SHIATSU FOR PREVENTING AND TREATING HEALTH CONDITIONS

EVIDENCE EVALUATION REPORT

prepared by
HTANALYSTS

for
National Health and Medical Research Council

NHMRC | Natural Therapies Working Committee
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Dates

This evidence evaluation report and accompanying technical reports received approval from the National Health and Medical Research Council (NHMRC) Natural Therapies Working Committee (NTWC) on 20 May 2024.

The protocol for the evidence evaluation received approval from the NHMRC NTWC on 11 March 2021 (PROSPERO: CRD42021243311).

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, **HT**ANALYSTS were engaged to conduct a systematic review of the evidence of clinical effectiveness of shiatsu. Eligible studies received from the Department's public call for evidence, the Department's Natural Therapies Review Expert Advisory Panel (NTREAP) and 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 shiatsu 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).

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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-working-committee

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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
PAHO	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 shiatsu is effective in preventing and/or treating certain injuries, diseases, medical conditions or pre-clinical conditions relevant to the Australian population. Shiatsu is a complex, whole-system intervention that draws on theories and philosophies of traditional Chinese medicine to identify body imbalances and promote self-healing. Treatment typically includes shiatsu massage, where practitioners apply body weight or physical pressure to acupressure points or meridians, using gentle stretching or muscle release techniques to restore balance and improve wellbeing.

This review was targeted for the Australian Government Department of Health and Aged Care ("the Department") to assist in their Natural Therapies Review, which is designed to determine whether certain natural therapies, including shiatsu, 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 shiatsu, nor is it intended to inform decisions about whether an individual or practitioner should use shiatsu.

Key messages

For the populations (or conditions) assessed, there is moderate to low certainty evidence that shiatsu may provide some benefit for people with some of the included conditions and outcomes, when compared with people who do not receive shiatsu. The results of this review are consistent with other systematic reviews of shiatsu that assess comparable conditions assessed in this review.

What was studied in this review?

This review identified studies using a planned literature search, with no limit on publication date. Included studies needed to compare the results of people who received shiatsu to a group of people who did not. Assessments 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 shiatsu with a sham intervention were eligible for inclusion, but there were no studies found. Studies that compared shiatsu 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 this review?

Using a planned approach, 2154 citations from 11 databases were collected and examined in the review for shiatsu, including 57 studies submitted by the public via the Department's public call for evidence. Out of 2154 citations screened, 27 studies covering 16 conditions were assessed in the evidence evaluation and are included in the results. A further 42 studies were awaiting classification (39 of these were not in English) and 14 studies had been registered but were not completed at the time the search was conducted for this review.

Shiatsu reported in eligible studies was consistent with how shiatsu is practised in Australia. Most studies evaluated shiatsu, acupoint or meridian massage using pressure applied to specified trigger points. The application of pressure varied from 20 seconds to between 3 and 5 minutes (or not specified), with treatment sessions being between 15 and 60 minutes in duration, performed up to 3 times per week. Outcomes were typically measured at the beginning and end of treatment, which varied from between 10 days and 10 months. No studies continued for more than 10-months. The treatment provider was often an experienced therapist or nurse trained in shiatsu massage.

As a component of shiatsu, acupressure was examined in a supplementary systematic review of systematic reviews. For the 17 conditions found for shiatsu, a total of 66 systematic reviews were assessed. Acupressure studies often evaluated acupressure that was self-administered or delivered through the use of acupressure bands.

What were the main results of the review?

The evidence provides moderate to very low certainty that receiving shiatsu probably is, or may be more, effective than not receiving shiatsu for some of the conditions assessed in this review. However, the evidence also provides low certainty that shiatsu may have little (or no) benefit for some of the conditions assessed in this review. There are some conditions assessed in this review where the effect of shiatsu is unknown.

The evidence provides moderate certainty that shiatsu probably:

- improves bowel recovery (1 RCT, 160 participants) in people recovering after minimally invasive surgery.

