60 [-7.28, 6.08]	
Saptharishi 2009	126	9.3	27	123.7	10.4	30	7.1%	2.30 [-2.81, 7.41]	+
Shetty 2017 (2)	132	3.8	30	152.9	9.8	30	7.4%	-20.90 [-24.66, -17.14]	
Thiyagarajan 2015	121	6	51	123	4	49	7.7%	-2.00 [-3.99, -0.01]	-
Wolff 2016 (3)	145.4	13.4	85	145.2	12.8	86	7.4%	0.20 [-3.73, 4.13]	
			290		04) 12	294	43.8%	-4.76[-10.87, 1.35]	
Heterogeneity: 1 au ² = 53.75	$Cn^2 = S$	95.29, 0 1 1 2 1	t = 5 (P	< 0.000	01); I ² =	95%			
Test for overall effect: $Z = 1$.	.53 (P = (J.13)							
6.1.2 hypertension (grade	1 or 2)								
McCaffery 2005	136.04	12.98	27	161 89	17.38	27	6 1%	-25 85 [-34 03 -17 67]	
Sujatha 2014	138.51	9.39	118	152.38	10.25	120	7.6%	-13.87 [-16.37, -11.37]	-
Subtotal (95% CI)			145			147	13.8%	-19.20 [-30.87, -7.53]	
Heterogeneity: Tau ² = 62.24	; Chi² = 7	7.53, df	= 1 (P =	= 0.006);	l² = 87%	6			
Test for overall effect: Z = 3	23 (P = ().001)	,	,.					
6.1.3 hypertension (any)									
Cramer 2018 (4)	136.9	10.6	25	135	8	25	7.0%	1.90 [-3.31, 7.11]	
Misra 2019 (5)	149.8	15.74	61	151.6	18.9	22	5.9%	-1.80 [-10.63, 7.03]	
Murugesan 2000	123.09	10.14	11	151.26	11.2	11	5.9%	-28.17 [-37.10, -19.24]	
Punita 2016	118.56	11.06	25	125.97	10.95	30	6.9%	-7.41 [-13.25, -1.57]	
Thanalakshmi 2020 (6)	124.12	14.72	50	139.72	12.9	50	7.0%	-15.60 [-21.03, -10.17]	·
Tolbanos Roche 2014	137.1	11.57	10	134.5	15.4	10	4.9%	2.60 [-9.34, 14.54]	
Subtotal (95% CI)	-0.30	10.3	196	-2.0	12.94	158	4.0% 42.4%	-2.00 [-10.00, 9.94] -7.54 [-15.43, 0.36]	
Heterogeneity: $Tau^2 = 94.68$	$Chi^2 = 4$	16 63 d	f = 6 (P	< 0.000	01) [.] I ² =	87%	-141-170	1.04 [10.40, 0.00]	-
Test for overall effect: Z = 1.	.87 (P = ().06)			51), 1	01 /0			
		,							
6.1.4 missing data									
Mourya 2009 (8)	0	0	20	0	0	20		Not estimable	
Pushpanathan 2015 (9)	0	0	34	0	0	36		Not estimable	
Subtotal (95% CI)			54			56		Not estimable	
Heterogeneity: Not applicab	le								
Test for overall effect: Not a	pplicable								
Total (95% CI)			685			655	100.0%	-7.95 [-12.313.59]	
Heterogeneity: $Tau^2 = 63.14$	· Chi² = 2	01 99	df = 14	(P < 0.0)	0001)· I²	² = 93%			
Test for overall effect: 7 = 3	.57 (P = (0,0004)	un n-r	(1 0.0	5001), 1	0070	,		-20 -10 0 10 20
Test for subgroup difference	es: $Chi^2 =$	4.62.d	f = 2 (P	= 0.10)	$ ^2 = 56.7$	7%			Favours yoga Favours control
Footnotes		, .	. – (.	•• <i>)</i> ,					
(1) Yoga vs control (delivere	ed as an a	adiunct	to educ	ation and	d walking	a proar	am)		
(2) Yogic breathing.		,					/		
(3) Kundalini yoga vs contro	I.								
(4) Yoga with postures.									
(5) Yogic breathing (in class) is comb	ined wi	th yogic	breathir	ng (with	home p	oractice) v	vs control.	
(6) Yogic breathing vs contr	ol.								
(7) Yoga vs control. Data re	ported as	mean	change	from bas	seline (S	5D).			
(8) Results not able to be ex	tracted.	Directio	n of effe	ect report	ted to far	vour int	terventior	l.	

(9) Results not able to be extracted. Direction of effect reported to favour intervention.
Figure 33 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Hypertension – diastolic blood pressure

		Yoga		С	ontrol			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
6.2.1 prehypertension (or	grade 1)							
Ankolekar 2019	82.05	3.434	51	88.97	5.27	51	9.2%	-6.92 [-8.65, -5.19]	-
Cohen 2013 (1)	78.6	14	46	80	13	48	7.3%	-1.40 [-6.87, 4.07]	
Saptharishi 2009	83.8	6.3	27	82.8	6.3	30	8.6%	1.00 [-2.28, 4.28]	-1
Thiyagarajan 2015	81	4	51	82	3	49	9.3%	-1.00 [-2.38, 0.38]	-
Wolff 2016 (2)	86.3	7.7	85	84.9	7.7	86	9.0%	1.40 [-0.91, 3.71]	
Subtotal (95% CI)			260			264	43.5%	-1.47 [-4.92, 1.97]	•
Heterogeneity: Tau ² = 13.1	5; Chi ² =	44.70,	df = 4 (F	o < 0.000	001); l ² :	= 91%			
l est for overall effect: $Z = 0$.84 (P =	0.40)							
6.2.2 hypertension (grade	1 or 2)								
McCaffery 2005	81.01	10.34	27	100.59	9.72	27	7.4%	-19.58 [-24.93, -14.23]	_ _
Sujatha 2014	86.17	6.3	118	94.23	6.43	121	9.3%	-8.06 [-9.67, -6.45]	-
Subtotal (95% CI)			145			148	16.6%	-13.53 [-24.80, -2.25]	
Heterogeneity: Tau ² = 62.29	9; Chi² =	16.31,	df = 1 (F	o < 0.000	01); l² =	94%			
Test for overall effect: Z = 2	.35 (P =	0.02)							
6.0.2 hypertension (any)									
6.2.3 hypertension (any)	00.4	40.0	05	04.0	0.4	05	7 50/	4 20 1 2 4 0 4 1	
Cramer 2018 (3)	83.1	10.3	25	81.8	8.1 40.07	25	1.5%	1.30 [-3.84, 6.44]	
Murugesan 2000	02.30 76.04	9.14	11	107.1	10.27	11	5.1% 0 ∩0/	-24.74 [-32.80, -10.02]	-
Punila 2010 Thonolokohmi 2020 (4)	76.46	0.70	20	01.0/ 06.10	1.20	51	0.0%	-5.03 [-9.32, -0.74]	
Thanalakshini 2020 (4)	10.10 20.6	4.40 9.26	50 10	70.12	10.00	10	0.0%	-9.90 [-13.11, -0.01]	
Tolbanos Roche 2014	3 71	13 16	1/	10.0	10.71	10	5.0%	2.30 [-7.13, 11.73] -6 71 [-16 28 -2 86]	
Subtotal (95% CI)	-5.71	15.10	135	5	10.71	138	39.9%	-7.08 [-13.34, -0.82]	
Heterogeneity: Tau ² = 49.29	9: Chi² =	36.25.	df = 5 (F	o < 0.000	001): l² :	= 86%		• • •	-
Test for overall effect: Z = 2	.22 (P =	0.03)	- (,,				
6.2.4 missing data									
Misra 2019 (6)	0	0	23	0	0	22		Not estimable	
Mourya 2009 (7)	0	0	20	0	0	20		Not estimable	
Pushpanathan 2015 (8)	0	0	34	0	0	37		Not estimable	
Shetty 2017 (9) Subtotal (95% CI)	0	0	30 107	0	0	30 109		Not estimable	
Heterogeneity: Not applicat	he		101						
Test for overall effect: Not a	pplicable	е							
Total (95% CI)			647			659	100.0%	-5.61 [-8.69, -2.54]	\bullet
Heterogeneity: Tau ² = 25.92	2; Chi² =	160.93	, df = 12	2 (P < 0.0	00001);	l² = 930	%		
Test for overall effect: Z = 3	.58 (P =	0.0003)						Favours voga Favours control
Test for subgroup difference	es: Chi²:	= 5.62,	df = 2 (F	P = 0.06)	, l² = 64	.4%			
Footnotes									
(1) Yoga vs control (delivered	ed as an	adjunc	to educ	cation ar	nd walki	ng prog	ıram)		
(2) Kundalini yoga vs contro	ol.								
(3) Yoga with postures									

(4) Yogic breathing vs control.

(5) Yoga vs control. Data reported as mean change from baseline (SD).

(6) Yogic breathing (in class) vs control. Study did not report diastolic blood pressure (but reported systolic blood pressure).

(7) Results not able to be extracted. Direction of effect reported to favour intervention.

(8) Results not able to be extracted. Direction of effect reported to favour intervention.

(9) Study did not report diastolic blood pressure (but reported systolic blood pressure).

Figure 34 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Hypertension – perceived stress

		Yoga			Control			Mean Difference		Me	an Differen	се	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% C		IV, F	Random, 95	% CI	
6.3.1 PSS-10													
Cramer 2018 (1)	20.2	10	25	21.2	8.9	25	24.0%	-1.00 [-6.25, 4.25]		_			
Tolbanos Roche 2017 (2)	-5	8.26	14	1.8	7.66	10	18.0%	-6.80 [-13.22, -0.38]					
Wolff 2016	-1.8	6.027	85	-1.3	6.5298	86	58.0%	-0.50 [-2.38, 1.38]			-		
Subtotal (95% CI)			124			121	100.0%	-1.75 [-4.89, 1.38]					
Heterogeneity: Tau ² = 3.48;	Chi ² = 3	3.40, df	= 2 (P =	= 0.18);	l² = 41%								
Test for overall effect: Z = 1.	.10 (P =	0.27)											
6.3.2 missing data													
Sujatha 2014 (3)	0	0	118	0	0	123		Not estimable					
Subtotal (95% CI)			118			123		Not estimable					
Heterogeneity: Not applicab	le												
Test for overall effect: Not a	pplicable	е											
Total (95% CI)			242			244	100.0%	-1.75 [-4.89, 1.38]					
Heterogeneity: Tau ² = 3.48;	Chi ² = 3	3.40, df	= 2 (P =	= 0.18);	l² = 41%				+				-+
Test for overall effect: Z = 1.	.10 (P =	0.27)							-20	-10 Equation		10 ura control	20
Test for subgroup difference	es: Not a	pplicab	le							ravours	yoya Favo		
Footnotes													

(1) Yoga with postures.

(2) Yoga vs control. Data reported as mean change from baseline (SD).

(3) Results not able to be extracted. Direction of effect reported to favour yoga.

Figure 35 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Hypertension – health-related quality of life^

	Y	oga		С	ontrol		9	Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD T	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl
5.4.1 SF-36 Physical O	compone	nt Scor	e						L
Cramer 2018 (1) Subtotal (95% CI)	-47.9	9.4	25 25	-48.5	10.3	25 25	100.0% 100.0%	0.06 [-0.49, 0.61] 0.06 [-0.49, 0.61]	
Heterogeneity: Not app	licable								
Test for overall effect: 2	2 = 0.21 (I	⊃ = 0.83	6)						
5.4.2 SF-36 Mental Co	mponent	Score							_
Cramer 2018 (2) Subtotal (95% CI)	-52.3	7.6	25 25	-48.7	10.2	25 25	100.0% 100.0%	-0.39 [-0.95, 0.17] -0.39 [-0.95, 0.17]	
Heterogeneity: Not app	licable								
Test for overall effect: 2	z = 1.38 (I	P = 0.17	')						
5.4.3 WHOQOL-BREF	(Questio	on 1)							\perp
Wolff 2016 (3) Subtotal (95% CI)	-4.2	0.6	85 85	-4.2	0.8	86 86	100.0% 100.0%	0.00 [-0.30, 0.30] 0.00 [-0.30, 0.30]	
Heterogeneity: Not ann	licahle								
Test for overall effect: 7	' = 0 00 (I	⊃ = 1 00))						
	- 0.00 (1.00	'						
5.4.6 Generic measure	e (not de	fined)							_
Ankolekar 2019 Subtotal (95% CI)	-92.98	12.12	51 51	-87.39	10.35	51 51	100.0%	-0.49 [-0.89, -0.10]	
Heterogeneity: Not ann	licabla		01			01	100.070	-0.40 [-0.00, -0.10]	
Test for overall effect: 7	10abie 1 = 2 45 (I	⊃ = 0 01)						
	2.10 (1	0.01)						
5.4.7 missing data									
Cohen 2013 (4)	0	0	46	0	0	48		Not estimable	
Subtotal (95% CI)			46			48		Not estimable	
Heterogeneity: Not app	licable								
lest for overall effect: I	lot applic	able							
									-1 -0.5 0 0.5 1
									Favours yoga Favours control
Footnotes_									
(1) Yoga with postures									

(I) Yoga with postures

(2) Yoga with postures

(3) Kundalini yoga vs control.

(4) Yoga vs control (delivered as an adjunct to education and walking program)

Note: ^ Values inverted for consistency in direction of effect. Original scale reported in GRADE table.

Figure 36 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Hypertension – anxiety

	,	Yoga		C	ontrol		:	Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
6.5.1 Hospital anxiety and	depress	sion sc	ale (an	xiety)					
Cramer 2018	12.1	2	25	12	2	25	24.5%	0.05 [-0.51, 0.60]	_
Wolff 2016 (1)	4.4	3.3	85	4.1	3.6	86	27.1%	0.09 [-0.21, 0.39]	
Subtotal (95% CI)			110			111	51.6%	0.08 [-0.19, 0.34]	•
Heterogeneity: Tau ² = 0.00	Chi ² = 0	.01, df	= 1 (P =	= 0.91);	l² = 0%				
Test for overall effect: Z = 0	.58 (P =	0.56)							
6.5.2 Beck anxiety invento	ory								
Tolbanos Roche 2017 (2)	-3.57	12.28	14	-0.3	10.01	10	21.1%	-0.28 [-1.09, 0.54]	
Subtotal (95% CI)			14			10	21.1%	-0.28 [-1.09, 0.54]	
Heterogeneity: Not applicat	ole	0.54							
lest for overall effect: $Z = 0$.66 (P =	0.51)							
6.5.3 State Anxiety (STAI)									
Suiatha 2014	10 33	7 1/	118	18 08	8 18	122	27.3%	-1 12 [-1 39 -0 85]	_ _
Subtotal (95% CI)	40.00	7.14	118	40.30	0.10	122	27.3%	-1.12 [-1.39, -0.85]	•
Heterogeneity: Not applicat	ole								•
Test for overall effect: Z = 8	.07 (P <	0.0000	1)						
			- /						
6.5.4 Trait anxiety (STAI)									
Sujatha 2014 (3)	37.27	8.18	118	45.55	7.75	122		Not estimable	
Subtotal (95% CI)			0			0		Not estimable	
Heterogeneity: Not applicat	ole								
Test for overall effect: Not a	pplicable	e							
			242			242	400.00/	0 22 [4 07 0 44]	
	O 1 10 O		242			243	100.0%	-0.33 [-1.07, 0.41]	
Heterogeneity: I au ² = 0.50	$Chl^2 = 3$	8.73, di	r = 3 (P	< 0.000)01); I² =	= 92%			-2 -1 0 1 2
Lest for overall effect: $\angle = 0.87$ (P = 0.38)									Favours yoga Favours control
lest for subgroup difference	es: Chi ² =	= 38.72	at = 2	(٢ < 0.(10001),	I ² = 94.	8%		
<u>Footnotes</u>									

(1) Kundalini yoga vs control.

(2) Yoga vs control. Data reported as mean change from baseline (SD).

(3) Trait-anxiey scores presented for completeness. Data are not included in the meta-analysis.

4.8 Asthma

4.8.1 Description of the condition

Asthma is a chronic inflammatory condition affecting the airways. The causes of asthma are unknown but are thought to be a combination of genetic and environmental factors (201). An asthma flare-up can be triggered by a variety of exposures including dust mites, pollen, air pollution, tobacco smoke, cold air and physical exercise (201). These stimuli cause a widespread narrowing of the airways resulting in symptoms such as wheezing, shortness of breath, chest tightness and fatigue (201). There are 5 common types of asthma, differentiated primarily based on their cause – allergic, non-allergic, occupational, exercise-induced, and nocturnal (202). The effects of asthma can range from mild, intermittent symptoms that cause relatively few problems, to a severe and life-threatening condition, with almost 400 people in Australia dying due to asthma in 2018 (201).

Around 2.7 million Australians (more than one in ten) report being diagnosed with asthma (129). Asthma is the tenth highest contributor to the total burden of disease in Australia, accounting for 2.5% of the total burden of disease in 2015 (43). This burden is highest among children, with asthma being the leading cause of burden for children aged between 5 and 14 years (43). It has been estimated that the total cost of asthma to Australia in terms of both economic and health costs were \$28 billion in 2015 (203).

The key method of managing asthma is through pharmacological intervention, which can be categorised as preventers and relievers (204). In addition, the Global Initiative for Asthma (GINA) found high quality evidence to support engaging in physical activity, although there was little evidence to support one type of physical activity over another (205). There was also strong evidence to support breathing exercises for symptom management, but these exercises were not found to improve physiological outcomes (205).

4.8.2 Description of studies

There were 24 citations (206-229) corresponding to 12 RCTs (Agnihotri 2013, Agnihotri 2017, Jiandani Mariya 2013, Malarvizhi 2019, Manocha 2002, Mekonnen 2010, Prem 2013, Raghavendra 2016, Sabina 2005, Saravanan 2019, Turan 2020, Yuce 2020) and 5 quasi RCTs (Bidwell 2012, Pushpa 2018, Satpathy 2012, Saxena 2009, Sodhi 2009) identified in the literature search. There were 4 <u>ongoing studies</u> and 9 <u>studies awaiting</u> <u>classification</u>, including 3 studies published in a language other than English (230-232) and 6 studies published as abstract only (233-239). No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of the included studies is provided in Appendix D5.1.1.

Fourteen studies were conducted at a single centre in India (Agnihotri 2013, Agnihotri 2017, Jiandani Mariya 2013, Malarvizhi 2019, Prem 2013, Pushpa 2018, Raghavendra 2016, Saravanan 2019, Satpathy 2012, Saxena 2009, Sodhi 2009), Ethiopia (Mekonnen 2010) or the United States (Bidwell 2012, Sabina 2005). Two multicentre studies were conducted in Turkey (Turan 2020, Yuce 2020), and one study conducted in Australia sourced participants from the community setting (Manocha 2002). Sample sizes ranged from 19 to 300 participants (total 1726). All trials included participants with mild to moderate asthma, except for one trial (Manocha 2002) that included participants with moderate to severe asthma.

There were 10 studies that evaluated the effectiveness of yoga compared with control (no intervention) (Agnihotri 2013, Agnihotri 2017, Bidwell 2012, Malarvizhi 2019, Mekonnen 2010, Prem 2013, Pushpa 2018, Satpathy 2012, Sodhi 2009, Turan 2020). One study (Prem 2013) included another intervention group (Buteyko breathing). Seven studies evaluated the effectiveness of yoga compared to another intervention, being either supervised slow/deep breathing (Raghavendra 2016, Saravanan 2019), meditation (Saxena 2009), physiotherapy (Jiandi Mariya 2013), or relaxation methods that included progressive muscle stretching (Sabina 2005, Manocha 2002, Yuce 2020). In most studies, all participants remained on their prescribed medical care, with 4 studies (Raghavendra 2016, Saravanan 2019, Saxena 2009, Turan 2020) not specifying if any co-interventions were permitted.

There were 9 studies (Agnihotri 2013, Agnihotri 2017, Bidwell 2012, Jiandani Mariya 2013, Malarvizhi 2019, Mekonnen 2010, Pushpa 2018, Sabina 2005, Turan 2020) in which the yoga program included asana and pranayamas (with or without meditation), with a typical yoga session being between 60 and 90 minutes in duration. In 6 studies (Prem 2013, Raghavendra 2016, Satpathy 2012, Saxena 2009, Sodhi 2009, Yuce 2020), vogic breathing (pranavama) was the focus, with sessions being between 15 and 45 minutes in duration. In one study (Saravanan 2019), yoga hand mudras were practised along with smooth and deep breathing. There was one study (Manocha 2002) that focused on yoga meditation (Sahaja yoga described as "thoughtless awareness" or "mental silence"). Program intensity varied from one or 2 sessions weekly for 6 months, up daily practice for 4 to 8 weeks; except one study that only included 2, 10-minute sessions (Raghavendra 2016).

Results for yoga versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings Table (see Section 4.8.4.1 and Appendix F2). Results of studies that compared yoga with another comparator are presented in Appendix F2.