The evidence provides low certainty that shiatsu may:

- improve quality of life (1 RCT, 101 participants) in people with functional constipation
- reduce overall symptom severity in people with dysmenorrhoea (1 RCT, 82 participants)
- reduce waist circumference (1 RCT, 54 participants) and improve systolic and diastolic blood pressure (1 RCT, 42 participants) in people with obesity
- improve quality of life (1 RCT, 63 participants) and reduce symptoms of stress (1 RCT, 63 participants) in people with stress
- reduce disability in people rehabilitating after stroke (1 RCT, 40 participants)
- improve cognitive function (1 RCT, 68 participants) in people with hypertension
- improve post-operative nausea and vomiting (1 RCT, 98 participants), post-operative pain (2 RCTs, 190 participants), and post-operative respiratory function (1 RCT, 98 participants) in people recovering after minimally invasive surgery.

The evidence provides low certainty that shiatsu has little (to no) effect on:

- pain, disability or improved quality of life (1 RCT, 59 participants) in people with chronic musculoskeletal pain
- pain intensity (1 RCT, 82 participants) in people with dysmenorrhoea
- labour duration (1 RCT, 288 participants) in pregnant females.

The effect of receiving shiatsu on diabetes and postpartum care is unknown as no studies were found with outcomes selected as critical or important.

For the supplementary assessment of the acupressure component, the results in acupressure were either inconsistent with the effect reported for shiatsu or the certainty of evidence was very low or unknown for either shiatsu or acupressure, such that a clear judgement about consistency of the effect could not be made.

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 receive shiatsu, or the reasons practitioners prescribe shiatsu and is not intended to inform individual choices about receiving shiatsu. This review listed, but did not assess shiatsu versus other interventions, so no comment can be made on whether shiatsu is better or worse than other interventions. Studies published in a language other than English were listed but were not included in the assessment. It is not known if including these studies would have affected the overall results, but it is possible that the inclusion of these studies could have modified the certainty of evidence across some outcomes.

The results of this review indicate that shiatsu may improve some conditions and outcomes and not others. However, these conclusions are sometimes based on a small number of studies with limited numbers of participants, with results across studies often imprecise and inconsistent and outcomes that are relevant to patients often not reported. Many of the studies focused on the effect of shiatsu at the end of treatment, which ranged from one session to up to 10 months, so we do not know if there are benefits of shiatsu that occur in people who continue the practice for more than 10 months. It is unknown whether the effects of shiatsu are sustained after people stop receiving shiatsu.

Future research could be improved by undertaking more studies of shiatsu versus control (or inactive comparator) for conditions considered relevant to the Australian context; including more participants; and including outcomes that are considered critical or important for decision-making.

How up to date is this review?

Searches were conducted from the earliest date included in the databases until 21 April 2021. Studies published after this date are not included in this review.

A search for recent systematic reviews was conducted up to June 2023 and results of this review were compared (where applicable) for completeness.

Executive summary

Background

Shiatsu is a complex, whole-system intervention that draws on theories and philosophies of traditional Chinese medicine. Shiatsu involves applying pressure to the body; and may also include the use of flowing stretches and gentle rotations of the limbs and joints, simple structural alignments and muscle release techniques. The word 'shiatsu' originates from the Japanese word meaning 'finger pressure', through which the therapist applies pressure to the acupuncture (tsubo) points on the body. Acupressure is often considered a component of shiatsu therapy, although may also be considered a therapy in its own right. Evidence for acupressure was therefore included in a supplementary report, for conditions where studies of shiatsu were found. Most individualised acupressure is administered by the therapist, however, there may be instances when the therapist provides instructions for self-administration or administration by a lay caregiver.

In 2015, an overview of systematic reviews commissioned by the Australian Government found no clear evidence demonstrating the effectiveness of shiatsu in treating any clinical condition. This systematic review includes a broader range of study types, such as studies assessing the effectiveness of shiatsu delivered for primary prevention in individuals at-risk of developing an injury, disease, or medical condition.

Objectives

The objective of this review was to evaluate the effectiveness of shiatsu in individuals with a described injury, disease, medical condition, or preclinical condition, including primary prevention in at-risk individuals, on outcomes that align with the reasons why people commonly receive shiatsu in Australia. As acupressure is a component of shiatsu, evidence of the effectiveness of acupressure was used to augment the evidence for conditions found in the review of shiatsu. This information will be used by the Australian Government in deciding whether to reinclude shiatsu as eligible for private health insurance rebates, after shiatsu was excluded in 2019. This review was not designed to assess all the reasons that people seek shiatsu, or the reasons practitioners prescribe shiatsu and is not intended to inform individual choices about receiving shiatsu.

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 21 April 2021. Reference lists of key relevant articles were checked to identify any additional studies not identified through searches of the primary databases. The public was also invited by the Department to submit references for published research evidence. There were no limits on language of publication or date of publication in the search.

Selection criteria

Population prioritisation was not needed for shiatsu because few populations were found. For populations where studies were found for shiatsu, acupressure was examined as a component of shiatsu.

Randomised controlled trials (RCTs) and non-randomised studies that examined shiatsu compared to sham, control (or another intervention, where applicable) were eligible, including quasi-randomised studies, cluster-randomised and crossover trials. For populations identified in the shiatsu review, systematic reviews that examined acupressure compared to sham, control (or another intervention, where applicable) were examined, noting only evidence from RCTs (or quasi-RCTs) were included. Studies that examined shiatsu (or acupressure) delivered as an adjunct to another therapy were also eligible for inclusion provided that both groups received the other therapy.

Any intervention named as shiatsu that was delivered by a practitioner, or shiatsu that was self-practised was eligible for inclusion. There were no limits on intensity, duration of practice or mode of delivery.

The search included studies of people of any age with any injury, disease, medical condition or preclinical condition. Studies examining shiatsu 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 2 main comparators of interest for this review were shiatsu versus sham and shiatsu versus 'inactive' control (including no intervention, waitlist, or usual care, if considered inactive). Another comparator of interest included shiatsu versus another 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

After initial searching and screening, and to determine what data to extract from studies, a blinded outcome prioritisation process was undertaken by NTWC. The process included all prespecified outcome domains and measures in each eligible RCT, supplemented with outcome domains or measures derived from core outcome sets (where available) or recent Cochrane reviews for that condition. As part of the process, NTWC was asked to specify up to 7 'critical' or 'important' outcomes 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, NTWC applied 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.

Data collection was performed by 2 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 most appropriate risk of bias assessment tool recommended by the Cochrane Collaboration (according to study type).

In the data analysis and synthesis for each population, the overall certainty of evidence for a maximum of 7 critical or important outcomes were reported in GRADE summary of findings tables, with corresponding evidence statements assigned to each outcome. 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 a threshold 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

There were 27 studies of shiatsu identified as eligible for inclusion in the review. Of these, all 27 studies covering 16 conditions were considered in the evidence evaluation and are included in the results. There were no studies found comparing shiatsu with a sham intervention. For the synthesis, there were 22 studies (14 RCTs, 6 quasi RCTs, 2 NRSI) covering 14 conditions that compared shiatsu with an inactive control (no intervention, waitlist or usual care). Results for 11 studies 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 42 studies were awaiting classification and an additional 14 studies were recorded as ongoing (registered but not published). Of the studies awaiting classification, 39 were published in languages other than English and 3 were conference abstracts or posters. Of the ongoing studies, 2 studies were listed as not yet recruiting participants, 3 studies were listed as recruiting participants, and 5 studies were listed as having completed recruitment, but the study data were not yet collected (at the time of the search). The status of 4 studies was listed as unknown. An additional 7 studies were unable to be translated or interpreted at the title/abstract stage.

For each population, the evidence synthesis typically comprised one or 2 studies and was limited to a small number of outcomes. 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. The results for two conditions (diabetes and postpartum care) could not be determined, as no studies were found with outcomes that were considered critical or important for this review.

All included studies examined shiatsu delivered in a manner that was considered applicable to the Australian context based on the description. Most studies evaluated shiatsu, acupoint or meridian massage using pressure applied to specified trigger points. The application of pressure varied from 20 seconds to between 3 and 5 minutes (or not specified), with treatment sessions being between 15 and 60 minutes in duration, performed up to 3 times per week. Outcomes were typically measured at the beginning and end of treatment, which varied from between 10 days and 10 months. No studies provided any longer-term data (more than 10-months). The treatment provider was often an experienced therapist or nurse trained in the shiatsu massage.

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 identified 16 conditions for which there was evidence about the effect of shiatsu on an outcome considered critical or important by NTWC.

Compared with a sham intervention, the effect of shiatsu is unknown.