4.8.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 37. Details are provided in Appendix D5.1.2. No studies were judged to be at overall low risk of bias.

		Risk of bias domains												
		D1	D2	D3	D4	D5	Overall							
	Agnihotri 2013	-	+	+	-	-	-							
	Agnihotri 2017	-	+	-	-	-	-							
	Bidwell 2012	-	+	+	-	-	-							
	Jiandani Mariya 2013	-	+	+	-	-	-							
	Malarvizhi 2019	+	+	+	-	-	-							
	Manocha 2002	+	+	-	-	-	-							
	Mekonnen 2010	-	+	+	-	-	-							
	Prem 2013	+	X	-	-	-	X							
Study	Pushpa 2018	-	+	+	+	-	-							
	Raghavendra 2016	-	+	+	+	-	-							
	Sabina 2005	-	X	-	+	-	X							
	Saravanan 2019	-	+	+	+	-	-							
	Satpathy 2012	-	+	+	+	-	-							
	Saxena 2009	-	+	+	+	-	-							
	Sodhi 2009	-	+	+	+	-	-							
	Turan 2020	-	+	+	-	-	-							
	Yuce 2020	+	+	-	-	-	-							
		Domains:	aing from the	randomization	process	Judge	ement							
		D2: Bias due	e to deviations	from intende	d intervention	. 💌	High							
		:	Some concerns											

Figure 37 Risk of bias summary: review author's judgements about each risk of bias item for each included study – Asthma

D4: Bias in measurement of the outcome. D5: Bias in selection of the reported result.

Low

4.8.4 Main comparison (vs control)

Ten RCTs comparing yoga with control (no intervention, waitlist or usual care) in people with asthma were eligible for this comparison and contributed data relevant to 4 outcomes considered critical or important for this review (Agnihotri 2013, Agnihotri 2017, Bidwell 2012, Malarvizhi 2019, Mekonnen 2010, Prem 2013, Pushpa 2018, Satpathy 2012, Sodhi 2009, Turan 2020).

There were 8 studies awaiting classification (total 353 participants) and one ongoing study (total 60 participants) that could have contributed data to these outcomes (see Appendix C6). Nonreporting of results is possibly because the *p* value, magnitude or direction of effect was considered unfavourable by the study investigators.

4.8.4.1 Summary of findings and evidence statements

Yoga compared to control (no intervention, waitlist or usual care) for asthma											
Patient or population: Asthma Setting: Community Intervention: Yoga Comparison: Control (no intervention, waitlist or usual care)											
	Anticipated ab (95% CI)	solute effects*	Relative	Nº of	Certainty of the						
Outcomes	Risk with control	Risk with Yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statements					
Asthma symptom control assessed with: ACT or ACQ (higher is worse) follow-up: range 6 weeks to 12 weeks	-	SMD 2.24 SD lower ** (6.71 lower to 2.22 higher)	-	188 (2 RCTs)	⊕○○○ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of yoga on asthma symptom control in people with asthma.					
Pulmonary function assessed with: FEV ₁ /FVC (typical values between 75% to 85%) follow-up: range 6 weeks to 6 months	The mean FEV1/FVC was range 70.36 to 93.13 %	MD 2.71 % higher (3.76 lower to 9.19 higher)	-	680 (6 RCTs) †	⊕⊕⊖⊖ LOW ^{c,d,f,g}	Yoga may result in little to no improvement in pulmonary function in people with asthma.#					
Health related Quality of life assessed with: AQLQ, SGRQ (higher is worse) follow-up: range 6 weeks to 6 months	-	SMD 3.35 SD lower ** (5.18 lower to 1.53 lower)	-	826 (6 RCTs) ^{††}	⊕⊕⊖⊖ LOW ^{c,fg,h}	Yoga may result in a large improvement in quality of life in people with asthma.					
Emotional function - not reported	-	-	-	-	-	No studies found. The effect of yoga on emotional function in people with asthma is unknown.					
Medication use assessed with: reduction in salbutamol use (inhaler) follow-up: 4 weeks	833 per 1000	333 per 1000 (142 to 775)	RR 0.40 (0.17 to 0.93)	24 (1 RCT)	⊕OOO VERY LOW d,e	The evidence is very uncertain about the effect of yoga on medication use in people with asthma ##					

Yoga compared to control (no intervention, waitlist or usual care) for asthma

Patient or population: Asthma Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated ab (95% CI)	solute effects*	Pelative	Nº of	Certainty of	
Outcomes	Risk with control	Risk with Yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statements
Days off work/ school - not reported	-	-	-	-	-	No studies found. The effect of yoga on days off work/ school in people with asthma is unknown.
Asthma specific hospitalisations - not reported	-	-	-	-	-	No studies found. The effect of yoga on hospitalisations in people with asthma is unknown.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

** As a rule of thumb, an SMD of 0.2 represents a small difference, 0.5 is moderate, and 0.8 is a large difference (58).

*** Effect estimates were considered on 3 levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).

Normalisation of the ratio is considered clinically important. ## A 25% relative reduction is considered important (i.e. RR < 0.75).

† Data from 4 studies (549 participants) missing/not able to be included in the meta-analysis. †† Data from 1 study (76 participants) not able to be included in the meta-analysis.

ACT: Asthma control test; ACQ: Asthma control questionnaire; AQLQ: Asthma quality of life questionnaire; CI: confidence interval; SMD: standardised mean difference

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. Serious risk of bias. Once RCT contributing ~50% of data was at high risk of bias. Certainty of evidence downgraded.

- b. No serious inconsistency. Point estimates vary widely and confidence intervals do not overlap. Substantial statistical heterogeneity (1² > 90%) may be explained by variances in the study PICOs.. Certainty of evidence not downgraded.
- c. No serious indirectness. The available evidence includes studies that examines yoga (pranayamas) that may not be applicable to the Australian context but could be sensibly applied. Certainty of evidence not downgraded.
- d. Serious imprecision. Wide confidence intervals (upper and lower bounds overlap with both and important and no important difference). Certainty of evidence downgraded.
- e. Publication bias suspected. Several studies (~120 participants) that could have contributed data to this outcome. There is a strong suspicion of non-reporting of results likely related to the *p* value, direction or magnitude of effect. Certainty of evidence downgraded.
- f. No serious risk of bias. One RCT contributing <20% of data was at high risk of bias, that did not materially influence the result. Certainty of evidence not downgraded.
- g. Serious inconsistency. Point estimates vary widely and confidence intervals do not overlap for some studies. Substantial statistical heterogeneity (l² > 90%) that cannot be explained. Certainty of evidence downgraded.
- h. Publication bias suspected. Several studies (~550+ participants) that could have contributed data to this outcome. There is a strong suspicion of non-reporting of results likely related to the *p* value, direction or magnitude of effect. Certainty of evidence downgraded.

4.8.4.2 Forest plots

Outcomes relating to asthma symptoms in people with asthma are presented in Figure 38.

Outcomes results related to pulmonary function in people with asthma are presented in Figure 39.

Outcome results related to asthma quality of life in people with asthma are presented in Figure 40.

Outcome results related to medication use in people with asthma are presented in Figure 41.

Figure 38 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Asthma – asthma symptoms

	Yoga		Control			5	Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean S) Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
7.1.1 Asthma control	test							
Turan 2020 (1)	-23.21 1.5	7 56	-12.66	2.87	56	49.8%	-4.53 [-5.24, -3.82]	
		00			90	49.0 %	-4.55 [-5.24, -5.62]	•
Heterogeneity: Not app	licable							
Test for overall effect: 2	Z = 12.53 (P < 0	.00001)						
7.1.2 Asthma control Prem 2013 (2) Subtotal (95% CI) Heterogeneity: Not app Test for overall effect: 2	questionnaire 0.13 0.827 licable Z = 0.11 (P = 0.	5 36 36 91)	0.11	0.7817	40 40	50.2% 50.2 %	0.02 [-0.43, 0.47] 0.02 [-0.43, 0.47]	F
Total (95% CI) Heterogeneity: Tau ² = ⁻ Test for overall effect: Z Test for subgroup differ	10.28; Chi² = 11 Z = 0.99 (P = 0. rences: Chi² = 1	-2.24 [-6.71, 2.22]	-10 -5 0 5 10 Favours yoga Favours control					

Footnotes

(1) Data inverted for the scale to point in the same direction of effect

(2) Yogic breathing vs control. Data are mean change from baseline.

Figure 39 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Asthma – pulmonary function (FEV₁/FVC)*

		Yoga		С	ontrol			Mean Difference	Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl		
6.2.1 FEV1/FVC											
Agnihotri 2013	-66.62	3.97	121	-70.36	4.92	120	17.4%	3.74 [2.61, 4.87]	+		
Prem 2013 (1)	4	9.44	36	-2.38	9.58	40	16.2%	6.38 [2.10, 10.66]			
Pushpa 2018 (2)	-79.95	5.44	30	-70.96	6.81	30	16.8%	-8.99 [-12.11, -5.87]			
Satpathy 2012 (3)	-73.96	3.04	37	-75.91	10.66	34	16.5%	1.95 [-1.76, 5.66]			
Sodhi 2009 (4)	-96.6	9.67	60	-93.13	8.94	60	16.7%	-3.47 [-6.80, -0.14]			
Turan 2020	-86.96	12.92	56	-71.03	5.66	56	16.5%	-15.93 [-19.62, -12.24]	- - -		
Subtotal (95% CI)			340			340	100.0%	-2.71 [-9.19, 3.76]			
Heterogeneity: Tau ² =	62.57; Cl	ni² = 15	5.85, df	[•] = 5 (P <	0.0000)1); l² =	97%				
Test for overall effect:	Z = 0.82	(P = 0.4	1)								
6.2.4 Not reported											
Agnihotri 2017 (5)	0	0	125	0	0	130		Not estimable			
Bidwell 2012 (6)	0	0	12	0	0	8		Not estimable			
Malarvizhi 2019 (7)	0	0	125	0	0	125		Not estimable			
Mekonnen 2010 (8)	0	0	12	0	0	12		Not estimable			
Subtotal (95% CI)			274			275		Not estimable			
Heterogeneity: Not ap	plicable										
Test for overall effect:	Not appli	cable									
								-			
									-20 -10 0 10 20		
Footnotes											

(1) Yogic breathing vs control. Mean (SD) change from baseline.

(2) Yogic breathing vs control.

(3) Yogic breathing vs control.

(4) Yogic breathing vs control.

(5) Not clear if outcome was measured.

(6) authors report no changes between groups at the end of treatment, but no data provided.

(7) Not clear if outcome was measured.

(8) Not clear if outcome was measured.

*Data inverted to ensure consistency in direction of effect.

Figure 40 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Asthma – health-related quality of Life

		Yoga		C	ontrol		;	Std. Mean Difference		Std. Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI		IV, Random, 95% CI	
6.3.1 AQLQ (15- or 3	2- item)										
Agnihotri 2017	-5.72	0.38	125	-5.43	0.34	130	17.3%	-0.80 [-1.06, -0.55]		•	
Malarvizhi 2019 (1)	-130.48	12.43	123	-78.82	4.37	120	17.1%	-5.50 [-6.05, -4.95]		+	
Prem 2013 (2)	-4.69	1.0882	36	-4.19	1.0882	40	17.2%	-0.45 [-0.91, 0.00]		*	
Sodhi 2009 (3)	-142.65	19.36	60	-130.05	21.92	60	17.2%	-0.61 [-0.97, -0.24]		+	
Turan 2020 Subtotal (95% CI)	-6.72	0.27	56 400	-2.62	0.55	56 406	15.9% 84.7%	-9.40 [-10.71, -8.09] - 3.26 [-5.24, -1.27]		•	
Heterogeneity: Tau ² =	5.01: Chi ²	= 410.10). df = 4	1 (P < 0.00	0001): l²	= 99%				-	
Test for overall effect:	Z = 3.22 (I	^D = 0.00 ⁴	1)								
6.3.3 SGRQ (0-100)											
Bidwell 2012 Subtotal (95% CI)	16.01	3	12 12	31.85	5	8 8	15.3% 15.3%	-3.89 [-5.50, -2.27] -3.89 [-5.50, -2.27]		→	
Heterogeneity: Not an	plicable							• • •		•	
Test for overall effect:	Z = 4.72 (I	> < 0.000	001)								
6.3.4 Not reported											
Agnihotri 2013 (4)	0	0	121	0	0	120		Not estimable			
Mekonnen 2010 (5) Subtotal (95% CI)	0	0	12 133	0	0	12 132		Not estimable Not estimable			
Heterogeneity: Not ap	plicable										
Test for overall effect:	Not applic	able									
Total (95% CI)			545			546	100.0%	-3.35 [-5.18, -1.53]		•	
Heterogeneity: Tau ² =	4.99; Chi ²	= 419.47	7, df = 5	5 (P < 0.00	0001); l²	= 99%					40
Test for overall effect:	Z = 3.60 (I	- = 0.00	03)						-10	-0 U 5	UI'
Test for subgroup diffe	erences: C	hi² = 0.23	3, df = 1	l (P = 0.63	3), I² = 09	%				r avours yoga i avours contr	UI
Footnotes											

(1) Total AQLQ score is beyond the typical 1-7-point range. It is assumed to be the sum of mean score for each item.

(2) Yogic breathing vs. control. Data estimated from mean between group difference of 0.50 (95% CI 0.01, 0.98); p = 0.042.

(3) Yogic breathing vs control. Total AQLQ score is beyond the typical 1-7-point range. It is assumed to be the sum of mean score for each item.

(4) Authors suggest a sigificant (P<0.00001) improvement in the yoga group, but no data are provided.

(5) Not clear if outcome was measured.

Risk Ratio (Non-event) **Risk Ratio (Non-event)** Yoga Control Events Total Events Total Weight M-H, Random, 95% Cl M-H, Random, 95% Cl Study or Subgroup 7.4.1 Reduction in salbutamol (puff) use Mekonnen 2010 8 12 2 12 100.0% 0.40 [0.17, 0.93] Subtotal (95% CI) 12 12 100.0% 0.40 [0.17, 0.93] Total events 8 2 Heterogeneity: Not applicable Test for overall effect: Z = 2.14 (P = 0.03) 7.4.2 Reduction in salbutamol (tablet) use Mekonnen 2010 7 12 1 12 100.0% 0.45 [0.23, 0.91] Subtotal (95% CI) 12 100.0% 0.45 [0.23, 0.91] 12 Total events 7 1 Heterogeneity: Not applicable Test for overall effect: Z = 2.24 (P = 0.03) 0.005 10 200 0.1 Favours yoga Favours control

Figure 41 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Asthma – medication use

4.9 Chronic pain conditions

4.9.1 Description of the conditions

Chronic pain is a persistent pain that continues beyond the normal healing time for an injury or illness – generally 3 to 6 months (240). Pain can result from an injury, surgery, musculoskeletal conditions such as arthritis (see Section 4.9.1.1 and Section 4.9.1.2) or other medical conditions such as endometriosis or fibromyalgia (see Section 4.9.1.3). While acute pain is a response to damaged tissue that usually resolves once the tissue heals, chronic pain is more complex. It may result from damage to body tissue from an acute or chronic condition, or changes in the nerves or nervous system that result in a continuing pain signal after the original condition has resolved.

Chronic pain is a common condition in Australia, with one in 5 Australians aged 45 and over living with persistent, ongoing pain (240). The prevalence of chronic pain is increasing with age, possibly because older people often experience more medical conditions (such as arthritis) that are associated with pain (240). Women are more likely than men to experience chronic pain (21% compared to 17%). Behavioural factors linked to chronic pain include sedentary behaviour, smoking, and being overweight or obese. Chronic pain can be disabling and stressful, resulting in reduced quality of life, and inability to work or partake in daily activities. In 2018, chronic pain cost an estimated \$139 billion in Australia, mostly associated with indirect costs such as reduced quality of life and productivity losses (240).

This section combines information across a variety of chronic pain conditions not reported elsewhere. The grouping was informed by survey data on what conditions are most often seen by yoga teachers and was done to reduce the number of sections with very few studies each.

4.9.1.1 Osteoarthritis

Osteoarthritis (OA) is a chronic disease that primarily impacts the articular cartilage and the subchondral bone of a synovial joint which eventually results in joint failure (241). Individuals with OA experience joint pain, stiffness and swelling which mainly affects the hands, knees and hips (242). As OA progresses it can impact a person's quality of life as it becomes difficult to perform everyday tasks (242).

OA is the most common form of arthritis in Australia, with a 2017-108 survey revealing an estimated 2.2 million (9.3%) Australians are living with OA (241-243). There is no specific cause of OA, however several factors contribute to the onset and progression of disease, including being female, overweight or obese. Although younger people can be affected, it most frequently occurs in people aged over 55 years with over one third of all adults aged 75 years or older experiencing this condition (242, 243). There is no cure for OA (243), with recommended treatments focused on relieving pain and improving joint function. International and local guidelines (241, 242, 244) recommend routine aerobic exercise and/or physiotherapy to assist in improving pain and maintain and strengthen joint function and range of motion. The Australian guidelines (242) strongly recommend regular land based exercise such as muscle strengthening exercise, Pilates, walking and Tai Chi.

4.9.1.2 Inflammatory arthropathies

Inflammatory arthropathies are a group of related conditions where joint inflammation and pain are caused by a chronic autoimmune reaction (245). Inflammatory arthropathies include conditions such as rheumatoid arthritis (RA), psoriatic arthritis, and juvenile idiopathic arthritis. RA is the most common inflammatory arthropathy in Australia (245) and is characterised by joint swelling, tenderness, and destruction of synovial joints (246). Instead of producing nourishing and lubricating fluid, the synovial membrane lining affected joints is attacked by the immune system and becomes thick and inflamed. This results in unwanted tissue growth, bone erosion, and irreversible joint damage (247). RA typically affects hand joints and both sides of the body at the same time (247). The estimated prevalence of RA in Australia is 1.9%, or around 456 000 people (247). RA is more common in women than in men, and occurs most commonly in people over age 75 (247). In 2017 to 2018, there were 12 045 hospitalisations for RA (247). Several pharmacological options are indicated for the management of inflammatory arthropathies. Disease-modifying anti-rheumatic drugs (DMARDs), biologic disease-modifying anti-rheumatic drugs (DMARDs), biologic disease-modifying anti-rheumatic drugs (bDMARDs), and corticosteroids can slow disease progression (247). If initiated early, these medications can help prevent irreversible damage and disability (247). In addition to pharmacological interventions, low-impact physical activity is also recommended to help reduce inflammation, increase and maintain mobility, and increase muscle strength around the joints (247).

4.9.1.3 Chronic widespread pain (fibromyalgia)

Chronic widespread pain is characterised as a diffuse pain that occurs in at least four of five body regions lasting for a minimum of three months, and is associated with significant emotional distress (anxiety, anger/frustration or depressed mood) or functional disability (interference in daily life activities and reduced participation in social roles) (248, 249).

One condition frequently associated with chronic widespread pain is fibromyalgia, which is defined by the American College of Rheumatologyⁱ (250), as a widespread and prolonged pain persisting for more than three months with pain on at least 11 of 18 specified tender points on the body when palpated. People diagnosed with fibromyalgia not only experience widespread pain but also experience poor sleep quality, fatigue, extreme sensitivity, irritable bowel (diarrhoea, stomach pain) and headaches (251). Fibromyalgia can be difficult to diagnose as there is no single diagnostic test, symptoms may fluctuate from day to day, and it often co-exists with other chronic illnesses such as arthritis, depression or sleep apnoea (252). In a North American survey, approximately half of the participants surveyed had consulted three to six healthcare professionals before receiving their diagnosis (253).

Fibromyalgia is a chronic and disabling condition that can affect all aspects of life, including work, family and leisure (254). In Australia, fibromyalgia is estimated to affect approximately 3-5% of the population, equating to as many as 1 million Australians, it can affect people of all ages and it has a significantly higher prevalence in females (255). For those who are successfully diagnosed, management of symptoms is the mainstay of treatment, with various drug and non-drug treatments playing a supportive role in managing pain, promoting sleep and reducing stress. International and local guidelines (256-258) therefore encourage physical therapy and exercise, including Yoga, Pilates as well as Tai Chi. Regular exercise is important to manage fibromyalgia as it can improve range of motion, flexibility, bone and muscle strength as well as balance (256). Sedentary lifestyles for people diagnosed with fibromyalgia can increase their risk for several chronic diseases and therefore, optimising overall health and quality of life through regular exercise and physical activity is important (259).