Compared with an inactive control (no intervention, waitlist or usual care), the evidence provides:

- moderate certainty that shiatsu probably results in:
  - improved bowel recovery (1 RCT, 160 participants) in people recovering after minimally invasive surgery.
- low certainty that shiatsu may result in:
  - a large improvement in quality of life (1 RCT, 101 participants) in people with functional constipation
  - a large reduction in overall symptom severity in people with dysmenorrhoea (1 RCT, 82 participants)
  - a reduction in waist circumference (1 RCT, 54 participants) in people with obesity
  - an improvement in quality of life (1 RCT, 63 participants) and a reduction in symptoms of stress (1 RCT, 63 participants) in people with stress
  - a reduction in disability in people rehabilitating after stroke (1 RCT, 40 participants)
  - an improvement in post-operative nausea and vomiting (1 RCT, 98 participants) and an improvement in post-operative pain (2 RCTs, 190 participants) in people recovering after minimally invasive surgery
  - a slight improvement in cognitive function (1 RCT, 68 participants) in people with hypertension
  - a slight improvement in systolic and diastolic blood pressure (1 RCT, 42 participants) in people with obesity

  - a slight improvement in post-operative respiratory function (1 RCT, 98 participants) in people recovering after minimally invasive surgery.

- low certainty that shiatsu provides little (to no) change in:
  - pain, disability or improvement in quality of life (1 RCT, 59 participants) in people with chronic musculoskeletal pain
  - pain intensity (1 RCT, 82 participants) in people with dysmenorrhoea
  - labour duration (1 RCT, 288 participants) in pregnant females.

Compared with an inactive control, the evidence provides very low certainty of the effect of shiatsu for 21 out of the 100 critical or important outcomes prioritised for analysis in this review. Of the 100 outcomes prioritised as critical or important in this review, 60 were not addressed by any studies, and therefore the effect of shiatsu on these 60 outcomes compared with an inactive control is unknown.

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

For the supplementary systematic review of systematic reviews of the acupressure component, 66 systematic reviews were identified as eligible for inclusion (i.e. covering conditions that were also identified in the systematic review for the effectiveness of shiatsu). Within these, 90 RCTs covering 9 conditions were considered in the evidence evaluation and are included in the results. For the synthesis, there were 49 RCTs covering 8 conditions that compared acupressure with a sham intervention and 41 RCTs covering 7 conditions that compared acupressure with an inactive control (no intervention, waitlist or usual care).

We are unable to comment about the consistency of results reported in studies of acupressure or the role it plays when used as part of the overall practice of shiatsu. Compared with an inactive control (no intervention) the results for acupressure were either inconsistent with the effect reported for shiatsu or the certainty of evidence was very low or unknown for either shiatsu or acupressure such that a clear judgement about consistency of the effect could not be made.

Limitations

This review is limited to analysis of conditions identified in the literature for shiatsu, therefore this report may not cover all the reasons people receive shiatsu. The outcomes assessed in this review were limited to those deemed critical or important by NTWC for each condition. Most conditions had evidence for one to 3 of the critical or important outcomes, with 2 conditions having no available evidence for critical or important outcomes comparing shiatsu with an inactive control.

Given the limited number of studies spread across a diverse range of conditions, it is challenging to conclude the effectiveness of shiatsu across these conditions. While not formally excluded from the review, studies in languages other than English do not contribute to the results or synthesis. Including these studies would not likely have affected the overall results but it is possible that the inclusion of these studies could have modified the certainty of evidence across some outcomes. Supplementing the evidence with studies in acupressure expanded the evidence to cover additional outcomes, particularly when compared with a sham intervention, but correlation across conditions and outcomes was limited. An assessment of the effectiveness of shiatsu compared with other active comparators was not conducted. Given the limited number of studies found for shiatsu (14), it is unlikely the results of these studies would impact the overall conclusions of this review.

Conclusions

The evidence provides moderate to low certainty that receiving shiatsu is more effective than not receiving shiatsu for a small number of conditions and outcomes assessed in this review. There are a few conditions where the evidence also provides low certainty that shiatsu has little (to no) benefit. For many of the identified conditions and outcomes assessed in this review, the effect of shiatsu is unknown. Attempts to supplement the evidence for conditions found in the review of shiatsu with evidence in acupressure were inconclusive.

The results of this review are generally consistent with systematic reviews of shiatsu published up until June 2023, which conclude that there is an absence of high certainty evidence that receiving shiatsu is more effective than not receiving shiatsu. More research is needed to reach a definitive conclusion on the effectiveness of shiatsu for preventing and treating health conditions.

1 Background

In 2015, an Australian Government review of shiatsu found no clear evidence demonstrating its efficacy in treating any clinical condition (1). The 2015 review was underpinned by an overview of systematic reviews (SRs) that focused solely on shiatsu and were published in the English language between 2008 and June 2014. Randomised controlled trials (RCTs) that were reported within included SRs and assessed shiatsu delivered to treat any clinical condition were eligible; however, no evidence was found (6, 7). SRs that assessed acupressure as a sole intervention were not eligible for inclusion. In this 2020 review, the search was not limited by publication date and a broader range of study types were eligible for inclusion (inclusive of nonrandomised studies of interventions [NRSIs]). This review also includes studies that assess shiatsu for primary prevention. Evidence from eligible primary studies of shiatsu is also supplemented with evidence identified from systematic reviews of acupressure, a core component of shiatsu, for conditions where studies of shiatsu was found. Similar to the 2015 review, eligible comparisons are shiatsu versus control (further delineated to shiatsu versus sham and shiatsu versus no intervention) and shiatsu versus other interventions. Studies not published in the English language were not translated, and databases in languages other than English were not searched.

1.1 Description of the condition

Shiatsu therapy is used by people of all ages for a wide of range of reasons (8). A 2016 workforce survey of 121 shiatsu therapists working in Australia found the most common reasons for providing shiatsu therapy were to alleviate or treat a broad range of clinical and preclinical conditions such as stress, mental health, pain and musculoskeletal problems, as well as rehabilitation and management of chronic health conditions including cancer and disability care (8). Other conditions that practitioners report using shiatsu therapy for include headaches, migraine, sciatica, respiratory illnesses, fatigue, menstrual problems, circulatory problems, and rheumatic and arthritic complaints (9).

The current review is not limited to any condition or setting. Given the breadth of the review and variety of potential conditions for which shiatsu is used, a concise description of each condition or problem and the relevant setting is provided before each result. An overview of the conditions identified is provided in Table 2.

1.2 Description of intervention

Shiatsu therapy is a complex, whole-system intervention that is based on the philosophy and theory of traditional Chinese medicine (10). Popularised in the West following the legislation in Japan of “Anma-Shiatsu-Massage” in the mid-20th Century, the word ‘shiatsu’ originates from the Japanese word meaning ‘finger pressure’, through which the therapist applies pressure to the acupuncture (tsubo) points on the body. This pressure is believed to assist with alleviating a variety of symptoms associated with health conditions (11).

Under standard terminologies published by the World Health Organisation (WHO) (12), ‘Traditional Chinese Tuina’ is the term used when referring to massage therapy that has its foundations in traditional Chinese medicine, including shiatsu. The term shiatsu, however, is also listed as an alternate word for acupressure, demonstrating that the two terms may be used interchangeably within the literature. Where Tuina uses a broad combination of techniques (including rubbing, effleurage etc.), shiatsu (and acupressure) focuses on applying pressure to the meridian points. Terminology is also specified for a number of components of practice used by shiatsu practitioners in Australia (see Table 1).

Table 1 Common components of practice used in shiatsu therapy

Component of practice taught and used by certified Australian shiatsu therapists (HLT52215)[a]	Corresponding WHO traditional medicine terminology (TRM)[b]	WHO TRM Codes
Shiatsu massage	**Traditional Chinese Tuina:** the branch of traditional Chinese medicine concerned with the principles and clinical use of Tuina (massage) therapy	0.0.18
Shiatsu massage techniques	**Massage:** rubbing, kneading, or percussion of the soft tissues and joints of the body with the hands, usually performed by one person on another, esp. to relieve tension or pain	4.2.326
	Manipulation: the term used when describing a wide range of manual therapy techniques (see manual for details)	4.2.327 – 4.2.344
	Tapping technique: a manipulation performed by tapping with the tips of fingers held together	4.2.346
Acupressure	**Finger Pressure:** a manipulation performed by pressing acupuncture points with the finger or thumb instead of needling, also known as shiatsu	4.2.347
Moxibustion	**Moxibustion:** a therapeutic procedure involving ignited material (usually moxa) to apply heat to certain points or areas of the body surface	5.2.0 – 5.2.39
Cupping	**Cupping:** suction by using a vacuumised cup or jar	5.3.0 – 5.3.11

Source:
a. https://training.gov.au/Training/Details/HLT52215 (see Core units HLTSHU001, HLTSHU002, HLTSHU003, HLTSHU004, HLTSHU005, HLTSHU006, HLTSHU007, HLTSHU008, HLTSHU009)
b. World Health Organization international standard terminologies on traditional medicine in the Western Pacific Region (12)

In Australia, shiatsu therapists work in a range of settings: solo or group shiatsu clinics, multidisciplinary health clinics, at their home or in a mobile practice that allows for home or office visits (8). Shiatsu treatment is traditionally performed on a futon on the floor with the recipient fully clothed or covered by a sheet in a sitting or lying position (13).