4.9.2 Description of studies

There were 37 citations (260-296) corresponding to 15 RCTs (Carson 2010, Cheung 2016, Cheung 2014, Ebnezar 2011, Evans 2011a, Flehr 2019, Ganesan 2020, Gautam 2019, Kuntz 2016, McCaffrey 2019, Moonaz 2015, Park 2016, Schmid 2018, Ward 2014) and 4 quasi RCTs (Bedekar 2012, Bhandari 2009, Deepeshwar 2018, Khan 2018, Park 2011) identified in the literature search. There were 15 <u>ongoing studies</u>, and 13 <u>studies awaiting</u> <u>classification</u> (297-309). No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D6.1.1

Five studies (Bhandari 2009, Evans 2011a, Ganesan 2020, Gautam 2019, Ward 2014) included participants with inflammatory arthropathies (rheumatoid arthritis, juvenile idiopathic arthritis). Nine studies (Bedekar 2012, Cheung 2016, Cheung 2014, Deepeshwar 2018, Ebnezar 2011, Kuntz 2016, McCaffrey 2019, Park 2011, Park 2016) included participants with osteoarthritis, predominantly of the knee and also including hip or other lower extremities. One study (Moonaz 2015) included participants with either osteoarthritis or rheumatoid arthritis. Four studies included participants with chronic pain attributed to various causes such as fibromyalgia (Carson 2010), trauma (Flehr 2019), myofascial dysfunction syndrome (Khan 2018), or not specified (Schmid 2018)

ⁱ the most frequently used criteria by clinicians to diagnose fibromyalgia.

The studies were predominantly carried out in single, community-care settings in a variety of countries including Australia (Flehr 2019), Canada (Kuntz 2016), India (Bedekar 2012, Deepeshwar 2018, Ebnezar 2011, Bhandari 2009, Ganesan 2020, Gautam 2019), New Zealand (Ward 2014) and the United States (Carson 2010, Schmid 2018, Cheung 2014, Cheung 2016, McCaffrey 2019, Park 2011, Park 2016, Evans 2011, Moonaz 2015). One study (Khan 2018) did not specify the setting or country (associated with 4 different colleges and hospitals in India and Saudi Arabia).

There were 12 studies that examined the effect of yoga compared with control, being either no intervention (Bedekar 2012, Bhandari 2009, Khan 2018, Ward 2014), waitlist (Carson 2010, Cheung 2014, Evans 2011a, Ganesan 2020, Moonaz 2015) or usual care (Deepeshwar 2018, Gautam 2019, Schmid 2018). Yoga was delivered as an adjunct to standard medical care in 9 studies (Bhandari 2009, Carson 2010, Evans 2011a, Ganesan 2020, Gautam 2019, Khan 2018, Moonaz 2015, Schmid 2018, Ward 2014), and as an adjunct to physiotherapy in 2 studies (Bedekar 2012, Ebnezar 2011).

Eight studies compared yoga with an active comparator, being either physical exercise (Cheung 2016, Ebnezar 2011, Flehr 2019, Kuntz 2016), chair exercise (McCaffrey 2019), guided meditation (Kuntz 2016, Khan 2018). reiki (Park 2011) or a wellness education program (Park 2016).

Most studies delivered a yoga program that included poses, breathing and mindfulness training, with sessions ranging from 30 minutes to 2 hours and program intensity ranging from once per week to daily. In 3 studies (McCaffrey 2019, Park 2011, Park 2016) participants practised yoga in a chair or using a chair as support. One study (Khan 2018) participants practised Raj-yoga that included meditation and pranayama. Yoga programs typically lasted for 8 weeks but ranged from 7 days to 12 weeks.

Results for yoga versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings Table (see Section 4.9.4.1) and Appendix F2. Results of studies that compared yoga with another comparator are presented in Appendix F2.

4.9.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 42. Details are provided in Appendix D6.1.2. No studies were judged to be at overall low risk of bias.



Figure 42 Risk of bias summary: review author's judgements about each risk of bias item for each included RCT – Chronic pain

4.9.4 Main comparison (vs control)

There were 12 RCTs (or quasi RCTs) comparing yoga with control (no intervention, waitlist or usual care) in people with chronic pain conditions that were eligible for this comparison and contributed data relevant to 9 outcomes considered critical or important for this review (Bedekar 2012, Bhandari 2009, Carson 2010, Cheung 2014, Deepeshwar 2018, Evans 2011a, Ganesan 2020, Gautam 2019, Khan 2018, Moonaz 2015, Schmid 2018, Ward 2014).

There were 10 studies awaiting classification (total 450+ participants) and 5 ongoing studiesⁱ (total 450+ participants) comparing yoga with control (no intervention, waitlist or usual care) that could have contributed data to these outcomes (see Appendix C6). The available information is insufficient to make a judgement about the nonreporting of results but may be because the *p* value, magnitude or direction of effect was considered unfavourable by the study investigators.

HTANALYSTS | NHMRC | EVIDENCE EVALUATION ON THE CLINICAL EFFECTIVENESS OF YOGA

^j Complete, results not available or published

4.9.4.1 Summary of findings and evidence statements

Chronic pain conditions

Yoga compared to control (no intervention, waitlist or usual care) for chronic pain conditions

Patient or population: Chronic pain conditions (inclusive of osteoarthritis, rheumatoid arthritis, chronic pain not specified)

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	solute effects*	Relative	Nº of	Certainty of			
Outcomes	Risk with control	Risk with Yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statements		
Health-related quality of life assessed with: SF- 36, EQ-5D-3L (higher is better) follow-up: 8 weeks	-	SMD 0.02 SD lower ** (0.35 lower to 0.31 higher)	-	139 (3 RCTs)	⊕⊕⊖⊖ LOW ^{a,b,c,d}	Yoga may result in little to no difference in health- related quality of life in people with chronic pain conditions (rheumatoid arthritis, chronic pain not specified).		
Pain assessed with: BPI, VAS, WOMAC, NRS (pain) (higher is worse) follow-up: range 6 to 9 weeks	-	SMD 0.75 SD lower ** (1.72 lower to 0.22 higher)	-	196 (4 RCTs)	⊕○○○ VERY LOW _{b,c,d,e,f}	The evidence is very uncertain about the effect of yoga on pain in people with a range of chronic pain conditions.		
Perceived stress assessed with: PSS- 10 (higher is worse) Scale from: 0 to 40 follow-up: 8 weeks	The mean PSS score was 15 points	MD 1.90 lower (9.07 lower to 5.27 higher)	-	75 (1 RCT)	⊕OOO VERY LOW b,c,d,g	The evidence is very uncertain about the effect of yoga on perceived stress in people with osteoarthritis or rheumatoid arthritis. #		
Emotional function SF-36, SF-12 MCS (higher is best) follow-up: 8 weeks	-	MD 0.06 higher ** (5.05 lower to 6.26 higher)	-	111 (2 RCTs)	⊕⊕⊖⊖ LOW ^{b,c,d,h}	Yoga may result in little to no difference on emotional function in people with osteoarthritis or rheumatoid arthritis. ##		
Physical function assessed with: WOMAC – function (higher is worse), SF-36 PCS follow-up: 8 weeks to 3 months	-	SMD 0.86 lower ** (1.32 lower to 0.39 lower)	-	162 (3 RCTs)	⊕OOO VERY LOW _{b,d,i}	The evidence is very uncertain about the effect of yoga on physical function in people with osteoarthritis or rheumatoid arthritis.		
Functional endurance and mobility assessed with: 6MWT (further is better) follow-up: 8 weeks	The mean distance was 885 metres	MD 18.76 m further (140.76 shorter to 178.28 further)	-	92 (2 RCTs)	⊕⊕⊖⊖ Low ^{b,fj}	Yoga may result in little to no difference in functional endurance or mobility in people with chronic pain conditions (mostly musculoskeletal). ###		

Yoga compared to control (no intervention, waitlist or usual care) for chronic pain conditions

Patient or population: Chronic pain conditions (inclusive of osteoarthritis, rheumatoid arthritis, chronic pain not specified)

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	solute effects*	Relative	Nº of	Certainty of	
Outcomes	Risk with control	Risk with Yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statements
Symptom severity - not reported ^ Fibromyalgia symptoms reported in table below	-	-	-	-	-	No studies found. The effect of yoga on symptom severity in people with chronic pain (trauma-related) is unknown. ^
Self-efficacy assessed with: CPPS (higher is better) follow-up: 8 weeks	The mean CPPS score was 56.19 points	MD 6.08 points higher (2.69 lower to 14.85 higher)	-	83 (1 RCT)	⊕OOO VERY LOW _{b,g,j}	The evidence is very uncertain about the effect of yoga on self-efficacy in people with chronic pain conditions.
Medication use - not reported	-	_	-	-	-	No studies found. The effect of yoga on medication use in people with chronic pain conditions is unknown.
Pain acceptance assessed with: CPAQ (higher is better) Scale from: 0 to 120 follow-up: 6 weeks	The mean CPAQ score was 72.7	MD 5.00 higher (6.38 lower to 16.38 higher)	-	30 (1 RCT)	⊕OOO VERY LOW ĸ!	The evidence is very uncertain about the effect yoga on pain acceptance in people with rheumatoid arthritis.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

** As a rule of thumb, an SMD of 0.2 represents a small difference, 0.5 is moderate, and 0.8 is a large difference (58).

*** Effect estimates were considered on 3 levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).

MCID between 2.19 and 11 points among students or adults with elevated stress (200, 311).
MCID for the SF-36 is estimated to be between 2 to 4 (312).
A change of 14.0 to 30.5 metres is suggested to be clinically important (313).

6MWT: Six-minute walk test; BPI: brief pain inventory; CPAQ: Chronic pain acceptance questionnaire; CPPS: Chronic pain self-efficacy scale; CI: confidence interval; FIQ: Fibromyalgia impact questionnaire; HAQ: Health Assessment Questionnaire; NRS: numeric rating scale PCS: physical component score; SF-36: 36-item short form; SMD: standardised mean difference; VAS: Visual analogue scale; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

- a. No serious risk of bias. Two out of 3 RCTs were at high risk of bias. Removal of these studies from the analysis does not materially change the estimate of effect. Certainty of evidence not downgraded.
- b. No serious indirectness. The available evidence is in people with inflammatory arthropathies or non-specific pain and is directly generalisable to the Australian population with few caveats. Certainty of evidence not downgraded
- c. Serious imprecision. Wide confidence intervals (upper and lower bounds overlap with both and important and no important difference). Certainty of evidence downgraded.
- d. Publication bias suspected. Several studies awaiting classification or ongoing that could have contributed data to this outcome. There is a strong suspicion of non-reporting of results likely related to the *p* value, direction or magnitude of effect. Certainty of evidence downgraded.
- e. Serious risk of bias. Two out of 4 RCTs contributing ~50% of the data were at high risk of bias. In a sensitivity analysis examining the impact of these RCTs, the size the effect estimate decreased. Certainty of evidence downgraded.
- f. No serious inconsistency. Point estimates vary widely and confidence intervals for some studies do not overlap. Substantial statistical heterogeneity (I² = 89%) possibly explained by differences in the PICOs. Certainty of evidence not downgraded.
- g. Serious risk of bias. One RCT contributing 100% of data at high risk of bias. Certainty of evidence downgraded.
- h. No serious risk of bias. One RCT contributing 48% of data at high risk of bias, not considered to materially change the result. Certainty of evidence not downgraded.
- i. Serious risk of bias. Two RCTs contributing ~70% of data at high risk of bias, which overstates the effect estimate in favour in yoga. Certainty of evidence downgraded.
- j. Very serious imprecision. Wide confidence intervals (upper and lower bounds overlap with both and important and no important difference). Certainty of evidence downgraded 2 levels.
- k. Serious risk of bias. One RCT contributing 100% of data at high risk of bias. Certainty of evidence downgraded.
- I. Very serious imprecision. Wide confidence intervals (upper and lower bounds overlap with both and important and no important difference). Certainty of evidence downgraded 2 levels.

Fibromyalgia

Yoga compared to control (no intervention, waitlist or usual care) for fibromyalgia

Patient or population: Fibromyalgia

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	solute effects*	Delativo	N ⁰ of	Certainty of	
Outcomes	Risk with control	Risk with Yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statements
Health-related quality of life assessed with: FIQ (higher is worse) follow-up: 8 weeks	The mean FIQ- total score was 48.69 points	MD 13.02 lower (23.03 lower to 3.37 lower)	-	53 (1 RCT)	⊕⊕⊖⊖ Low ª,b	Yoga may result in slight improvement in quality of life in people with fibromyalgia. #
Physical function assessed with: FIQ (function) (higher is worse) follow-up: 8 weeks	The mean FIQ- function score was 12.4 points	MD 2.67 lower (6.50 lower to 1.16 higher)	-	53 (1 RCT)	⊕⊕⊖⊖ Low ª,b	Yoga may result in little to no difference in quality of life in people with fibromyalgia. #
Fibromyalgia symptoms – pain assessed with FIQ (higher is worse) follow-up: 8 weeks	The mean FIQ- pain score was 5.14 points	MD 1.02 lower (2.18 lower to 0.14 higher)	-	53 (1 RCT)	⊕⊕⊖⊖ Low ª,b	Yoga may result in little to no difference in pain in people with fibromyalgia. #
Fibromyalgia symptoms – stiffness assessed with FIQ (higher is worse) follow-up: 8 weeks	The mean FIQ- stiffness score was 5.82 points	MD 1.10 lower (2.10 lower to 0.10 lower)	-	53 (1 RCT)	⊕⊕⊖⊖ Low ª,b	Yoga may result in little to no difference in stiffness in people with fibromyalgia. #

Yoga compared to control (no intervention, waitlist or usual care) for fibromyalgia

Patient or population: Fibromyalgia

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	solute effects*	Delative	N ⁰ of	Certainty of	
Outcomes	Risk with control	Risk with Yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statements
Fibromyalgia symptoms – tenderness assessed with FIQ (higher is worse) follow-up: 8 weeks	The mean FIQ- tenderness score was 5.96 points	MD 0.96 lower (2.42 lower to 0.50 higher)	-	53 (1 RCT)	⊕⊕⊖⊖ Low ^{a,b}	Yoga may result in little to no difference in tenderness in people with fibromyalgia. #
Fibromyalgia symptoms – morning tiredness assessed with FIQ (higher is worse) follow-up: 8 weeks	The mean FIQ- morning tiredness score was 6.11 points	MD 0.39 lower (2.01 lower to 1.23 higher)	-	53 (1 RCT)	⊕⊕⊖⊖ Low ^{a,b}	Yoga may result in little to no difference in morning tiredness in people with fibromyalgia. #
Fatigue assessed with FIQ - fatigue (higher is worse) follow-up: 8 weeks	The mean FIQ- fatigue score was 6.71 points	MD 2.01 lower (3.16 lower to 0.86 lower)	-	53 (1 RCT)	⊕⊕⊖⊖ Low ^{a,b}	Yoga may result in a slight improvement in fatigue in people with fibromyalgia. #
Pain acceptance assessed with: CPAQ (higher is better) Scale from: 0 to 120 follow-up: 8 weeks	The mean CPAQ score was 65.61	MD 9.79 higher (1.50 higher to 18.08 higher)	-	53 (1 RCT)	⊕⊕⊖⊖ Low ª,b	Yoga may result in a slight improvement in pain acceptance in people with fibromyalgia.##

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

** As a rule of thumb, an SMD of 0.2 represents a small difference, 0.5 is moderate, and 0.8 is a large difference (58).

*** Effect estimates were considered on 3 levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).

A 14-point change (or 14%) in the FIQ total score is considered clinically relevant (310). ## A score of 74.9 or above on the CPAQ suggests high level of pain acceptance (184);

Cl: confidence interval; CPAQ: Chronic pain acceptance questionnaire; FIQ: Fibromyalgia impact questionnaire; SMD: standardised mean difference

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

- a. No serious indirectness. The available evidence is in people with fibromyalgia and is directly generalisable to the Australian population with few caveats. Certainty of evidence not downgraded.
- b. Serious imprecision. One study. Wide confidence intervals (upper and lower bounds overlap with both and important and no important difference). Certainty of evidence downgraded two levels.

4.9.4.2 Forest plots

Chronic pain conditions

Outcomes relating to health-related quality of life in people with chronic pain conditions are presented in Figure 43.

Outcomes relating to pain in people with chronic pain conditions are presented in Figure 44. Outcomes relating to perceived stress in people with chronic pain conditions are presented in Figure 45. Outcomes relating to emotional function in people with chronic pain conditions are presented in Figure 46. Outcomes relating to physical function in people with chronic pain conditions are presented in Figure 47. Outcomes relating to mobility in in people with chronic pain conditions are presented in Figure 48. Outcomes relating to self-efficacy in in people with chronic pain conditions are presented in Figure 49. Outcomes relating to pain acceptance in people with chronic pain conditions are presented in Figure 50.

Fibromyalgia

Outcomes relating to health-related quality of life in people with fibromyalgia are presented in Figure 51. Outcomes relating to physical function in people with fibromyalgia are presented in Figure 52. Outcomes relating to symptom severity in in people with fibromyalgia are presented in Figure 53. Outcomes relating to pain acceptance in people with fibromyalgia are presented in Figure 54.

Figure 43 Forest plot of comparison: Yoga vs control (no intervention, usual care): Chronic pain conditions – health-related quality of life^

	Y	roga		C	ontrol		5	Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
7.1.1 EQ-5D-3L									
Ward 2014 (RA)	-0.76	0.14	13	-0.73	0.26	13	18.7%	-0.14 [-0.91, 0.63]	
Subtotal (95% CI)			13			13	18.7%	-0.14 [-0.91, 0.63]	
Heterogeneity: Not applicable									
Test for overall effect: Z = 0.35 (P = 0.72)									
- / 0.05.00									
7.1.2 SF-36									
Evans 2011 (RA or JIA)	-59.1	19.2	14	-59.3	26.4	16	21.6%	0.01 [-0.71, 0.73]	
Schmid 2018 (pain clinic)	-94.07	8.6	44	-94.63	6.07	39	59.7%	0.07 [-0.36, 0.50]	
	=		58			55	61.3%	0.06 [-0.31, 0.43]	
Heterogeneity: $1 au^2 = 0.00$; $Chi^2 = 0.02$, o	if = 1 (P	= 0.88); I ² = 0'	%					
Test for overall effect: $Z = 0.30 (P = 0.76)$									
7.1.3 Outcome not reported, probably I	oecause	it was	s not m	easured	I				
Bedekar 2012 (OA, after TKA)	0	0	25	0	0	26		Not estimable	
Bhandari 2009 (RA)	0	0	40	0	0	40		Not estimable	
Cheung 2014 (OA, knee) (1)	0	0	18	0	0	18		Not estimable	
Deepeshwar 2018 (OA, knee)	0	0	31	0	0	35		Not estimable	
Ganesan 2020 (RA)	0	0	83	0	0	83		Not estimable	
Gautam 2019 (RA)	0	0	36	0	0	36		Not estimable	
Khan 2018 (myofascial pain syndrome)	0	0	10	0	0	10		Not estimable	
Moonaz 2015 (RA or OA, knee) (2)	0	0	40	0	0	35		Not estimable	
Subtotal (95% CI)			283			283		Not estimable	
Heterogeneity: Not applicable									
Test for overall effect: Not applicable									
Total (95% CI)			354			351	100.0%	0 02 [-0 31 0 35]	
Hotorogonoity: Tou $2 = 0.00$; Ch ² = 0.02	if = 0 (D	- 0 00). 12 - 0	0/		551	100.0 /0		
Therefore every and the every state of the every s	ii - 2 (P	- 0.69), i [_] = 0	70					-1 -0.5 0 0.5 1
Test for subgroup differences: $Chi^2 = 0.97$) df = 1 /	D - 0	65) 12 -	0%					Favours yoga Favours control
Festive subgroup unierences. Chir = 0.20	, ui – I (F - U.	03), P =	070					
(1) SE 12 shuried and mental services	+			rotoly					
(1) SF-12 physical and mental componen	t scores	report	ea sepa	rately.					

(2) SF-36 physical and mental component scores reported separately.

Note: A Scores for the quality of life measures EQ-5D-3L and SF-36 have been inverted for consistency in direction of effect. These measures are usually reported as higher is better. Original scale reported in GRADE table.