Shiatsu therapists working in Australia may have differing qualifications (including some that also receive training in acupuncture and other oriental therapies) and be registered as a shiatsu therapist and/or oriental massage therapist with one or more of the Australian natural therapy associations (8). The Shiatsu Therapy Association of Australia (STAA), a national peak body representing shiatsu therapists, requires practitioners to hold a Diploma in Shiatsu and Oriental Therapies HLT52215 (or equivalent), to undertake a minimum of 20 hours continuing professional education annually and hold a current first aid certificate (14). The same (HLT52215) course may also be recognised by other associations as qualifying for Oriental (TCM) Remedial Massage Therapy. The HLT52215 curriculum covers a range of shiatsu and traditional oriental/Chinese medicine modalities. While the curriculum focuses on the application of acupressure and massage, students are also trained in traditional Chinese medicine diagnosis and the application of moxibustion, cupping, self-acupressure, oriental diet, corrective exercises, lifestyle, relaxation, breathing techniques and meditation (8).

Shiatsu draws on traditional Chinese philosophies and theories such as Yin and Yang, the energy meridians, the 5 elements and the concept of Ki. The therapist aims to identify and correct imbalances in the flow of Ki or energy in a recipients meridians to promote self-healing (13, 15). A shiatsu session typically begins with a clinical history followed by an examination to formulate a traditional Chinese medicine diagnosis that is used to individualise the therapy (13, 15, 16). Examination methods include palpation (ampuku) of the hara (abdomen) or back, pulse, tongue and face diagnosis to assess the relative constitutional and energetic qualities of the internal organs and their related meridians (13).

Shiatsu massage is a derivative of traditional Japanese (Anma or Amna) massage that has its origins in traditional Chinese (Tuina) massage.

There are various styles of shiatsu practised in Australia which include: barefoot (macrobiotic) shiatsu, healing shiatsu, Jin Shin Do, Namikoshi (or Nippon shiatsu), ohashiatsu, quantum shiatsu, Tao shiatsu, tsubo therapy, Zen shiatsu, and watsu (water shiatsu). Like Anma and Tuina massage, shiatsu massage employs a wide range of traditional techniques. Some are vigorous (e.g. kneading, rubbing, tapping and shaking) while other techniques involve slow and firm or quick and gentle movements (e.g. pressure, stroking, stretches, rotations of the limbs and joints, simple structural alignments and muscle release techniques) (10, 13). All styles, however, have commonality in their underpinning traditional Chinese medicine and the use of body weight and physical pressure in one way or another when delivering a shiatsu massage (17).

Acupressure is the application of pressure on the traditional Chinese medicine acupuncture (tsubo) points (11, 18). It may be applied to specific points by the use of finger, hand, elbow, foot, and/or acupressure band or bead (11). Like shiatsu, acupressure has its roots in traditional Chinese medicine. However, acupressure is only one component of shiatsu therapy. Some authors note that while similar, there are differences in both the technique and philosophy of shiatsu and acupressure (11, 16, 18). While others, including the WHO International Standard Terminologies for Traditional Medicine in the Western Pacific Region (12), use the terms interchangeably (8, 18, 19).

For the purpose of this review, individualised acupressure refers to the selection of one or more acupressure (tsubo) points tailored to the individual recipient that is informed by a traditional Chinese medicine diagnosis. It may be delivered in the context of a shiatsu treatment (or alongside other traditional Chinese medicine treatment). Most individualised acupressure is administered by the therapist, however, there may be instances when the therapist provides instructions for self-administration or administration by a lay caregiver.