Figure 44 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Chronic pain conditions - pain

		Yoga		С	ontrol			Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
7.2.1 Visual analogue scale (0-10)									
Ward 2014 (RA) Subtotal (95% CI)	33	21	13 13	33	32	13 13	24.0% 24.0%	0.00 [-0.77, 0.77] 0.00 [-0.77, 0.77]	
Heterogeneity: Not applicable Test for overall effect: Z = 0.00 (P = 1.00)									
7.2.2 Brief pain inventory (total score)									
Schmid 2018 (pain clinic) Subtotal (95% CI)	6.45	1.61	44 44	6.5	1.5	39 39	26.7% 26.7%	-0.03 [-0.46, 0.40] -0.03 [-0.46, 0.40]	
Heterogeneity: Not applicable Test for overall effect: Z = 0.14 (P = 0.89)									
7.2.3 WOMAC Osteoathritis Index - pain									
3edekar 2012 (OA, after TKA) (1)	1.76	1.27	25	5	1.65	26	24.6%	-2.16 [-2.86, -1.46] -	— — —
Cheung 2014 (OA, knee) (2) Subtotal (95% CI)	5.8	2.84	18 43	8.3	2.84	18 44	24.7% 49.3%	-0.86 [-1.55, -0.17] -1.51 [-2.78, -0.23]	
Heterogeneity: Tau² = 0.72; Chi² = 6.74, df = Test for overall effect: Z = 2.32 (P = 0.02)	1 (P = 0).009);	l² = 85%	6					
7.2.4 Pain intesntiy scale (0-5)									
Bhandari 2009 (RA) (3) Subtotal (95% CI)	0	0	40 40	0	0	40 40		Not estimable Not estimable	
Heterogeneity: Not applicable Test for overall effect: Not applicable									
7.2.5 Outcome not reported									
Carson 2010 (Fibromyalgia) (4)	0	0	25	0	0	28		Not estimable	
Deepeshwar 2018 (OA, knee) (5)	0	0	31	0	0	35		Not estimable	
Evans 2011 (RA or JIA) (6)	0	0	14	0	0	16		Not estimable	
Ganesan 2020 (RA) (7)	0	0	83	0	0	83		Not estimable	
Gautam 2019 (RA) (8)	0	0	36	0	0	36		Not estimable	
Khan 2018 (myofascial pain syndrome) (9)	0	0	10	0	0	10		Not estimable	
<i>l</i> loonaz 2015 (RA or OA, knee) (10) Subtotal (95% CI)	0	0	40 239	0	0	35 243		Not estimable Not estimable	
Heterogeneity: Not applicable Test for overall effect: Not applicable									
Total (95% CI)			379			379	100.0%	-0.75 [-1.72, 0.22]	
Heterogeneity: Tau ² = 0.87; Chi ² = 28.56, df	= 3 (P <	0.000	01); l² =	89%				_	
Test for overall effect: Z = 1.52 (P = 0.13)									-2 -1 U 1 2 Eavours voga Eavours control
Test for subgroup differences: Chi ² = 4.80, d	f = 2 (P =	= 0.09)), l² = 58	3.3%					i avours yoga ravours control
Footnotes	`	,							
(1) Study authors reported a combined score	of the r	ain an	d stiffne	ee euh	ecolee				

Study authors reported a combined score of the pain and stiffness

(2) Authors reported adjusted mean (SE). SD calculated as per protocol.

(3) Study authors do not report post-treament mean (SD) for either arm.

(4) FIQ-pain reported under fibromyalgia symptoms

(5) Outcome not reported, probably because it was not measured.

(6) Numeric Rating Scale pre-specified in study protocol but not reported. SF-36 bodily pain included within the SF-36 physical component score. Outcome not included...

(7) Outcome not reported, probably because it was not measured.

(8) Outcome not reported, probably because it was not measured.

(9) Study authors report pain as an outcome but do not report the outcome measure. Data not able to be included in meta-analysis.

(10) SF-36 bodily pain included within the SF-36 physical component score. Outcome not included separately here.

Figure 45 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Chronic pain conditions – perceived stress

	'oga		Co	ontro			Mean Difference	Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
7.3.1 Perceived stress scale									
Moonaz 2015 (RA or OA, knee) Subtotal (95% CI)	13.1	5.6	40 40	15	21	35 35	100.0% 100.0%	-1.90 [-9.07, 5.27] -1.90 [-9.07, 5.27]	
Heterogeneity: Not applicable Test for overall effect: Z = 0.52 (P =	0.60)								
Total (95% CI) Heterogeneity: Not applicable Test for overall effect: Z = 0.52 (P = Test for subgroup differences: Not a	0.60)	ble	40			35	100.0%	-1.90 [-9.07, 5.27]	-20 -10 0 10 20 Favours yoga Favours control

Figure 46 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Chronic pain conditions – emotional function^

		Yoga			Control			Mean Difference Mean Difference			
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI		
7.4.1 SF-12 or SF-36 - Mental											
Cheung 2014 (OA, knee)	-49.7	4.1578	18	-51.7	5.0912	18	55.1%	2.00 [-1.04, 5.04]			
Moonaz 2015 (RA or OA, knee)	-55.4	8.1	40	-51.6	12.1	35	44.9%	-3.80 [-8.53, 0.93]			
Subtotal (95% CI)			58			53	100.0%	-0.60 [-6.26, 5.05]			
Heterogeneity: Tau ² = 12.71; Chi ² = 4.09,	df = 1 (I	P = 0.04)	; l² = 76	6%							
Test for overall effect: Z = 0.21 (P = 0.83)											
7.4.2 Outcome not reported											
Bedekar 2012 (OA, after TKA)	0	0	25	0	0	26		Not estimable			
Bhandari 2009 (RA)	0	0	40	0	0	40		Not estimable			
Carson 2010 (Fibromyalgia)	0	0	25	0	0	28		Not estimable			
Deepeshwar 2018 (OA, knee)	0	0	31	0	0	35		Not estimable			
Evans 2011 (RA or JIA)	0	0	14	0	0	16		Not estimable			
Ganesan 2020 (RA)	0	0	83	0	0	83		Not estimable			
Gautam 2019 (RA)	0	0	36	0	0	36		Not estimable			
Khan 2018 (myofascial pain syndrome)	0	0	10	0	0	10		Not estimable			
Schmid 2018 (pain clinic)	0	0	44	0	0	39		Not estimable			
Ward 2014 (RA)	0	0	13	0	0	13		Not estimable			
Subtotal (95% CI)			321			326		Not estimable			
Heterogeneity: Not applicable											
Test for overall effect: Not applicable											
Total (95% CI)			379			379	100.0%	-0.60 [-6.26, 5.05]			
Heterogeneity: $Tau^2 = 12.71$ Cbi ² = 4.09	df = 1 /	P = 0.04	· 2 = 76	3%					-+-+-+		
Test for overall effect: $7 = 0.21$ (P = 0.83)	u	5.04)	, / (-10 -5 0 5 10		
Test for subgroup differences: Not applica	ahle								Favours yoga Favours control		

Note: A Results for SF-36 and SF-12 MCS inverted for consistency in direction of effect. Original scale reported in GRADE table.

Figure 47 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Chronic pain – physical function

		Yoga			Control		5	Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl
7.4.2 WOMAC Osteoarthritis Index - fu	nction								
Bedekar 2012 (OA, after TKA)	5.5	2.07	25	8.91	2.93	26	31.4%	-1.32 [-1.93, -0.71]	_
Cheung 2014 (OA, knee) (1)	22	9.7581	18	26.2	9.7581	18	28.7%	-0.42 [-1.08, 0.24]	
Subtotal (95% CI)			43			44	60.0%	-0.88 [-1.76, 0.00]	
Heterogeneity: Tau ² = 0.30; Chi ² = 3.83, o	df = 1 (P	= 0.05);	l² = 749	6					
Test for overall effect: Z = 1.96 (P = 0.05))								
7.4.3 SF-36 physical ^									
Moonaz 2015 (RA or OA, knee)	-43.4	9	40	-35.3	11	35	40.0%	-0.80 [-1.28, -0.33]	_ _
Subtotal (95% CI)			40			35	40.0%	-0.80 [-1.28, -0.33]	\bullet
Heterogeneity: Not applicable									
Test for overall effect: Z = 3.33 (P = 0.000	09)								
7.4.4 Outcome not reported									
Bhandari 2009 (RA)	0	0	40	0	0	40		Not estimable	
Deepeshwar 2018 (OA, knee)	0	0	31	0	0	35		Not estimable	
Evans 2011 (RA or JIA)	0	0	14	0	0	16		Not estimable	
Ganesan 2020 (RA)	0	0	83	0	0	83		Not estimable	
Gautam 2019 (RA)	0	0	36	0	0	36		Not estimable	
Khan 2018 (myofascial pain syndrome)	0	0	10	0	0	10		Not estimable	
Schmid 2018 (pain clinic)	0	0	44	0	0	39		Not estimable	
Ward 2014 (RA)	0	0	13	0	0	13		Not estimable	
Subtotal (95% CI)			0			0		Not estimable	
Heterogeneity: Not applicable									
Test for overall effect: Not applicable									
Total (95% CI)			83			79	100.0%	-0.86 [-1.32, -0.39]	
Heterogeneity: Tau ² = 0.08; Chi ² = 3.92, o	df = 2 (P	= 0.14);	l² = 490	6				-	
Test for overall effect: Z = 3.60 (P = 0.000	03)								Favours voga Favours control
Test for subgroup differences: Chi ² = 0.02	2, df = 1	(P = 0.88), l² = (1%					. Stone jega i atomo control
Footnotes									
(1) Authors reported adjusted mean (SE)	. SD calo	culated as	s per pr	otocol.					

Note: ^ SF-36 PCS score inverted for consistency in direction of effect with other outcome measures. SMD reported in GRADE table.

Figure 48 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Chronic pain conditions – mobility

	,	Yoga	Control				Mean Difference	Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
7.5.1 6 minute walk test									
Moonaz 2015 (RA or OA, knee)	-1,588	243	40	-1,494	302	35	53.9%	-94.00 [-219.22, 31.22]	
Schmid 2018 (pain clinic) (1) Subtotal (95% CI)	-207.528	197.507	9 49	-276.806	128.595	9 44	46.1% 100.0%	69.28 [-84.70, 223.25] -18.76 [-178.28, 140.76]	
Heterogeneity: Tau ² = 8202.95; Chi ² = 2.6	0, df = 1 (P	= 0.11); F	² = 62%						
Test for overall effect: Z = 0.23 (P = 0.82)									
7.5.3 Outcome not reported									
Bedekar 2012 (OA, after TKA)	0	0	25	0	0	26		Not estimable	
Bhandari 2009 (RA)	0	0	40	0	0	40		Not estimable	
Carson 2010 (Fibromyalgia)	0	0	25	0	0	28		Not estimable	
Cheung 2014 (OA, knee)	0	0	18	0	0	18		Not estimable	
Deepeshwar 2018 (OA, knee)	0	0	31	0	0	35		Not estimable	
Evans 2011 (RA or JIA)	0	0	0	0	0	0		Not estimable	
Ganesan 2020 (RA)	0	0	83	0	0	83		Not estimable	
Gautam 2019 (RA)	0	0	36	0	0	36		Not estimable	
Khan 2018 (myofascial pain syndrome)	0	0	10	0	0	10		Not estimable	
Ward 2014 (RA)	0	0	13	0	0	13		Not estimable	
Subtotal (95% CI)			281			289		Not estimable	
Heterogeneity: Not applicable Test for overall effect: Not applicable									
									-200 -100 0 100 200
Test for subgroup differences: Not applica	ble								Favours yoya Favours control

Footnotes

(1) Subgroup of people with chronic pain and type 2 diabetes (secondary analysis). Data converted from feet.

Figure 49 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Chronic pain conditions – self-efficacy

		Yoga Control						I Mean Difference Mean Difference			
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl		
7.6.1 Chronic pain self-efficacy scale											
Schmid 2018 (pain clinic) Subtotal (95% CI)	-62.27	22.44	44 44	-56.19	18.3	39 39	100.0% 100.0%	-6.08 [-14.85, 2.69] -6.08 [-14.85, 2.69]			
Heterogeneity: Not applicable											
Test for overall effect: Z = 1.36 (P = 0.17)											
7.6.2 Outcome not reported											
Bedekar 2012 (OA, after TKA)	0	0	25	0	0	26		Not estimable			
Bhandari 2009 (RA)	0	0	40	0	0	40		Not estimable			
Carson 2010 (Fibromyalgia)	0	0	25	0	0	28		Not estimable			
Cheung 2014 (OA, knee)	0	0	18	0	0	18		Not estimable			
Deepeshwar 2018 (OA, knee)	0	0	31	0	0	35		Not estimable			
Evans 2011 (RA or JIA)	0	0	14	0	0	16		Not estimable			
Ganesan 2020 (RA)	0	0	83	0	0	83		Not estimable			
Gautam 2019 (RA)	0	0	36	0	0	36		Not estimable			
Khan 2018 (myofascial pain syndrome)	0	0	10	0	0	10		Not estimable			
Moonaz 2015 (RA or OA, knee)	0	0	40	0	0	35		Not estimable			
Ward 2014 (RA)	0	0	13	0	0	13		Not estimable			
Subtotal (95% CI)			335			340		Not estimable			
Heterogeneity: Not applicable											
Test for overall effect: Not applicable											
									-20 -10 0 10 20		

Favours yoga Favours control

Figure 50 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Chronic pain conditions – pain acceptance^

	١	/oga		Control				Mean Difference	Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI		
7.7.1 Chronic pain acceptance question	nnaire										
Evans 2011 (RA or JIA)	-77.7	18.6	14	-72.7	12	16	100.0%	-5.00 [-16.38, 6.38]	 _		
Subtotal (95% CI)			14			16	100.0%	-5.00 [-16.38, 6.38]			
Heterogeneity: Not applicable											
Test for overall effect: Z = 0.86 (P = 0.39)											
7.7.2 Outcome not reported											
Bedekar 2012 (OA, after TKA)	0	0	25	0	0	26		Not estimable			
Bhandari 2009 (RA)	0	0	40	0	0	40		Not estimable			
Cheung 2014 (OA, knee)	0	0	18	0	0	18		Not estimable			
Deepeshwar 2018 (OA, knee)	0	0	31	0	0	35		Not estimable			
Ganesan 2020 (RA)	0	0	83	0	0	83		Not estimable			
Gautam 2019 (RA)	0	0	36	0	0	36		Not estimable			
Khan 2018 (myofascial pain syndrome)	0	0	10	0	0	10		Not estimable			
Moonaz 2015 (RA or OA, knee)	0	0	40	0	0	35		Not estimable			
Schmid 2018 (pain clinic)	0	0	44	0	0	39		Not estimable			
Ward 2014 (RA)	0	0	13	0	0	13		Not estimable			
Subtotal (95% CI)			340			335		Not estimable			
Heterogeneity: Not applicable											
Test for overall effect: Not applicable											
									-20 -10 0 10 20		
									ravours yoga ravours control		

Note: ^ Scores inverted for consistency in direction of effect. Original scale reported in GRADE table.

Figure 51 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Fibromyalgia – health-related quality of life

		Yoga		C	Control			Mean Difference		Mean D	ifference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% C		IV, Rando	om, 95% C		
8.1.1 FIQ - Total score													
Carson 2010 (Fibromyalgia) Subtotal (95% CI)	35.49	17.61	25 25	48.69	18.88	28 28	100.0% 100.0%	-13.20 [-23.03, -3.37] -13.20 [-23.03, -3.37]					
Heterogeneity: Not applicable Test for overall effect: Z = 2.63	3 (P = 0.	008)											
Test for subgroup differences:	Not app	licable							-20 -1	0 Yoga	l 0 Control	10	20

Figure 52 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Fibromyalgia – physical function



Figure 53 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Fibromyalgia – symptom severity

	,	Yoga		С	ontrol			Mean Difference		Mean Difference	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% C	I	IV, Random, 95% CI	
7.6.1 FIQ - Pain											
Carson 2010 (Fibromyalgia) Subtotal (95% CI)	4.12	2.05	25 25	5.14	2.27	28 28	100.0% 100.0%	-1.02 [-2.18, 0.14] -1.02 [-2.18, 0.14]			
Heterogeneity: Not applicable											
Test for overall effect: Z = 1.72	2 (P = 0.	.09)									
7.6.2 FIQ - Stiffness											
Carson 2010 (Fibromvalgia)	4 72	19	25	5 82	1 79	28	100.0%	-1 10 [-2 10 -0 10]		-	
Subtotal (95% CI)		1.0	25	0.02	10	28	100.0%	-1.10 [-2.10, -0.10]			
Heterogeneity: Not applicable										•	
Test for overall effect: $7 = 2.16$	i (P = 0	03)									
	(,									
7.6.3 FIQ - Tenderness											
Carson 2010 (Fibromyalgia)	5	2.97	25	5.96	2.36	28	100.0%	-0.96 [-2.42, 0.50]			
Subtotal (95% CI)			25			28	100.0%	-0.96 [-2.42, 0.50]			
Heterogeneity: Not applicable											
Test for overall effect: Z = 1.29	(P = 0.	.20)									
7.6.4 FIQ - Poor sleep											
Carson 2010 (Fibromyalgia)	5.72	3.09	25	6.11	2.9	28	100.0%	-0.39 [-2.01, 1.23]			
Subtotal (95% CI)			25			28	100.0%	-0.39 [-2.01, 1.23]		\bullet	
Heterogeneity: Not applicable											
Test for overall effect: Z = 0.47	' (P = 0.	.64)									
7.6.5 FIQ - Fatigue										_	
Carson 2010 (Fibromyalgia)	4.7	2.52	25	6.71	1.61	28	100.0%	-2.01 [-3.16, -0.86]			
Subtotal (95% CI)			25			28	100.0%	-2.01 [-3.16, -0.86]		\bullet	
Heterogeneity: Not applicable											
Test for overall effect: Z = 3.41	(P = 0.	.0006)									
									1		
									-10	-5 0 5	
										Favours yoga Favours control	
Test for subgroup differences:	Chi ² = 3	3.09, d	f = 4 (P	= 0.54)	, l² = 0	%				, ,	

Figure 54 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Fibromyalgia – pain acceptance

	١	roga		Control				Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
8.4.1 Chronic pain acceptan	ce ques	tionna	aire						
Carson 2010 (Fibromyalgia) Subtotal (95% CI)	-75.4	13.1	25 25	-65.61	17.57	28 28	100.0% 100.0%	-9.79 [-18.08, -1.50] -9.79 [-18.08, -1.50]	
Heterogeneity: Not applicable Test for overall effect: Z = 2.31	1 (P = 0.0	02)							

4.10 Low back pain

4.10.1 Description of the condition

Low back pain (LBP) is defined by the location of pain, typically between the lower rib margins and the buttock creases and is commonly accompanied by pain in one or both legs. Some may also experience associated neurological symptoms in the lower limbs (314). In most cases there is no specific cause of LBP and is subsequently labelled nonspecific LBP^k. Individuals with other general physical and mental health conditions are more likely to experience LBP and pain in other body sites. While the cause of LBP remains unclear, risk factors include genetics, previous episode of LBP, poor posture, physically demanding tasks and lack of physical activity (314).

LBP is the most encountered musculoskeletal problem in general practice in Australia and the leading cause of disability globally (314-316). National data reports approximately 16% of Australians experienced back pain in 2017-18 (317). While LBP is generally benign and self-limiting, approximately 10-40% with acute LBP develop persistent and debilitating chronic LBP that continues for more than 3 months (316). Direct and indirect costs of LBP in Australia are reportedly \$1 billion and \$8 billion, respectively (318).

International guidelines consistently recommend excluding serious and/or specific causes of LBP but spinal imaging should not be routinely requested (315, 316). Advice to stay active and return to normal activities as soon as possible is a core recommendation and if the problem continues, the international guidelines recommend various forms of exercise as therapy, but no one approach appears superior to another (315). However, evidence-based guidelines are not consistently translated into clinical practice and medications including opioids are overprescribed (319). Help seeking behaviours are primarily driven by characteristic factors of pain, impaired daily activities, diminished ability to work, and reduced enjoyment of life (320). Providers commonly sought include general practitioners, physiotherapists, chiropractors, massage therapists and acupuncturists and as per guidelines, exercise is commonly prescribed for people experiencing LBP (320). Various nonpharmacological therapies that may be beneficial for LBP include rehabilitation, spinal manipulation, exercise therapy and mind-body interventions (321).

4.10.2 Description of studies

There were 47 citations (322-368) corresponding to 22 RCTs (Aboagye 2015, Cox 2010, Cox 2010, Demirel 2019, Groessl 2016, Highland 2018, Jacobs 2004, Kim 2014, Monro 2015, Nambi 2014, Neyaz 2019, Patil 2018, Pushpika Attanayake 2010, Saper 2009, Saper 2014, Sherman 2005, Sherman 2010, Tekur 2008, Teut 2016, Williams 2005, Williams 2009) identified in the literature search. There were 13 <u>ongoing studies</u> and 6 <u>studies awaiting classification</u> (369-375), of which 2 were published in a language other than English. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D6.2.1.

The studies were predominantly carried out in single care settings in a variety of countries including Germany (Teut 2016), India (Nambi 2014, Neyaz 2019, Patil 2018, Pushpika Attanayake 2010, Tekur 2008), South Korea (Kim 2014), Sweden (Aboagye 2015), Turkey (Demirel 2019) the United Kingdom (Cox 2010) and the United States (Groessl 2016, Highland 2018). Ten studies recruited participants from local community or multiple care settings in India (Monro 2015), the United Kingdom (Cox 2010) and the United States (Galantino 2004, Jacobs 2004, Saper 2009, Saper 2014, Sherman 2005, Sherman 2010, Williams 2005, Williams 2009). Participant ages ranged from 18-70 in all studies except one (Teut 2016) that enrolled adults aged 65 years and older. Sample sizes ranges from 10 to 320 participants (total 2257).

Twelve studies included participants with chronic LBP defined as pain lasting for at least 2 months; with 5 other studies (Galantino 2004, Groessl 2016, Jacobs 2004, Teut 2016, Williams 2005) enrolling participants with chronic LBP defined as constant pain lasting for 6 months or longer. In one study (Pushpika Attanayake 2010) pain had been persistent for at least 3 weeks. Aboagye 2015 included participants with a score equal to or greater than 90 on the Orebro Musculoskeletal Pain screening questionnaire. Cox 2010a and Cox 2010b included participants that scored 4 or higher on the Roland and Morris Disability Scale whereas Monro 2015 included participants that scored 3 or higher on the same scale.

^k Mechanical causes of LBP related to spondylolisthesis were not included as priority populations.

There were 12 studies that examined the effect yoga compared with an inactive control, being either no intervention (Pushpika Attanayake 2010, Williams 2005), usual care (Cox 2010a, Cox 2010b, Highland 2018, Monro 2015) or a waitlist (Galantino 2004, Groessl 2016, Jacobs 2004, Saper 2009, Teut 2016, Williams 2009). Four other studies were also considered in the evidence synthesis comparing yoga with control, where the control group received an educational booklet providing advice about back care (Aboagye 2015, Saper 2014, Sherman 2005, Sherman 2010). Among the 16 studies, there were 8 studies where yoga was delivered as an adjunct to standard medical care (inclusive of physical therapy, pain medication and educational advice), 2 studies where all participants received educational advice, and one study where all participants received a diet and lifestyle modification plan.

Eleven studies compared yoga with an active comparator¹. The interventions typically involved standard therapeutic exercises (such as stretching or strengthening or core stabilisation exercises) delivered as part of a physical therapy program (Aboagye 2015, Demirel 2019, Kim 2014b, Nambi 2014, Neyaz 2019, Patil 2018, Saper 2014, Sherman 2005, Sherman 2010, Tekur 2008). In one study (Teut 2016) the comparator group practised Qigong.

Most studies delivered a yoga program that included poses, breathing and mindfulness training, with a typical yoga session being between 60 and 90 minutes. In 3 studies sessions lasted 30-45 minutes (Kim 2014, Neyaz 2019, Teut 2016) and one study had yoga sessions lasting for 2 hours or more (Tekur 2008). Two studies did not include a prescribed session time-period (Aboagye 2015, Monro 2015). Program intensity tended to range from one to 3 sessions per week. In one study, participants had 5 sessions a week (Patil 2018) and another was a weeklong intensive yoga program (Tekur 2008). Treatment duration ranged from one (Tekur 2008) to 24 weeks (Williams 2009), with most programs lasting between 8 and 12 weeks.

Results for yoga versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see Section 4.10.4.1) and Appendix F2. Results of studies that compared yoga with another comparator are presented in Appendix F2.

4.10.3 Risk of bias – per item

The risk of bias for each item in the included RCTs for low back pain is presented in Figure 55. Details are provided in Appendix D6.2.2.

No studies were judged to be at overall low risk of bias.

¹ Five of these studies (Aboagye 2015, Saper 2014, Sherman 2005, Sherman 2010, Teut 2016) also compared yoga with an inactive control.

			Ri	sk of bia	s domai	ins			
		D1	D2	D3	D4	D5	Overall		
	Aboagye 2015	-	-	X	-	-	X		
	Cox 2010a	+	X	X	-	-	×		
	Cox 2010b	+	+	+	-	-	-		
	Demirel 2019	-	+	+	-	-	-		
	Galantino 2004	X	X	X	-	-	X		
	Groessl 2016	+	X	+	-	+	X		
	Highland 2018	+	+	+	-	-	-		
	Jacobs 2004	+	X	+	-	-	X		
	Kim 2014	-	-	+	-	-	-		
	Monro 2015	+	-	-	-	-	-		
udy	Nambi 2014	-	-	+	-	-	-		
Sti	Neyaz 2019	+	-	-	-	X	X		
	Patil 2018	-	+	+	-	-	-		
	PushpikaAttanayake 2010	-	+	+	-	X	X		
	Saper 2009	+	+	+	-	-	-		
	Saper 2014	-	+	+	-	-	-		
	Sherman 2005	+	+	+	-	-	-		
	Sherman 2010	+	+	+	-	+	-		
	Tekur 2008	+	X	+	-	-	X		
	Teut 2016	+	+	+	-	-	-		
	Williams 2005	X	-	-	-	-	X		
	Williams 2009	+	X	X	-	-	X		
	Domains:	ricing from	the reade-	vization pr-	0000	Judgem	nent		
	D2: Bias due to deviations from intended intervention.								
	D3: Bias o	lue to missi	ing outcome	e data.		- So	ome concerns		
	D4: Bias in measurement of the outcome.								

Figure 55 Risk of bias summary: review author's judgements about each risk of bias item for each included study – Low back pain

4.10.4 Main comparison (vs control)

There were 16 RCTs comparing yoga with control (no intervention, waitlist, usual care or educational advice) in people with low back pain that were eligible for this comparison, 13 of which contributed data relevant to at least one outcome considered critical or important for this review (Aboagye 2015, Cox 2010a, Cox 2010b, Groessl 2016, Highland 2018, Monro 2015, Saper 2009, Saper 2014, Sherman 2005, Sherman 2010, Teut 2016, Williams 2005, Williams 2009).

There were 4 studies awaiting classification (360+ participants) and 3 ongoing studies^m (300+ participants) that compared yoga with control (no intervention or educational advice) in people with low back pain that could have contributed data to these outcomes (see Appendix C6). The available information is insufficient to make a judgement about the nonreporting of results but may be because the *p* value, magnitude or direction of effect was considered unfavourable by the study investigators.

4.10.4.1 Summary of findings and evidence statements

Yoga compared to control for low back pain

Patient or population: Low back pain Setting: Community Intervention: Yoga Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	olute effects*	Polativo	Nº of	Certainty of	
Outcomes Risk with control		Risk with Yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statement
Pain assessed with: ABPS, BPI, NPRS or VAS (higher is worse) follow-up: range 6 to 24 weeks	-	SMD 0.36 SD lower ** (0.21 lower to 0.51 lower)	-	1101 (10 RCTs) †	⊕⊕⊖⊖ LOW ^{a,b,c}	Yoga may result in a slight reduction in pain in people with low back pain.
Quality of life assessed with: EQ- 5D (higher is best) Scale from: 0 to 1 follow-up: range 6 to 12 weeks	The mean EQ- 5D score was 0.72 points	MD 0.06 points lower (0.10 lower to 0.02 lower)	-	590 (4 RCTs) ^{††}	⊕⊕⊕⊖ MODERATE _{b,d,e}	Yoga probably results in a slight increase in quality of life in people with low back pain. #
Coping strategies – not reported	-	-	-	-	-	No studies found. The effect of yoga on coping strategies in people with low back pain is unknown
Pain medication use assessed with: use in the previous week follow-up: range 12 to 16 weeks	546 per 1,000	284 per 1,000 (175 to 475)	RR 0.52 (0.32 to 0.87)	465 (5 RCTs) ⁺⁺⁺	⊕⊕⊖⊖ LOW ^{b,c,f,g}	Yoga may reduce pain medication use in people with low back pain. ##
Work status – not reported	-	-	-	-	-	No studies found. The effect of yoga on work status in people with low back pain is unknown

HTANALYSTS | NHMRC | EVIDENCE EVALUATION ON THE CLINICAL EFFECTIVENESS OF YOGA

 $^{^{\}rm m}$ complete, results not published or of unknown status.

Yoga compared to control for low back pain

Patient or population: Low back pain

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	olute effects*	Polativo	Nº of	Certainty of	
Outcomes	Risk with control	Risk with Yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statement
Physical function assessed with: PROMIS-29, SF-12 or SF-36 PCS (higher is best) Scale from: 0 to 100 follow-up: range 6 weeks to 12 weeks	The mean score was 40.31 points	MD 1.57 points higher (3.34 higher to 0.19 lower)	-	710 (5 RCTs)	⊕⊕⊖⊖ LOW ^{b,e,f,h}	Yoga may result in little to no difference on physical function in people with low back pain. ###
Emotional function assessed with: SF- 12 or SF-36 MCS (higher is best) Scale from: 0 to 100 follow-up: 12 weeks	The mean score was 46.48 points	MD 1.59 points higher (3.35 higher to 0.16 lower)	-	642 (4 RCTs)	⊕⊕⊖⊖ LOW ^{b,e,f,h}	Yoga may result in little to no difference on emotional function in people with low back pain ###

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

** As a rule of thumb, an SMD of 0.2 represents a small difference, 0.5 is moderate, and 0.8 is a large difference (58).

*** Effect estimates were considered on 3 levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).

The minimal change score for the EQ-5D in participants with chronic lower back pain is estimated to be 0.03 (376). ## A 25% relative risk reduction was considered important (i.e. RR < 0.75). ### The MCID is estimated to be between 2 to 4 for the SF-36 (312) and around 5-points for the PROMIS-29 (377).

† Data from one study (12 participants) not able to be included in the meta-analysis.

++ Data from 3 studies (287 participants) reporting no difference between groups were not included in the meta-analysis (missing data).

+++ Data from one study (90 participants) reporting a decrease in medication use in the yoga group was not included in the metaanalysis (missing data).

ABPS: Aberdeen Back Pain Scale; BPI: Brief Pain Inventory; CI: confidence interval; MCS: mental component score: OR: odds ratio; PCS: physical component score; PRS: Pain Rating Scale; PSS: Perceived Stress scale; SF-12: 12-item short form; SF-36: 36-item short form; SMD: standardised mean difference; VAS: visual analogue scale

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. Serious risk of bias. 4 studies contributing ~33% of the data were at high risk of bias. A sensitivity analysis suggests the studies may overestimate the size of the effect estimate. Certainty of evidence downgraded.

- b. No serious indirectness. The available evidence is in people with nonspecific low back pain of variable duration, and in people with pain attributed to other causes (e.g. spondylosis, disc prolapse) and can be sensibly applied to the Australian population. Certainty of evidence not downgraded.
- c. Publication bias suspected. Four ongoing studies (200+ participants) with results not published. It was considered likely that this missing data was due to the *p* value, direction or magnitude of effect. Certainty of evidence downgraded.
- d. No serious risk of bias. 3 of 4 studies contributing ~54% of data were at high risk of bias. A sensitivity analysis suggests the studies do not materially influence the result. Certainty of evidence not downgraded.
- e. Publication bias suspected. Missing data from 2 studies and several ongoing studies (300+ participants) with results not published. It was considered likely that this missing data was due to the *p* value, direction or magnitude of effect. Certainty of evidence downgraded.
- f. No serious risk of bias. One study contributing less than 10% of data was at high risk of bias. A sensitivity analysis suggests the study does not materially influence the result. Certainty of evidence not downgraded.
- g. Serious imprecision. Magnitude of statistical heterogeneity is high (l² = 70%). Wide confidence intervals (lower bound overlaps with little or no important difference). Certainty of evidence downgraded.
- h. Serious imprecision. Wide confidence intervals (upper and lower bounds overlap with both important and no important difference). Certainty of evidence downgraded.

4.10.4.2 Forest plots

Outcome results related to pain in people with low back pain are presented in Figure 56.

Outcome results related to health-related quality of life in people with low back pain are presented in Figure 57.

Outcome results related to pain medication use in people with low back pain are presented in Figure 58.

Outcome results related to physical function in people with low back pain are presented in Figure 59.

Outcome results related to emotional function in people with low back pain are presented in Figure 60.

Figure 56 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Low back pain – pain

		Yoga			Control			Std. Mean Difference	Std. Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl		
8.1.1 Aberdeen Back Pain Sca	le										
Cox 2010a (1)	-7.72	9.2037	10	-5.16	9.2037	10	2.8%	-0.27 [-1.15, 0.61]			
Cox 2010b (2)	-3.62	12.2662	156	-1.2	12.877	157	20.7%	-0.19 [-0.41, 0.03]			
Monro 2015	16.36	8.08	30	17.04	6.94	31	7.4%	-0.09 [-0.59, 0.41]			
Subtotal (95% CI)			196			198	30.9%	-0.18 [-0.38, 0.02]	\bullet		
Heterogeneity: Tau ² = 0.00; Chi	² = 0.17,	df = 2 (P =	= 0.92);	l ² = 0%							
Test for overall effect: Z = 1.78 (P = 0.08	3)									
8.1.3 Brief Pain Inventory - pa	in intens	sitv									
Groessl 2016 (3)	-0.61	1.4343	75	0.04	1.3474	75	13.9%	-0.46 [-0.79, -0.14]	_ _		
Subtotal (95% CI)	0.0.1		75			75	13.9%	-0.46 [-0.79, -0.14]	\bullet		
Heterogeneity: Not applicable											
Test for overall effect: Z = 2.81 (P = 0.00)5)									
		,									
8.1.4 Visual Analog Scale (0-1	00)										
Teut 2016 (4)	39.04	20.1865	61	44.05	18.8817	57	12.0%	-0.25 [-0.62, 0.11]			
Williams 2005	10	11	30	21	23	30	7.1%	-0.60 [-1.12, -0.08]			
Williams 2009	22.9	17.4428	43	36.9	19.8128	47	9.5%	-0.74 [-1.17, -0.31]			
Subtotal (95% CI)			134	12 0.00	.,	134	28.6%	-0.51 [-0.82, -0.20]			
Heterogeneity: Tau ² = 0.03; Chi	² = 3.13,	df = 2 (P =	= 0.21);	12 = 36%	%						
lest for overall effect: $\angle = 3.20$ (P = 0.00)1)									
8.1.5 Numeric Pain Rating Sca	ale (0-10)									
Highland 2018	2.48	2.34	34	3.67	1.86	34	7.8%	-0.56 [-1.04, -0.07]			
Saper 2009 (5)	-2.3	2.1	15	-0.4	1.8	15	3.7%	-0.95 [-1.71, -0.18]			
Saper 2014	5.3	2.1	127	5.6	2.2	64	15.2%	-0.14 [-0.44, 0.16]			
Subtotal (95% CI)			176			113	26.7%	-0.45 [-0.89, -0.01]			
Heterogeneity: Tau ² = 0.09; Chi ² = 4.88, df = 2 (P = 0.09); l ² = 59%											
Test for overall effect: Z = 2.01 (P = 0.04)											
8.1.7 outcome not measured (or repor	rted)									
Aboaqve 2015	0	0	52	0	0	55		Not estimable			
Galantino 2004	0	ů 0	11	0	0 0	11		Not estimable			
Pushpika Attanavake 2010 (6)	0	0	6	0	0	6		Not estimable			
Sherman 2005	0	0	36	0	0	30		Not estimable			
Sherman 2010	0	0	92	0	0	45		Not estimable			
Subtotal (95% CI)			0			0		Not estimable			
Heterogeneity: Not applicable											
Test for overall effect: Not applie	cable										
Total (95% CI)			581			520	100.0%	-0.36 [-0.51, -0.21]	•		
Heterogeneity: Tau ² = 0.02; Chi	² = 12.71	l, df = 9 (P	= 0.18); l² = 29	9%						
Test for overall effect: Z = 4.62 (P < 0.00)001)							-1 -0.5 0 0.5 1 Eavours voga Eavours control		
Test for subgroup differences: C	chi² = 4.4	1, df = 3 (l	- = 0.2	2), l² = 3	32.0%				i avouis yoga i avouis contion		
Footnotes											
(1) Data reported as mean chan	ge from	baseline (95% CI). SD ca	alculated a	s per p	rotocol.				
(2) Data reported as mean change from baseline (95% CI). SD calculated as per protocol.											

(3) Data reported as mean change from baseline (SD).

(4) Authors reportedd adjusted data as mean change from baseline (95% CI). SD calculated as per protocol.

(5) Data reported as mean change from baseline (SD).

(6) Data not able to be used. Authors reported proportion of participants experiencing statistically significant change.

Figure 57 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Low back pain – health-related quality of life

		Yoga	Control					Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	IV, Random, 95% Cl
8.2.1 EQ-5D									
Aboagye 2015 (1)	-0.8	0.11	26	-0.7	0.22	52	21.2%	-0.10 [-0.17, -0.03]	-
Aboagye 2015 (2)	-0.64	0.31	26	-0.74	0.11	3	4.3%	0.10 [-0.07, 0.27]	+
Cox 2010a (3)	-0.06	0.4221	10	-0.04	0.4221	10	1.0%	-0.02 [-0.39, 0.35]	
Cox 2010b	-0.776	0.166	156	-0.717	0.236	157	46.0%	-0.06 [-0.10, -0.01]	=
Groessl 2016 (4)	-0.08	0.2173	75	-0.02	0.1739	75	27.5%	-0.06 [-0.12, 0.00]	
Subtotal (95% CI)			293			297	100.0%	-0.06 [-0.10, -0.02]	•
Heterogeneity: Tau ² = 0.00; C	Chi ² = 4.5	50, df = 4	(P = 0.3	34); l² =	11%				
Test for overall effect: Z = 3.2	9 (P = 0	.0010)							
8.2.2 SF-36 (total score)									
Saper 2009 (5)	0	0	15	0	0	15		Not estimable	
Saper 2014 (6)	0	0	127	0	0	64		Not estimable	
Sherman 2005 (7)	0	0	36	0	0	30		Not estimable	
Sherman 2010 (8)	0	0	92	0	0	45		Not estimable	
Teut 2016 (9)	0	0	61	0	0	57		Not estimable	
Subtotal (95% CI)			331			211		Not estimable	
Heterogeneity: Not applicable	;								
Test for overall effect: Not ap	plicable								
8.2.3 outcome not measure	d								
Galantino 2004	0	0	11	0	0	11		Not estimable	
Highland 2018	0	0	34	0	0	34		Not estimable	
Monro 2015	0	0	30	0	0	31		Not estimable	
Pushpika Attanayake 2010	0	0	6	0	0	6		Not estimable	
Williams 2005	0	0	30	0	0	30		Not estimable	
Williams 2009	0	0	43	0	0	47		Not estimable	
Subtotal (95% CI)			154			159		Not estimable	
Heterogeneity: Not applicable	;								
Test for overall effect: Not ap	plicable								
									Favours voga Favours control

Footnotes

(1) Participants attending \geq 2 classes per week.

(2) Participants attending < 2 classes per week.

(3) Data reported are mean change from baseline (95% CI). SD calculated as per protocol.

(4) Data reported are mean change from baseline (95% Cl). SD calculated as per protocol

(5) Outcome was assessed but not reported. Authors noted no change between groups.

(6) Total score not reported. Physical and mental component scores are included in the evidence synthesis for physical and emotional functioning.

(7) Outcome was assessed but not reported. Authors reported no significant difference between groups over time.

(8) Total score not reported. Physical and mental component scores are included in the evidence synthesis for physical and emotional functioning.

(9) Total score not reported. Physical and mental component scores are included in the evidence synthesis for physical and emotional functioning.
	Yoga	a	Contr	ol		Risk Ratio	Risk Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% Cl	M-H, Random, 95% Cl	
8.3.1 Medication use								
Saper 2009 (1)	2	15	10	15	10.1%	0.20 [0.05, 0.76]		
Saper 2014 (2)	68	127	46	64	32.6%	0.74 [0.60, 0.93]	-	
Sherman 2005 (3)	8	36	18	30	21.4%	0.37 [0.19, 0.73]		
Teut 2016 (4)	22	61	22	57	26.8%	0.93 [0.59, 1.49]		
Williams 2005 (5)	2	30	11	30	9.3%	0.18 [0.04, 0.75]		
Subtotal (95% CI)		269		196	100.0%	0.52 [0.32, 0.87]	\bullet	
Total events	102		107					
Heterogeneity: Tau ² = 0.19; (Chi² = 13.1	3, df =	4 (P = 0.0	01); l² =	: 70%			
Test for overall effect: Z = 2.5	51 (P = 0.0	1)						
8.3.2 missing data								
Williams 2009 (6)	0	43	0	47		Not estimable		
Subtotal (95% CI)	Ũ	43	·	47		Not estimable		
Total events	0		0					
Heterogeneity: Not applicable	9							
Test for overall effect: Not ap	plicable							
8.3.3 outcome not measure	d							
	0	52	٥	52		Not estimable		
Cox 2010a	0	10	0	10		Not estimable		
Cox 2010b	0	156	0	157		Not estimable		
Galantino 2004	ů 0	11	0	11		Not estimable		
Groessl 2016	0	75	0	75		Not estimable		
Highland 2018	0	34	0	34		Not estimable		
Monro 2015	0	30	0	31		Not estimable		
Pushpika Attanavake 2010	0	6	0	6		Not estimable		
Sherman 2010	0	36	0	30		Not estimable		
Subtotal (95% CI)		410		406		Not estimable		
Total events	0		0					
Heterogeneity: Not applicable	е							
Test for overall effect: Not ap	plicable							
								100
							Eavours voga Eavours control	100

Figure 58 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Low back pain – pain medication use

Footnotes

(1) Values estimated from reported percentage of participants using pain medication at end of treatment.

(2) percentage of participants using pain medication at end of treatment.

(3) Values estimated from reported percentage of participants using pain medication at end of treatment. RR: 0.35 (0.17 to 0.73)

(4) Values estimated from reported percentage of participants using pain medication at endd of treatment.

(5) Participants with no change or increased use.

(6) Authors report a nonsignificant reduction in pain medication use.

Figure 59 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Low back pain – Physical function

		Yoga		(Control			Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
8.4.1 PROMIS-29 Physical F	unction	ing (0-100)						
Highland 2018 Subtotal (95% CI)	-47.44	7.44	34 34	-42.72	5.55	34 34	20.3% 20.3%	-4.72 [-7.84, -1.60] -4.72 [-7.84, -1.60]	
Heterogeneity: Not applicable	9								-
Test for overall effect: Z = 2.9	07 (P = 0.	003)							
8.4.2 SF-12 or SF-36 PCS (0	-100)								
Cox 2010a (1)	-1.2	13.8274	10	-6.88	13.8274	10	2.0%	5.68 [-6.44, 17.80]	
Cox 2010b (2)	-2.65	9.99	156	-1.29	10.4031	157	29.1%	-1.36 [-3.62, 0.90]	
Saper 2014	-41.4	8.6	127	-41.2	9	64	24.5%	-0.20 [-2.86, 2.46]	_
Teut 2016 (3) Subtotal (95% CI)	-38.2	7.8481	61 354	-37.01	7.1607	57 288	24.1% 79.7%	-1.19 [-3.90, 1.52] - 0.87 [-2.31, 0.57]	•
Heterogeneity: Tau ² = 0.00; C	Chi² = 1.6	0, df = 3 (F	P = 0.6	6); l² = 0	%				
Test for overall effect: Z = 1.1	8 (P = 0.	24)							
8.4.3 missing data									
Saper 2009 (4)	0	0	15	0	0	15		Not estimable	
Sherman 2005 (5) Subtotal (95% CI)	0	0	36 51	0	0	30 45		Not estimable Not estimable	
Heterogeneity: Not applicable	9								
Test for overall effect: Not ap	plicable								
8.4.5 outcome not measure	d								
Aboagye 2015	0	0	52	0	0	52		Not estimable	
Groessl 2016	0	0	75	0	0	75		Not estimable	
Pushpika Attanayake 2010	0	0	6	0	0	6		Not estimable	
Saper 2014	0	0	127	0	0	64		Not estimable	
Sherman 2010	0	0	92	0	0	45		Not estimable	
Williams 2005	0	0	30	0	0	30		Not estimable	
Williams 2009 Subtotal (95% CI)	0	0	43 0	0	0	47 0		Not estimable Not estimable	
Heterogeneity: Not applicable	2		•			·			
Test for overall effect: Not ap	, plicable								
Total (95% CI)			439			367	100.0%	-1.57 [-3.34, 0.19]	
Heterogeneity: Tau ² = 1.45: 0	Chi² = 6.4	1. df = 4 (F	P = 0.1	7): ² = 3	8%				
Test for overall effect: Z = 1.7	'5 (P = 0	08)		,,					-10 -5 0 5 10
Test for subgroup differences	: Chi ² = 4	4.81, df = 1	(P = 0	.03), l² =	79.2%				Favours yoga Favours control
Footnotes									

(1) Data reported as mean change from baseline (95% CI). SD calculated as per protocol.

(2) Data reported are mean change from baseline (95% CI). SD calculated as per protocol.

(3) Adjusted data reported as mean change from baseline (95% CI). SD calculated as per protocol.

(4) Outcome was assessed but no data provided. Authors report there was no significant difference between groups.

(5) Outcome was assessed but no data provided. Authors report there was no significant difference between groups over time.

Figure 60 Forest plot of comparison: Yoga vs control (no intervention, waitlist, usual activities): Low back pain – Emotional function

	Yoga Control				Mean Difference	Mean Difference			
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% C	IV, Random, 95% CI
8.5.1 SF-12 or SF-36 MCS (0-100)								
Cox 2010a (1)	-3.4	15.4246	10	-0.59	15.4246	10	1.7%	-2.81 [-16.33, 10.71]	
Cox 2010b (2)	-1.94	11.3811	156	0.08	11.7987	157	46.6%	-2.02 [-4.59, 0.55]	-8+
Saper 2014	-47.1	12.4	127	-44.2	11.9	64	23.4%	-2.90 [-6.53, 0.73]	
Teut 2016 (3)	-48.5	9.9956	61	-48.76	8.216	57	28.3%	0.26 [-3.03, 3.55]	
Subtotal (95% CI)			354			288	100.0%	-1.59 [-3.35, 0.16]	\bullet
Heterogeneity: Tau ² = 0.00; 0	Chi² = 1.	85, df = 3	(P = 0.6	60); l² = ()%				
Test for overall effect: Z = 1.7	78 (P = 0	0.08)							
8.5.3 outcome not reported									
Aboagye 2015	0	0	52	0	0	52		Not estimable	
Galantino 2004	0	0	11	0	0	11		Not estimable	
Groessl 2016	0	0	75	0	0	75		Not estimable	
Highland 2018	0	0	34	0	0	34		Not estimable	
Monro 2015	0	0	30	0	0	31		Not estimable	
Pushpika Attanayake 2010	0	0	6	0	0	6		Not estimable	
Saper 2009 (4)	0	0	15	0	0	15		Not estimable	
Sherman 2005 (5)	0	0	36	0	0	30		Not estimable	
Sherman 2010	0	0	92	0	0	45		Not estimable	
Teut 2016	0	0	61	0	0	57		Not estimable	
Williams 2005	0	0	30	0	0	30		Not estimable	
Williams 2009	0	0	43	0	0	47		Not estimable	
Subtotal (95% CI)			0			0		Not estimable	
Heterogeneity: Not applicable	е								
Test for overall effect: Not ap	plicable								
Total (95% CI)			354			288	100.0%	-1.59 [-3.35, 0.16]	
Heterogeneity: Tau ² = 0.00; (Chi² = 1.	85, df = 3	(P = 0.6	60); l² = ()%				
Test for overall effect: Z = 1.7	78 (P = (0.08)	,						-20 -10 0 10 20
Test for subgroup differences	s: Not ap	plicable							i avouis yoga Favouis contiol
Footnotes									

(1) Data reported as mean change from baseline (95% CI). SD calculated as per protocol.

(2) Data reported as mean change from baseline (95% Cl). SD calculated as per protocol.

(3) Adjusted data reported as mean change from baseline (95% CI). SD calculated as per protocol.

(4) SF-36 total score included in the evidence synthesis for overall health-related quality of life.

(5) SF-36 total score included in the evidence synthesis for overall health-related quality of life.

4.11 Neck and/or shoulder pain

4.11.1 Description of the condition

Neck and shoulder pain are common complaints that can impact a person's ability to carry out normal daily activities (378), leading to considerable disability and economic burden (379). There are multiple origins of neck and shoulder pain, which may be located anywhere between the back of the head to the upper thoracic spine (with the associate musculature) (380). In some situations, neck and shoulder pain occur concurrently and are treated as a single diagnostic entity. It may also be accompanied by pain in other anatomical sites. Other times pain isolated to the neck may be reflective of local pathology such as cervical spondylitis and subacromial bursitis, or for shoulder pain such as rotator cuff tendonitis, acromio-clavicular bursitis and frozen shoulder (378). However, in many cases the pathophysiological mechanisms underlying pain are unclear (378). With no readily or accurately identifiable pain source, neck pain is often classified as non-specific (380). The duration of neck or shoulder pain can be grouped as acute (less than 30 days), subacute (30 to 90 days), or chronic (longer than 90 days) (381).

The prevalence of neck pain is high. In Australia, the number of incident cases of neck pain were reportedly 190 000 in 2017 (379). Shoulder pain, the third most frequent musculoskeletal presentation in general practice in Australia, has a reported prevalence of 7 to 34% in the general population (382). Risk factors for non-specific neck and shoulder pain include individual factors (e.g. sex, low physical capacity, history of neck or back pain), workplace factors (e.g. physical workload, organisational structure and psychosocial factors) and a person's general physical health and wellbeing (383).

Optimal management of nonspecific neck pain comprises a whole system approach that includes education, reassurance and exercise, as well as manual therapies and oral analgesics or topical medications (384, 385). Mind-body therapies such as yoga, are thought to improve outcomes for people with neck pain by improving movement, and increasing strength and function through physical activity (386-388).

4.11.2 Description of the studies

Twelve citations (389-400) corresponding to 5 RCTs (Cramer 2013, Michalsen 2012a, Rajalaxmi 2018a, Ulug 2018, Yogitha 2010) and one quasi RCT (Jain 2020) were identified in the literature search. There was one <u>ongoing study</u> and 4 <u>studies awaiting classification</u> (401, 402). No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in the Appendix D6.3.1.

All 6 studies were carried out in single settings in Germany (Cramer 2013, Michalsen 2012a), India (Jain 2020, Rajalaxmi 2018a, Yogitha 2010) or Turkey (Ulug 2018). Sample sizes ranged between 51 and 77 (total 360 participants). Two studies enrolled participants who experienced self-reported, non-specific neck pain for a minimum of 3 months (Cramer 2013, Ulug 2018) or painful restriction of cervical spine mobility (Michalsen 2012a, Rajalaxmi 2018a). One study included participants with chronic neck pain due to spasm or strain of the neck muscles (Yogitha 2010) and one study included people diagnosed with frozen shoulder (Jain 2020).

Two studies (Jain 2020, Rajalaxmi 2018) examined the effectiveness of yoga compared to an inactive control (no intervention). Five studies compared yoga to an active comparator, being either self-directed exercise (Cramer 2013, Michalsen 2012), non-guided supine rest (Yogitha 2010) or another mind-body intervention, including Pilates (Rajalaxmi 2018, Ulug 2018) and Tai Chi (Rajalaxmi 2018). In 4 studies participants in all groups also received either isometric neck exercises (Rajalaxmi 2018) or physical therapy (Ulug 2018, Yogitha 2010) or standard care that included both NSAIDs and physical therapy (Jain 2020).

The intensity of the yoga program varied from 90-minute yoga sessions once per week (Cramer 2013, Michalsen 2012a) to daily yoga sessions (Jain 2020, Rajalaxmi 2018, Ulug 2018 and Yogitha 2018). Program duration varied between 10 days (Yogitha 2010), 3 weeks (Rajalaxmi 2018), 4 weeks (Jain 2020, 6 weeks (Ulug 2018), 9 weeks (Cramer 2013) and 10 weeks (Michalsen 2012a).

Results for yoga versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings Table (see Section 4.11.4.1) and Appendix F2. Results of studies that compared yoga with another comparator are presented in Appendix F2.

4.11.3 Risk of bias - per item

The risk of bias for each item in the included RCTs for neck and shoulder pain is presented in Figure 61. Details are provided in Appendix D6.3.2. No studies were judged to be at overall low risk of bias.

Figure 61 Risk of bias summary: review author's judgements about each risk of bias item for each included study – neck and/or shoulder pain



4.11.4 Main comparison (vs control)

Two RCTs (total 92 participants) comparing yoga with no intervention (delivered as an adjunct to isometric neck exercises or NSAIDs plus physical therapy) were eligible for this comparison and contributed data to 3 outcomes considered critical or important for this review (Jain 2020, Rajalaxmi 2018).

There were 2 studies awaiting classification (total 106 participants) and one ongoing study (10 participants) that was completed (but results not published) that compared yoga with control (no intervention) in people with shoulder pain that could have contributed data to this comparison (see Appendix C6). The available information is insufficient to make a judgement about the nonreporting of results.

4.11.4.1 Summary of findings and evidence statements

Yoga compared to Control (no intervention or usual care) for neck and/or shoulder pain

Patient or population: Neck pain and/or shoulder pain

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated at (95% CI)	osolute effects*	Rela tive	N ^o of participants	Certainty	Evidence		
Outcomes	Risk with Control	Risk with Yoga ^	t (95% CI)	(studies)	evidence (GRADE)	statement		
Neck pain assessed with: NPQ (higher is worse) Scale from: 0 to 100 follow-up: 3 weeks	The mean NPQ score was 56 points	MD 31.40 lower (35.71 lower to 27.09 lower)	-	20 (1 RCT)	⊕⊕⊖⊖ LOW ^{a,b,c,d,e}	Yoga may result in a large reduction in pain in people with neck pain. #		
Shoulder pain assessed with: SPADI - pain (higher is worse) Scale from: 0 to 100 follow-up: 4 weeks	The mean SPADI score was 20.14 points	MD 0.33 higher (1.18 lower to 1.84 higher)	-	72 (1 RCT)	⊕⊕⊖⊖ LOW ^{a,b,c,d,e}	Yoga may result in little to no difference in pain in people with shoulder pain. ##		
Health-related quality of life – not reported	-	-	-	-	-	No studies found. The effect of yoga on health-related quality of life in people with chronic neck or shoulder pain is unknown.		
Physical function/ disability assessed with: SPADI - disability (higher is worse) Scale from: 0 to 100 follow-up: 4 weeks	The mean SPADI score was 19.7 points	MD 0.77 higher (1.81 lower to 3.35 higher)	-	72 (1 RCT)	⊕⊕⊖⊖ LOW ^{a,b,c,d,e}	Yoga may result in little to no difference in physical function in people with shoulder pain. ##		
Emotional function – not reported	-	-	-	-	-	No studies found. The effect of yoga on emotional function in people with chronic neck or shoulder pain is unknown.		
Return to work – not reported	-	-	-	-	-	No studies found. The effect of yoga on the ability of people with chronic neck pain to return to work is unknown.		

Yoga compared to Control (no intervention or usual care) for neck and/or shoulder pain

Patient or population: Neck pain and/or shoulder pain

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated al (95% CI)	osolute effects*	Rela tive effec	Nº of posticipants	Certainty	Evidence		
Outcomes	Risk with Control	Risk with Yoga ^	effec t (95% CI)	(studies)	evidence (GRADE)	statement		
Kinesiophobia assessed with: Tampa scale for kinesiophobia (higher is worse) Scale from: 17 to 68 follow-up: 3 weeks	The mean score was 63.7	MD 8.50 lower (11.25 lower to 5.75 lower)	-	20 (1 RCT)	⊕⊕⊖⊖ LOW ^{a,b,c,d,e}	Yoga may reduce kinesophobia in people with neck pain.###		
Global perceived effects – not reported	-	-	-	-	-	No studies found. The effect of yoga on global perceived effects in people with chronic neck or shoulder pain is unknown.		

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

** As a rule of thumb, an SMD of 0.2 represents a small difference, 0.5 is moderate, and 0.8 is a large difference (58).

*** Effect estimates were considered on 3 levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).

The MCID in people with neck pain is a reduction of at least 25% from baseline (403). ## The MCID in people with chronic shoulder pain is between 8 and 13.2 points (404). ### Both groups remain above a cut-point of 37, which indicates kinesiophobia is present.

^ Yoga delivered as an adjunct to isometric neck exercises or NSAIDs and physical therapy.

CI: confidence interval; NPQ: Northwick Park Neck Pain Questionnaire; SMD: standardised mean difference

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. No serious risk of bias. Certainty of evidence not downgraded.

b. Inconsistency not able to be assessed. Single study. Certainty of evidence not downgraded.

c. No serious indirectness. The available evidence is in people with chronic mechanical neck pain or frozen shoulder and may not be applicable to people with chronic, nonspecific neck or shoulder pain but could be sensibly applied. Certainty of evidence not downgraded.

d. Serious imprecision. One small study contributing data. Certainty of evidence downgraded.

e. Publication bias suspected. Evidence is limited to one study. There is a strong suspicion of non-reporting of results likely related to the *p* value, direction or magnitude of effect. Certainty of evidence downgraded.

4.11.4.2 Forest plots

Outcome results related to pain in people with neck or shoulder pain are presented in Figure 62.

Outcome results related to disability in people with shoulder pain are presented in Figure 63.

Outcome results related to kinesiophobia in people with neck pain are presented in Figure 64.

Figure 62 Forest plot of comparison: Yoga vs control (no intervention, usual care): Neck and shoulder pain – pain



Figure 63 Forest plot of comparison: Yoga vs control (no intervention, usual care): Neck and shoulder pain – disability

		Yoga		С	ontrol			Mean Difference		Mea	n Differen	ce	
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI		IV, Ra	andom, 95	% CI	
9.2.1 Shoulder pain and disability index - disa	bility sc	ore											
Jain 2020 (adhesive capsulitis) Subtotal (95% Cl)	20.47	5.84	36 36	19.7	5.31	36 36	100.0% 100.0%	0.77 [-1.81, 3.35] 0.77 [-1.81, 3.35]			\checkmark	- -	
Heterogeneity: Not applicable Test for overall effect: Z = 0.59 (P = 0.56)													
9.2.2 Outcome not measured or reported													
Rajalaxmi 2018 (chronic, mechanical neck pain) Subtotal (95% Cl)	0	0	10 10	0	0	10 10		Not estimable Not estimable					
Heterogeneity: Not applicable Test for overall effect: Not applicable													
									-10	-5	0	5	10
										Favours ye	oga Favo	urs control	

Figure 64 Forest plot of comparison: Yoga vs control (no intervention, usual care): Neck and shoulder pain – kinesiophobia

	Y	Yoga Control				Mean Difference		Mean Difference					
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI		IV, Ran	dom, 95	5% CI	
9.2.1 Tampa scale for	r kinesio	phobi	ia										
Rajalaxmi 2018 Subtotal (95% CI)	55.2	2.29	10 10	63.7	3.8	10 10	100.0% 100.0%	-8.50 [-11.25, -5.75] -8.50 [-11.25, -5.75]					
Heterogeneity: Not app Test for overall effect:	plicable Z = 6.06	(P < 0	0.00001)									
Total (95% CI) Heterogeneity: Not app Test for overall effect: Test for subgroup diffe	plicable Z = 6.06 erences: N	(P < 0 Not ap	10 0.00001 plicable)		10	100.0%	-8.50 [-11.25, -5.75]	-20	-10 Favours yog	0 Ja Favo	10 Durs control	20

4.12 Stress

4.12.1 Description of the condition

Stress is a multifactorial phenomenon that can impact a person's developmental, emotional or behavioural wellbeing, increasing the risk of developing a mental health condition (or problem, symptom or disorder) that can be temporary or persistent (94). Stressors can be external (environment, psychological, or social situations) or internal (illness or from a medical procedure), causing a 'fight or flight response' – a complex reaction of the endocrinologic and neurologic systems (405). If poorly managed, chronic stress can cause or exacerbate many serious health problems, including additional mental health problems (e.g. depression and anxiety) and physical condition, such as stroke, cardiovascular disease, headaches, loss of appetite, sexual dysfunction and insomnia (94). For example, adverse workplace environments can lead to substantial stress and burnout, which can cause negative mental health outcomes such as depression (406). Families and other informal caregivers providing long-term care to older adults or persons with chronic illness and disabilities also face additional stressors that can be associated with poorer mental health (407). Social inequalities such as poverty and limited access to education and healthcare have a clear relationship with poor mental health, particularly in children and adolescents (408).

According to the Stress and Wellbeing in Australia survey, 35% have reported having a significant level of distress in their lives, with personal finances (49%), family issues (45%), personal health (44%), maintaining a healthy lifestyle (40%) and issues with the health or others close to us (38) being the top 5 contributors to stress during 2015 (409). Even though the majority of Australians reported that stress impacts their physical health (72%) and mental health (64%), a very small proportion of individuals seek professional help (409). A healthy diet, exercise, sleep and relaxation techniques (yoga, meditation, deep breathing and massage) are self-care strategies used for stress management, as well as professional help (409).

4.12.2 Description of studies

Sixteen citations (410-425) corresponding to 11 RCTs (Daukantaite 2018, Godse 2015, Grensman 2018, Harkess 2016, Hartfiel 2012, Hewett 2017, Köhn 2013, Kumar 2016, Maddux 2018, Michalsen 2012a, Smith 2007) and one quasi RCT (Granath 2006) were identified in the literature search. There were 3 <u>ongoing studies</u> and one study <u>awaiting classification</u>. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of the included studies is provided in Appendix D7.1.1.

All studies were carried out in the community setting in either Australia (Harkess 2016, Hewett 2017, Smith 2007), India (Godse 2015, Kumar 2016), Germany (Michalsen 2012), Sweden (Granath 2006, Grensman 2018, Maddux 2018, Daukantaite 2018, Köhn 2013), or the United Kingdom (Hartfiel 2012) Sample size ranged from 37 to 131 (total 1040), with five studies (Granath 2006, Grensman 2018, Harkess 2016, Hartfiel 2012, Maddux 2018) enrolling people with employment-related stress conditions, while the remainder of the studies (Daukantaite 2018, Köhn 2013, Kumar 2016, Michalsen 2012a, Smith 2007) enrolled members of the general population with elevated stress or presenting with symptoms of stress.

Eight studies compared yoga to control, being either no intervention (Köhn 2013) or waitlist (Daukantaite 2018, Godse 2015, Harkess 2016, Hartfiel 2012, Hewett 2017, Maddux 2018, Michalsen 2012a). In one study (Köhn 2013) all participants continued to receive standard medical care (that included pharmacological treatment and consultations with other allied health personnel. One study (Michalsen 2012a) included 2 yoga groups of different intensity, being either one or 2 yoga sessions per week. One study (Daukantaite 2018) included a second yoga group that practised yoga plus psychoeducation and mindfulness. Four studies compared yoga to an active comparator, including cognitive behavioural therapy (Granath 2006, Grensman 2018), mindfulness based cognitive psychotherapy (Grensman 2018), mental imagery (Kumar 2016) or muscle relaxation (Smith 2017).

Yoga interventions generally consisted of yoga poses, breathing and relaxation with program duration ranging from 2 to 20 weeks. Intensity varied from 20 to 90 minutes sessions practised between one and 7 yoga times per week.

Results for yoga versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings Table (see Section 4.12.4.1) and Appendix F2. Results of studies that compared yoga with another comparator are presented in Appendix F2.

4.12.3 Risk of bias - per item

The risk of bias for each item in the included studies is presented in Figure 65. Details are provided in Appendix D.7.1.2.

No studies were judged to be at overall low risk of bias.

Figure 65 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Stress



4.12.4 Main comparison (vs control)

Eight RCTs (Daukantaite 2018, Godse 2015, Harkess 2016, Hartfiel 2012, Hewett 2017, Köhn 2013, Maddux 2018, Michalsen 2012a) comparing yoga with no intervention, waitlist or usual care in people with elevated perceived stress were eligible for this comparison and contributed data to 6 outcomes considered critical or important for this review.

There was one study awaiting classification (total participants unknown) that compared yoga with no intervention in military personnel at risk of stress, anxiety or depression that could have contributed data to 2 outcomes (see Appendix C6).

4.12.4.1 Summary of findings and evidence statements

Yoga compared to control (no intervention, waitlist or usual care) for elevated perceived stress

Patient or population: Elevated perceived stress

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	solute effects*	Relative	Nº of	Certainty of the			
Outcomes	Risk with control	Risk with yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statement		
Health-related quality of life assessed with: EQ-5D VAS or SF-36 (higher is better) follow-up: range 12 to 17 weeks	An effect favour all four domains mental wellbein emotion, social f health) as well a perceptions (ME to 31.60 higher) No difference in functioning, role bodily pain was range from 4.00	ing yoga across associated with g (vitality, role- function, mental s general health D range from 11.00 physical e-physical, and observed (MD 0 to 12.70 higher).		172 (3 RCTs)	⊕⊕○○ Low ^{a,b}	Yoga may improve some but not all aspects of quality of life in people with elevated perceived stress. **		
Perceived stress assessed with: PSS-10 or PSS-14 (higher is worse) follow-up: range 6 to 17 weeks	-	SMD 0.60 SD lower ** (0.96 lower to 0.23 lower)	-	401 (6 RCTs) †	⊕⊕⊖⊖ Low ^{c,d}	Yoga may reduce perceived stress in people with elevated perceived stress. #		
Emotional wellbeing assessed with: PANAS-X, PANAS-PA (higher is better), or PANAS-NA (higher is worse) follow-up: range 8 to 16 weeks	One study repor favouring yoga f (SMD 0.39 high difference in neg 0.17 lower). One study repor favouring yoga f SMD 0.90 SD hi g	ted an effect for positive affect er but no gative affect SMD ted an effect for overall mood gher) **	-	159 (2 RCTs)	⊕⊕⊖⊖ Low ª,e	Yoga may improve positive emotional affect and overall mood but have little to no effect on negative emotional affect in people with elevated perceived stress.		
Life satisfaction assessed with: HILS, PWI (higher is better) follow-up: 8 weeks	-	SMD 0.21 SD higher ** (0.11 lower to 0.52 higher)	-	178 (2 RCTs) ⁺⁺	⊕⊕⊖⊖ Low ^{b,e}	Yoga may result in little to no effect on life satisfaction in people with elevated perceived stress.		
Fatigue / burnout assessed with: SMBQ (higher is worse) follow-up: 12 weeks	The mean SMBQ score was 3.7 points	MD 0.50 points lower (0.89 lower to 0.11 lower)	-	37 (1 RCT)	⊕⊕⊖⊖ Low ^{a,b}	Yoga may result in little to no effect on burnout in people with elevated perceived stress. ##		
Cognitive function – not measured	-	-	-	-	-	No studies found. The effect of yoga on cognitive function in people with elevated perceived stress is unknown.		

Yoga compared to control (no intervention, waitlist or usual care) for elevated perceived stress

Patient or population: Elevated perceived stress

Setting: Community

Intervention: Yoga

Comparison: Control (no intervention, waitlist or usual care)

	Anticipated abs (95% CI)	solute effects*	Relative	Nº of	Certainty of			
Outcomes	Risk with control	Risk with yoga	effect (95% CI)	participants (studies)	evidence (GRADE)	Evidence statement		
Sleep quality assessed with: ISI (higher is worse) follow-up: range 5 to 16 weeks	The mean ISI score was 16.13 points	MD 2.58 points lower (5.93 lower to 0.77 higher)	-	179 (3 RCTs)	⊕⊕⊖⊖ Low ^{a,f}	Yoga may result in little to no difference in sleep quality in people with elevated perceived stress. ###		

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

** As a rule of thumb, an SMD of 0.2 is considered a small difference, 0.5 is medium, and 0.8 is large difference (58).

*** Effect estimates were considered on 3 levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).

Estimated MCID of between 2.19 and 11 points among students or adults with elevated stress (200, 311)

Neither the yoga or control groups had clinically significant burnout post-intervention (proposed cut-off score 4.0 (426)). After adjusting for the baseline score, the study reported no difference in burnout between the yoga and control groups. ### MCID of 8.4 points corresponds to a moderate improvement in insomnia.

+ Data from one RCT (72 participants) not included in the meta-analysis. The study reports an effect in favour of yoga but did not provide usable data.

++ Data from one RCT (64 participants) not included in the meta-analysis. The outcome was pre-specified in the trial protocol but the study did not report the results.

CI: confidence interval; HILS: Harmony in Life Scale; ISI: Insomnia Severity Index; MD: mean difference; PANAS: Positive and negative affect schedule; PSS: Perceived Stress Scale; PWI: Personal Wellbeing Index; SMD: standardised mean difference; X: expanded

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

- a. Serious imprecision. Wide confidence intervals (upper and lower bounds overlap with both a large and small important difference). Certainty of evidence downgraded.
- b. Publication bias suspected. There is a strong suspicion of non-reporting of results likely related to the *p* value, direction or magnitude of effect. Certainty of evidence downgraded.
- c. Serious risk of bias. Three out of 6 RCTs contributing ~50% of the data were at high risk of bias. In a sensitivity analysis examining the impact of these RCTs, the size of the effect estimate increased. Certainty of evidence downgraded.
- d. Serious inconsistency. Point estimates vary widely and confidence intervals of some studies do not overlap. The magnitude of statistical heterogeneity was high (l² > 60%). Certainty of evidence downgraded.
- e. Serious risk of bias. One of 2 studies at high risk of bias that overestimates the size of the effect estimate in favour of yoga. Certainty of evidence downgraded.
- f. Serious risk of bias. Two out of 3 RCTs contributing ~70% of the data were at high risk of bias. In a sensitivity analysis examining the impact of these RCTs, the size of the effect estimate increased. Certainty of evidence downgraded.

4.12.4.2 Forest plots

Outcome results related to quality of life for people with elevated perceived stress are presented in Figure 66.

Outcome results related to perceived stress for people with elevated perceived stress are presented in Figure 67.

Outcome results related to emotional wellbeing for people with elevated perceived stress are presented in Figure 68.

Outcome results related to life satisfaction for people with elevated perceived stress are presented in Figure 69.

Outcome results related to fatigue for people with elevated perceived stress are presented in Figure 70.

Outcome results related to sleep quality for people with elevated perceived stress are presented in Figure 71.

Figure 66 Forest plot of comparison: Yoga vs control (no intervention, waitlist or usual care): Stress -Quality of life ^

	Yoga		С	ontrol			Mean Difference	Mean Difference
Study or Subgroup	lean SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
10.1.1 EuroQoL - Visua	Analogue S	Scale	10.0	47 -		400.007	00 00 1 00 70 7 10	
Köhn 2013 Subtotal (95% CI)	-69.8 22.9	18 18	-49.2	17.5	19 19	100.0% 100.0%	-20.60 [-33.78, -7.42] -20.60 [-33.78, -7.42]	-
Heterogeneity: Not applic Test for overall effect: Z =	cable = 3.06 (P = 0	.002)						
10.1.2 SF-36 - emotiona	l wellbeing							
Hewett 2017 Subtotal (95% CI)	-76.6 17.9	29 29	-63.1	16.9	34 34	100.0% 100.0%	-13.50 [-22.14, -4.86] -13.50 [-22.14, -4.86]	-
Heterogeneity: Not applie Test for overall effect: Z =	cable = 3.06 (P = 0	.002)						
10.1.3 SF-36 - social fur	nctioning							
Hewett 2017 Subtotal (95% CI)	-84.1 23.4	29 29	-72.1	23.6	34 34	100.0% 100.0%	-12.00 [-23.64, -0.36] -12.00 [-23.64, -0.36]	1
Heterogeneity: Not applie Test for overall effect: Z :	cable = 2.02 (P = 0	.04)						-
10.1.4 SF-36 - role emo	tional							
Hewett 2017 Subtotal (95% CI)	-79.3 37.2	29 29	-47.7	41.1	34 34	100.0% 100.0%	-31.60 [-50.94, -12.26] - 31.60 [-50.94, -12.26]	
Heterogeneity: Not applic Test for overall effect: Z :	cable = 3.20 (P = 0	.001)						
Hewett 2017 Subtotal (95% CI)	-54.5 18	29	-43.5	17.9	34 34	100.0%	-11.00 [-19.89, -2.11]	1
Heterogeneity: Not applic	able	23			J4	100.070	-11.00 [-13.03, -2.11]	•
	- 2.42 (F - 0	.02)						
10.1.6 SF-36 - physical	functioning							_
Hewett 2017 Subtotal (95% CI)	-89.1 19.6	29 29	-83.2	18.5	34 34	100.0% 100.0%	-5.90 [-15.36, 3.56] - 5.90 [-15.36, 3.56]	
Heterogeneity: Not applic Test for overall effect: Z :	cable = 1.22 (P = 0	.22)						
10.1.7 SF-36 bodily pair	ı							
Hewett 2017 Subtotal (95% CI)	-79.1 20.2	29 29	-75.1	17.2	34 34	100.0% 100.0%	-4.00 [-13.35, 5.35] -4.00 [-13.35, 5.35]	4
Heterogeneity: Not applic Test for overall effect: Z :	cable = 0.84 (P = 0	.40)						
	leal							
Hewett 2017	-86.2 28	29	-73.5	40.3	34	100.0%	-12.70 [-29.65, 4.25]	_ _
Subtotal (95% CI)		29			34	100.0%	-12.70 [-29.65, 4.25]	
Heterogeneity: Not applic Test for overall effect: Z =	cable = 1.47 (P = 0	.14)						
10.1.9 SF-36 - general h	ealth							_
Hewett 2017 Subtotal (95% CI)	-65.5 20.9	29 29	-54.3	20.2	34 34	100.0% 100.0%	-11.20 [-21.40, -1.00] -11.20 [-21.40, -1.00]	-
Heterogeneity: Not applie Test for overall effect: Z :	cable = 2.15 (P = 0	.03)						
10.1.10 missing data								
Michalsen 2012 (1)	0 0	48	0	0	24		Not estimable	
Heterogeneity: Not applic	able	48			24		NOT ESTIMADIE	
i est for overall effect: No	or applicable							
							-	
								-50 -25 0 25 50 Favours yoga Favours control

Footnotes

(1) Study reports the between-group change scores for SF-36 MCS (MD 0.6' 95%Cl 0.1, 1.1) and PCS (MD -0.1; 95%Cl -0.4, 0.2).

Note: ^ Values for all quality of life measures inverted to ensure consistency in direction of effect. Original scale reported in GRADE table.

		Yoga			Control		;	Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
10.2.1 Perceived stre	ess scale	e (PSS-1	0)						
Daukantaitė 2018	14.1	8.28	34	14.71	6.6	30	17.3%	-0.08 [-0.57, 0.41]	
Harkess 2016	22.53	7.2	51	24.3	5.6	49	19.4%	-0.27 [-0.67, 0.12]	
Hartfiel 2012 (1)	21.3	5.3424	33	25.4	6.6287	26	16.4%	-0.68 [-1.21, -0.15]	
Hewett 2017	12.9	7.6	29	19.1	6.6	34	16.6%	-0.87 [-1.38, -0.35]	_
Maddux 2018 (2) Subtotal (95% CI)	16.1	7.0434	41 188	18.9	6.691	37 176	18.2% 88.0%	-0.40 [-0.85, 0.05] - 0.44 [-0.70, -0.18]	•
Heterogeneity: Tau ² =	: 0.03; CI	ni² = 6.15	, df = 4	(P = 0.	19); l² = 3	35%			
Test for overall effect:	Z = 3.28	8 (P = 0.0	01)	·					
10.2.2 Perceived stre	ess scale	e (PSS-1	4)						
Köhn 2013 (3)	18.7	6.7	18	32.1	8.9	19	12.0%	-1.66 [-2.42, -0.90]	
Subtotal (95% CI)			18			19	12.0%	-1.66 [-2.42, -0.90]	
Heterogeneity: Not ap	plicable								
Test for overall effect:	Z = 4.28	8 (P < 0.0	001)						
10.2.3 Missing data									
Michalsen 2012 (4)	0	0	48	0	0	24		Not estimable	
Subtotal (95% CI)			0			0		Not estimable	
Heterogeneity: Not ap	plicable								
Test for overall effect:	Not app	licable							
Total (95% CI)			206			195	100.0%	-0.60 [-0.96, -0.23]	\blacklozenge
Heterogeneity: Tau ² =	: 0.14; Cl	ni² = 15.5	7, df =	5 (P = 0).008); l²	= 68%		-	
Test for overall effect:	Z = 3.20) (P = 0.0	01)						Favours voga Favours control
Test for subgroup diffe	erences:	Chi ² = 8.	88, df =	= 1 (P =	0.003), I ^s	² = 88.7	'%		
Footnotes									

Figure 67 Forest plot of comparison: Yoga vs control (no intervention, waitlist or usual care): stress -Perceived stress

(1) Post-treatment results reported as mean (SE). Standard deviation calculated as per protocol.

(2) Study reports post-treatment results as mean (SE). Standard deviation calculated as per protocol.

(3) 14-item PSS

(4) 14-item PSS. Post-treatment results not reported. Study reports a between-group difference favouring yoga (p=0.003).

Figure 68 Forest plot of comparison: Yoga vs control (no intervention, waitlist or usual care): stress -Emotional wellbeing



Footnotes

(1) Values inverted for consistency in direction of scale.Original scale reported in GRADE table.

(2) Post-treatment results reported as mean (SE). Standard deviation calculated as per protocol. Values inverted for consistency in direction of scale. Original scale reported in GRADE table.

Figure 69 Forest plot of comparison: Yoga vs control (no intervention, waitlist or usual care): stress -Life satisfaction

		Yoga		(Control Std. Mean Difference			Std. Mean Difference	Std. Mean Difference		
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% Cl		
2.4.2 Harmony in Life	Scale										
Daukantaitė 2018 (1)	0	0	34	0	0	30		Not estimable			
Maddux 2018 (2)	-23.7	7.0434	41	-20.9	7.2993	37	44.1%	-0.39 [-0.84, 0.06]			
Subtotal (95% CI)			75			67	44.1%	-0.39 [-0.84, 0.06]	\bullet		
Heterogeneity: Not app	licable										
Test for overall effect:	<u>Z</u> = 1.69	(P = 0.09	9)								
2.4.3 Psychological w	vellbeing	j index -	Adult								
Harkess 2016	-53.3	12.3	51	-52.6	10.1	49	55.9%	-0.06 [-0.45, 0.33]	-#-		
Subtotal (95% CI)			51			49	55.9%	-0.06 [-0.45, 0.33]	•		
Heterogeneity: Not app	licable										
Test for overall effect:	Z = 0.31	(P = 0.76	6)								
2.4.4 Outcome not re	ported, p	probably	becau	ise it wa	as not m	easure	d				
Godse 2015	0	0	40	0	0	40		Not estimable			
Hartfiel 2012	0	0	33	0	0	26		Not estimable			
Hewett 2017	0	0	29	0	0	34		Not estimable			
Köhn 2013	0	0	18	0	0	19		Not estimable			
Michalsen 2012	0	0	48	0	0	24		Not estimable			
Subtotal (95% CI)			168			143		Not estimable			
Heterogeneity: Not app	licable										
Test for overall effect:	Not appli	cable									
Total (95% CI)			294			259	100.0%	-0.21 [-0.52, 0.11]	•		
Heterogeneity: Tau ² =	0.01; Chi	i² = 1.14,	df = 1	(P = 0.2	8); l² = 1	3%		_			
Test for overall effect:	Z = 1.27	(P = 0.20))						-2 -1 U I Z		
Test for subgroup diffe	rences: (Chi ² = 1.1	4, df =	1 (P = 0).28), l² =	12.6%)				
Footnotes											

(1) Outcome is pre-specified in the clinical trial record but not reported, probably because the result was considered unfavourable by study authors.

(2) Study reports post-treatment results as mean (SE). Standard deviation calculated through RevMan.

Figure 70 Forest plot of comparison: Yoga vs control (no intervention, waitlist or usual care): stress – Fatigue (including burnout)

	Yoga			Co	ontro	I		Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI	IV, Random, 95% CI
10.5.1 Shirom-Melamed Burnout Questionnaire									
Köhn 2013 (1) Subtotal (95% CI)	3.2	0.6	18 18	3.7	0.6	19 19	100.0% 100.0%	-0.50 [-0.89, -0.11] - 0.50 [-0.89, -0.11]	
Heterogeneity: Not app	olicable								
Test for overall effect:	Z = 2.53	(P =	0.01)						
10.5.4 Outcome not re	eported	, pro	bably I	pecaus	e it w	as not	measure	d	
Daukantaitė 2018	0	0	34	0	0	30		Not estimable	
Godse 2015	0	0	40	0	0	40		Not estimable	
Harkess 2016	0	0	51	0	0	49		Not estimable	
Hartfiel 2012	0	0	33	0	0	26		Not estimable	
Hewett 2017	0	0	29	0	0	34		Not estimable	
Maddux 2018	0	0	41	0	0	37		Not estimable	
Michalsen 2012	0	0	48	0	0	24		Not estimable	
Subtotal (95% CI)			276			240		Not estimable	
Heterogeneity: Not app	olicable								
Test for overall effect:	Not app	icable	е						
Total (95% CI)			294			259	100.0%	-0.50 [-0.89, -0.11]	
Heterogeneity: Not applicable									
Test for overall effect: Z = 2.53 (P = 0.01)								-1 -0.5 0 0.5 I	
Test for subgroup differences: Not applicable									Favours yoga Favours control

Footnotes

(1) After adjusting for baseline imbalance in the SMBQ score, the study reported no between-group difference.

Figure 71 Forest plot of comparison: Yoga vs control (no intervention, waitlist or usual care): stress -Sleep quality

		Yoga			Control		Mean Difference			Mean Difference			
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI		IV, Ra	ndom, 95	5% CI	
10.6.1 Insonia Severi	ty Index	l											
Daukantaitė 2018	17.07	7.02	34	16.9	5.69	30	34.1%	0.17 [-2.95, 3.29]			-	-	
Köhn 2013 (1)	8	6.3	18	14.1	5.1	19	30.4%	-6.10 [-9.81, -2.39]		-			
Maddux 2018 (2) Subtotal (95% CI)	15.2	7.0434	41 93	17.4	6.0828	37 86	35.4% 100.0%	-2.20 [-5.11, 0.71] - 2.58 [-5.93, 0.77]					
Heterogeneity: Tau ² = Test for overall effect:	6.04; Ch Z = 1.51	ni ² = 6.46 (P = 0.1	, df = 2 3)	(P = 0.	04); l² = (39% measu	rod						
Codec 2015	eporteu	, probab	19 000		was not	100	icu	Not optimoble					
Gouse 2015	0	0	40 51	0	0	40		Not estimable					
Hartfiel 2012	0	0	33	0	0	49 26		Not estimable					
Hewett 2017	0	0	29	0	0	34		Not estimable					
Michalsen 2012 Subtotal (95% CI)	0	0	48 201	0	0	24 173		Not estimable Not estimable					
Heterogeneity: Not ap	plicable	liaahla											
Test for overall effect:	ічог аррі	eldeoil											
									-10		0	5	
Test for submusid		Not on all								Favours yo	oga Favo	ours contro	ol

Test for subgroup differences: Not applicable

Footnotes

(1) After adjusting for baseline imbalance in the ISI score, the study reported no between-group difference.

(2) Study reports post-treatment results as mean (SE). Standard deviation calculated as per protocol.

5 Discussion

5.1 Summary of main results

We conducted a systematic review of RCTs to evaluate the effectiveness of yoga for 15 clinical or pre-clinical conditions prioritised (by NTWC) as most relevant to the practice of yoga in Australia. These were combined into 11 groupings for reporting purposes. We identified 147 RCTs that were included in the results. Of these studies, 95 RCTs compared yoga with the main comparator of interest, 'inactive control'. All 15 conditions prioritised by NTWC that included either critical or important outcomes were included in the final analysis and are presented in the 12 summary of findings tables.

Results for studies of prioritised conditions with active comparators are presented in Appendix F2 and described in the results section. These are not included in the synthesis or summary of findings tables, as the wide range of comparators and outcomes did not allow for synthesis as planned in the protocol.

Our confidence in the result from the body of evidence for each outcome was assessed using the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) framework. GRADE combines information to assess overall how certain systematic review authors can be that the estimates of the effect (reported across a study/s for each critical or important outcome) are correct.

Certainty of evidence is interpreted as follows:

Certainty	Definition
High certainty	The authors have a lot of confidence that the true effect is similar to the estimated effect.
Moderate certainty	The true effect is probably close to the estimated effect.
Low certainty	The true effect may be markedly different from the estimated effect.
Very low certainty	The true effect is probably markedly different from the estimated effect. Reviewers' confidence was so limited that interpretation was not provided.

For 15 prioritised conditions there was moderate or low certainty evidence about the effect of yoga on at least one of the outcomes considered critical or important by NTWC.

The review found:

- moderate certainty evidence that yoga probably results in:
 - a large (>5 mmHg) reduction in systolic (15 RCTs, 1230 participants) and diastolic (13 RCTs, 1090 participants) blood pressure in people with hypertensive heart disease
 - a moderate improvement (10-20%) in emotional wellbeing in people with anxiety (2 RCTs, 131 participants)
 - a moderate reduction (10-20%) in symptoms of depression in people with depression (10 RCTs, 434 participants)
 - a slight improvement (<10%) in overall health-related quality of life in people with low back pain (4 RCTs, 590 participants).
- low certainty evidence that yoga may result in:
 - a large improvement (>20%) in self-compassion (1 RCT, 46 participants) in people with depression
 - a large improvement (>20%) in emotional wellbeing (1 RCT, 65 participants) and a large reduction (>20%) in headache frequency (4 RCTs, 317 participants) in people with headache disorders
 - a large improvement (>20%) in health-related quality of life (6 RCTs, 826 participants) in people with asthma
 - a large reduction (>20%) in pain and reduced kinesiophobia (1 RCT, 20 participants) in people with neck pain

- a moderate improvement (10-20%) in health-related quality of life (3 RCTs, 172 participants), perceived stress (6 RCTs, 401 participants) and emotional wellbeing (2 RCTs, 159 participants) in people with elevated perceived stress
- a moderate improvement (10-20%) in life satisfaction (1 RCT, 40 participants), quality of life (1 RCT, 56 participants) and perceived stress (2 RCTs, 62 participants) in people with depression
- a moderate reduction (10-20%) in pain medication use (5 RCTs, 465 participants) in people with low back pain
- a moderate reduction (10-20%) in number of acute "rescue" pills used over preventative medication (1 RCT, 65 participants) in people with headache disorders
- a slight improvement (<10%) in pain acceptance in people with fibromyalgia (1 RCT, 53 participants).
- a slight reduction (<10%) in pain intensity (10 RCTs, 1101 participants) in people with low back pain
- a slight reduction (<10%) in perceived stress (1 RCT, 101 participants) in people with anxiety
- a slight improvement (<10%) in health-related quality of life (1 RCT, 53 participants) and a slight reduction (<10%) in fatigue (1 RCT, 53 participants) in people with fibromyalgia.
- low certainty evidence that yoga may result in little (to no) change in:
 - life satisfaction (2 RCTs, 178 participants), fatigue (1 RCT, 37 participants) or sleep quality (3 RCTs, 179 participants) in people with elevated perceived stress
 - physical (5 RCTs, 710 participants) or emotional functioning (4 RCTs, 642 participants) in people with low back pain
 - shoulder pain (1 RCT, 72 participants) or physical function (1RCT, 72 participants) in people with frozen shoulder
 - psychological distress (1 RCT, 50 participants) or emotional function (1 RCT, 50 participants) in people with depression
 - health-related quality of life (3 RCTs, 139 participants, non-fibromyalgia), emotional functioning (2 RCTs, 111 participants) or mobility (2 RCTs, 92 participants) in people with chronic pain conditions
 - physical functioning, pain, stiffness, tenderness or morning tiredness in people with fibromyalgia (1 RCT, 53 participants)
 - perceived stress (3 RCTs, 245 participants) or health-related quality of life (2 RCT, 221 participants) in people with hypertensive heart disease
 - o pulmonary function (6 RCTs, 680 participants) in people with asthma.

The evidence provides very low certainty of the effect of yoga versus inactive control (no intervention, waitlist or usual care) for 20 out of the 88 critical or important outcomes prioritised for analysis in this review. For these outcomes, the true effect is probably markedly different from the estimated effect, with more studies needed to determine the true effect.

Of the 88 outcomes prioritised as critical or important in this review, there were no studies found reporting on 23 of those outcomes. and therefore the effect of yoga on these outcomes is unknown.

An assessment of benefits and harms of yoga was not conducted for this review, as it was out of scope of this review to assess adverse effects of yoga.

Overall, the evidence suggests that yoga may provide people with some benefit for someⁿ of the outcomes (up to three for a given condition) considered important or critical by the NTWC, when compared with inactive control (no intervention, waitlist or usual care). In many cases the true size of the effect was uncertain (19 outcomes) or unknown (23 outcomes). Many of the effect estimates were based on results from fewer than 3 RCTs (typically 50 to 200 total participants) which can impact the precision of the results by either under- or overestimating the effect.

ⁿ small benefit (5 outcomes); moderate benefit (11 outcomes); large benefit (6 outcomes)

5.2 Overall completeness and applicability of evidence

This review aimed to identify the available RCT evidence on the effectiveness of yoga. Only studies that assessed yoga versus inactive control (no intervention, waitlist, usual care if considered inactive) were included in the synthesis. Studies of prioritised conditions with active comparators were not able to be included in the synthesis or summary of findings tables, as the wide range of comparators and outcomes did not allow for synthesis as planned in the protocol.

There were 373 studies that met the eligibility criteria for the review but were not included in the evidence evaluation. This is because they either examined the effects of yoga in populations (or conditions) not prioritised by NTWC for analysis or synthesis (250 studies°) or examined the effects of yoga in populations that were of lower priority (123 studies°). These studies are listed in an inventory titled *Citation details of studies from low and non-priority populations* (Appendix C3, Table C.3).

Databases in languages other than English were not searched. Studies published in a language other than English (identified through English databases) were not translated and were not included in the synthesis but are listed in an inventory for completeness (Appendix C4.2). There were 33 publications identified in a language other than English.

The available evidence was from a range of countries including Australia, Brazil, Canada, Germany, India, Iran, New Zealand, South Korea, Spain, Sweden, Turkey, the United Kingdom and the United States. Most studies examined yoga delivered in a manner that would be considered applicable to the Australian context, inclusive of poses, controlled breathing and meditation; but some yoga programs were specifically designed for the condition, and focused solely on laughter, breathing or meditative techniques. Participant ages generally ranged between 18 to 75 years, with some more focused on participants aged older than 50 years. Most studies evaluated group yoga classes that were 45 to 90 minutes in duration, with outcomes measured at the beginning and at the end of treatment. In some studies, the yoga was practised by the individual at home (after some initial instruction). Sessions varied from one to 5 sessions per week and programs typically lasted around 12 weeks (range 6 weeks to 6 months). No program continued for more than 6 months, but some studies followed participants for an additional 6 months with encouragement to maintain their practice at home. The treatment provider was specified in about 60% of studies and tended to be experienced yoga instructors trained or certified in a particular yoga style (e.g. hatha, vinyasa, lyengar).

The included studies provided a clear description of the condition, outcomes and interventions examined in the study. Among the 15 prioritised conditions for yoga versus inactive control (no intervention, waitlist or usual care), 23 (~26%) out of the 88 outcomes prioritised as critical or important, were not measured or reported in studies. There were very few studies with missing outcome information or information that was not translatable (such as that included in graphs). As per the protocol, we made no requests to authors for this information and did not attempt to translate information contained in graphs. It is considered unlikely this information would have impacted the overall conclusions of this review.

Studies included in this review are those published up until the end of July 2020. There was also a large amount of evidence for yoga not published at the time of the search (308 studies listed as ongoing [33 700+ participants) or not yet evaluated (216 studies awaiting classification [14 000+ participants]). Among the priority populations included in this review, an estimated 47 RCTs (2288 participants) comparing yoga with an inactive control are awaiting classification (6 RCTs in a language other than English) and a further 51 RCTs (7100+ target participants) were listed as ongoing. It is likely that many of these studies would meet the eligibility criteria for this review, the results of which may (or may not) have an impact on the overall results.

^{° 166} studies comparing yoga with control (no intervention, waitlist or usual care)

^p 82 studies comparing yoga with control (no intervention, waitlist or usual care)

5.3 Certainty of the evidence

The certainty of evidence across outcomes was generally downgraded for issues with imprecision (related to sample size and wide confidence intervals that were compatible with both important benefit and little or no difference) and suspected publication bias (relating to the likelihood that studies with negative outcome results were not published at the time of the search). In rare instances, the certainty of evidence was downgraded for inconsistency, when the effect estimates differed importantly across studies, as indicated by minimal or no overlap in the confidence intervals, and no clear explanation for statistical heterogeneity. We did not downgrade for indirectness, although in some cases noted that the studies may not be directly applicable to the Australian healthcare context, meaning the delivery of the intervention or the participants included within the trial may have unknown factors that do not directly match yoga as delivered in Australia or a broader population group.

The certainty of evidence was downgraded due to serious risk of bias when sensitivity analysis showed clear interaction between the effect estimates and the studies judged to be at high risk of bias. It is noted that many studies were at high risk of bias relating to missing outcome data or deviations from the intended intervention. Concerns of bias relating to the inability of studies to blind participants, and outcome assessors being aware of the intervention received, were considered reasonable and generally did not raise serious concerns when assessing the certainty of the evidence. For most studies we were unable to obtain and therefore assess published protocols or statistical analysis plans, and as per the protocol, did not attempt to contact study authors to obtain this information.

5.4 Potential biases in the review process

To ensure transparency in the review process, we published the final NTWC-endorsed research protocol on PROSPERO. In order to capture the majority of studies assessing the effectiveness of yoga, we comprehensively searched multiple databases and did not apply date, language, population or outcome restrictions in our search. In addition, we provided detailed documentation of the inclusion criteria to avoid inconsistent application of study selection criteria and used standardised procedures for data collection and critical appraisal. Where possible, we have applied a methodological approach consistent with the *Cochrane Handbook for Systematic Reviews of Interventions* and other best practice methods.

While we have attempted to control for potential biases, some deviations from the protocol were necessary for pragmatic reasons. To ensure these deviations from protocol are clear, deviations and post-hoc decisions have been documented and explained in **Appendix G**.

Data collection was performed by two researchers, the first collected data using data extraction forms and the second checked for completeness and accuracy in data extraction. Decisions regarding prioritisation of conditions and critical or important outcomes were made by the NTWC, with input from NTREAP, who were blinded to the number and details of the studies found.

We did not specifically search for or include studies published in languages other than English in the analysis, so it is possible that we may have missed studies that may (or may not) have impacted the overall conclusions of this review.

5.5 Agreements and disagreements with other studies or reviews

The results of this review are generally consistent with systematic reviews of yoga published up until January 2023 that assess comparable priority populations. There are several Cochrane reviews specific to yoga that are focused on people with asthma (427), chronic non-specific low back pain (428), primary prevention of cardiovascular disease (429), secondary prevention of coronary heart disease (430), epilepsy (431), stroke rehabilitation (432), schizophrenia (433-435), breast cancer (436), haematological malignancies (437) and treating urinary incontinence in women (438).

The Cochrane review exploring yoga in people with asthma (updated July 2015) included evidence from 15 RCTs (1048 participants) and found there was some evidence that yoga may improve quality of life, improve symptoms, and reduce medication usage but the effects of yoga on FEV₁ were not statistically significant (427). The authors noted that the MCID for asthma symptoms is uncertain due to the lack of an established MCID in the severity scores used in the included studies and that due to very significant heterogeneity evidence from 2 studies for asthma control were not pooled. No serious adverse events associated with yoga were reported, but the data on this outcome were limited. These results are in general agreement with that reported in this review, which found low certainty evidence that yoga results in a large improvement in health-related quality of life but provides little to no benefit in pulmonary function (FEV₁/FVC ratio). The evidence for asthma control and medication usage was considered very uncertain. This review included for the main comparison (compared yoga with an active intervention) or were not eligible (yoga was delivered in combination with other lifestyle modification programs). The results are also generally consistent with other reviews that have focused on breathing exercises in adults (439) or children (440) with asthma.

The Cochrane review that assessed yoga in people with chronic non-specific low back pain (updated August 2021) included evidence from 15^q trials that compared yoga to a non-exercise control (including waiting list, usual care, or education) (428). The authors reported moderate certainty evidence of a small improvement in physical and mental quality of life but a clinically unimportant improvement in pain. There was also evidence of low-certainty that yoga provides a small clinically unimportant improvement in backspecific function, little to no improvement in depression but increased the risk of adverse events (increased back pain). The results are slightly mixed compared to those reported in this review, which found moderate certainty evidence that yoga provides a slight improvement in overall health-related quality of life and low certainty evidence that yoga provides a slight reduction in pain intensity. This review also found low certainty evidence that yoga provides little to no benefit in physical or mental functioning. The reviews differ with respect to judgements regarding the clinical importance of the observed effects, which is generally related to different outcome measures being used (e.g. PROMIS included for physical functioning) or whether the clinical importance is based on an established MCID or based off Cohen's estimates for SMD (e.g. pain outcome). Back-specific function, depression or adverse events were not critical or important outcomes for this review. The results of this review are consistent with another non-Cochrane systematic review that reports short-term improvements in pain intensity, and mental and physical functioning (441).

The Cochrane review exploring yoga primary prevention of cardiovascular disease (updated December 2013) included evidence from 11 RCTs (800 participants) and found that yoga has favourable effects on diastolic blood pressure, high-density lipoprotein (HDL) cholesterol and triglycerides (a blood lipid), and uncertain effects on low-density lipoprotein (LDL) cholesterol (429). It was noted that none of the studies were large enough or of long enough duration to examine the effects of yoga on decreasing death or non-fatal endpoints. This review did not look at cholesterol or fatal outcomes, but reported evidence of moderate certainty that yoga provides a large (>5 mmHg) reduction in both systolic and diastolic blood pressure in people with hypertensive heart disease. This review also found low certainty evidence that yoga provides little to no benefit on perceived stress or health-related quality of life in this population. The results of the current review are consistent with another non-Cochrane systematic review that reports yoga significantly reduces blood pressure in people with prehypertension (442).

Numerous other systematic reviews published up until January 2023 were found that focused on the effect of yoga in some of the conditions included in this review including depression (443), chronic pain conditions including fibromyalgia (444, 445), insomnia (446) and migraine (447). However, for other priority populations no reviews were found (anxiety, stress) or the reviews included yoga among other exercise or mindfulness therapies (PTSD (448) and neck pain (449)). Like this review, these systematic reviews suggest that yoga may be an effective intervention to achieve a desired outcome such as depression in people with bipolar disorder (443) or decreasing headache frequency in people with migraine (447); but yoga may have no effects in reducing insomnia (446) or improving quality of life in people with chronic pain conditions (445).

^q Including 5 trials that included a third intervention group (another form of exercise).

As concluded in this review, whilst there is promising evidence for yoga to improve outcomes in a variety of health conditions, there is an absence of high certainty evidence, with the limited number of studies, small sample size and heterogeneous outcomes making it difficult to definitively conclude the effectiveness of yoga as an exercise intervention.

5.6 Limitations

5.6.1 At study and outcome level

The main limitation at the study and outcome level is the low number of trials and small sample sizes per comparison, which reduced the statistical precision of the effect estimate and prevented any subgroup analyses. Among the 64 outcomes with available evidence, 41 included evidence from 1 or 2 RCTs (sample size range 24 to 188 participants), 14 included evidence from 3 or 4 RCTs (sample size range 118 to 642 participants), and only 9 included evidence from 5 or more RCTs (total sample size range 283 to 1230 participants). An additional limitation is that it was not possible to statistically assess publication bias using funnel plots for all conditions, as there were fewer than 10 studies included across 60 of the 64 outcomes with available evidence.

5.6.2 At review level

This review was limited to the assessment of the evidence for certain conditions and groups of people to inform the Australian Government about health policy decisions for private health insurance rebates. This review was not designed to assess all the reasons that people practise yoga, or the reasons practitioners prescribe yoga and was not intended to inform individual choices about practising yoga. Conditions were prioritised by NTWC, who were guided by relevant patient and/or practitioner reported Australian survey data (where available) and expert advice from NTREAP during the prioritisation process. Given the large number of studies identified across a diverse range of conditions and as agreed *a priori*, the evidence synthesis was limited to 15 priority conditions, combined under 11 groupings.

The main comparator of interest was yoga compared to inactive control (no intervention, waitlist or usual care, if inactive) with the outcomes assessed limited to those deemed critical or important by NTWC for each priority condition. Most conditions that had evidence available for 4 or more critical or important outcomes. However, it is challenging to conclude the effectiveness of yoga for the prioritised conditions as the evidence was of very low certainty in 20 out of 88 (23%) outcomes and the effectiveness of 23 of 88 outcomes (26%) remain unknown. In addition, approximately 100 RCTs were found in the priority conditions that were awaiting classification or remain ongoing at the time of the search. Results of these studies may (or may not) support the use of yoga.

The effectiveness of yoga compared with other forms of exercise or active comparators was not assessed, due to the wide variety of active comparators, outcomes and conditions identified. Data from these studies are listed in Appendix F2. It is unknown whether the results of these studies would impact the overall conclusions of this review.

It was out of scope of the review to assess safety. Consistent with the previous review (6), it was noted that evidence regarding safety was rarely measured in the primary studies. Information regarding the sustainability of the effect is also unknown, as the review did not assess any follow-up data.

The breadth and diversity of conditions identified for inclusion in this review means that it is possible that some conditions, outcome domains and outcome measures have been misclassified or missed during the outcome prioritisation process.

A final limitation is that the literature search for primary studies was last conducted in at the end of July 2020, it is possible that given the identification of a number of studies awaiting classification and ongoing studies, there may be additional evidence that may (or may not) impact the overall conclusions of this review. However, systematic reviews were searched up to 2023 and compared to the current results.

6 Authors' conclusions

6.1 Implications for health policy

This report was commissioned by the Australian Government as part of the Natural Therapies Review, with findings intended to inform decisions relating to whether private health insurance cover should be reinstated to yoga. As such, specific recommendations are not provided.

Whilst there is promising evidence for yoga to improve outcomes in a variety of common health conditions, there remains an absence of high certainty evidence examining the effectiveness of yoga compared with no intervention, waitlist or inactive control for the 15 priority conditions or outcomes that align with the reasons why consumers commonly practise yoga in Australia.

There are 5 conditions for which the evidence provides moderate certainty of benefit for one outcome (anxiety, depression, hypertension, chronic pain conditions, low back pain) and 6 conditions for which the evidence provides low certainty of benefit for 1 (anxiety, asthma), 2 (low back pain, fibromyalgia) or 3 (headache disorders, neck pain, stress) or 4 (depression) outcomes. In contrast, there were 7 conditions where the evidence provides low certainty that yoga provides little to no benefit for one (asthma), 2 (depression, low back pain, hypertension), 3 (chronic pain conditions, stress) or 5 (fibromyalgia) outcomes.

The effect of yoga remains uncertain or is unknown in 42 outcomes across the 15 conditions.

6.2 Implications for research

Trials evaluating the effectiveness of yoga compared with no intervention or inactive control are in abundance, with reporting of the methods used and the analysis of results from all randomised participants generally well defined. However, the available evidence could be enhanced by larger sample sizes and improved reporting of results from all registered studies as well as measuring and reporting outcomes that are considered critical or important for decision-making. Many of the studies focused on the effect of yoga in participants who received treatment for 12 weeks or less, so it is possible the benefits of yoga may be more apparent in people who continue the practise for more than 12 weeks.

There were 308 studies (33 700+ total target participants) identified in our search that were listed as ongoing, with 224 studies (24 000+ target participants) having an inactive control or placebo listed as a comparator group. Of these ongoing studies not yet published, 32 were in conditions included in synthesis in this review and were listed as complete or unknown (i.e. might be complete) suggesting that they might have provided data. The lack of publication of these results may indicate they did not show a positive effect of yoga over control (potential publication bias). Evidence reported in ongoing studies are expected to contribute to future updates where studies are completed, and results published.

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