Standardised (non-individualised) acupressure refers to one or more predetermined acupressure points for a specific condition, symptom or symptom cluster. While informed by the principles of traditional Chinese medicine, a traditional diagnosis of the recipient is not required for administration. The acupressure intervention may be administered by a qualified therapist, lay caregiver or self. Most self-administered acupressure is non-individualised, examples include the use of an acupressure band or large bead as a replacement for finger pressure. However, there may be some instances when a therapist uses this type of acupressure or provides instructions to their patient or lay caregiver for self-administration.

1.3 How the intervention might work

The exact mechanisms for how shiatsu might work for different conditions has not been elucidated. However, some of the massage techniques included in shiatsu are similar to massage more generally. Consequently, shiatsu massage techniques may affect the body through similar mechanisms. The physical and psychological effects of massage more generally are thought to be explained (in part) by relaxation of the nervous system and musculature and through the release of neurotransmitters and hormones (20-22). Like all human interaction, touch is believed to induce an immediate calming effect, mediated by production of the hormone oxytocin (23, 24). Physiologically, massage may increase oxygenation to the muscles through inducing local biochemical changes that help blood and lymph flow, as well as affecting mood and pain perception through a subsequent effect on neural activity (21, 25-27). One study suggests that by supporting individuals to take control of their self-care, shiatsu practitioners encourage patients to make lifestyle changes (e.g. relaxing more, working less) which could impact their health (28).

A limited number of exploratory studies of shiatsu applied to various anatomic regions on healthy adults have observed mixed results on autonomic nervous system functions including changes in heart rate, blood pressure and pupil diameter (21). In shiatsu, the role of connective tissue in delivering energy and information to the whole body is thought to be integral to correcting imbalances in the flow or energy of a recipients Ki (9). Here, the mechanical effect of stretching and applied pressure is believed to encourage hydration and flexibility of connective tissue that has become congested or brittle through inadequate circulation or after injury. Due to continuity and electromagnetic signalling properties between cells, the connective tissue is suggested to distribute and enhance communication throughout the body to promote self-healing (9). Shiatsu practitioners work directly with the energy flow along the meridian because bioelectric flow is believed to happen more readily along meridian lines due to differing electrical resistance (9).

The practice of acupressure is thought to produce benefits for conditions closely associated with the nervous system, based on the similar principles of acupuncture (29-31). Stimulation (or pressure) applied to points connected to or located near neural structures is thought to transmit information along pathways in the nervous system, inducing various changes including pain perception, and hormonal and neurochemical changes (29-31).

1.4 Why it is important to do this review

In Australia, complementary therapies, including shiatsu, are most often used in conjunction with conventional medicine and other strategies for maintaining good health and wellness. For this reason, it is important to synthesise the evidence for the effectiveness of shiatsu, to enable consumers, health care providers and policy makers to make informed decisions about care.

The 2015 Overview identified 4 systematic reviews that included 2 RCTs; however, the effect of shiatsu could not be independently evaluated from either RCT, as shiatsu was combined with other interventions in both studies. There was no independent evidence to suggest that shiatsu may have some health benefits compared with control or active comparators. Therefore, the overall efficacy, safety, quality or cost-effectiveness of shiatsu was not able to be assessed (6).

The rationale for conducting this review is to update and enhance the evidence used to inform the 2015 Overview of shiatsu (6). That is, to identify studies published since, or not included in, the 2015 review, and address the evidence gaps noted. This is to ensure recommendations relating to the use of shiatsu remain relevant and up to date.

2 Objectives

To conduct a systematic review of RCTs and NRSIs to evaluate the effectiveness of shiatsu in individuals with a described injury, disease, medical condition or preclinical condition, including disease prevention in at-risk individuals. The review was supplemented with evidence for acupressure – a core component of shiatsu – identified in SRs (of RCTs and quasi-RCTs) for conditions where studies for shiatsu were found.

The questions for the review were as follows:

1. What is the effectiveness of shiatsu compared to sham on outcomes considered critical or important among individuals with any condition, pre-condition, injury or risk factor?
2. What is the effectiveness of shiatsu compared to an inactive control (no intervention, waitlist or usual care [if considered inactive]) on outcomes considered critical or important among individuals with any condition, pre-condition, injury or risk factor?
3. What evidence exists examining the effectiveness of shiatsu compared to active comparators (including usual care [or other] if considered active) on outcomes considered critical or important among individuals with any condition, pre-condition, injury or risk factor?

The intent is to evaluate the evidence representative of the populations (or conditions) commonly seen by shiatsu therapists in Australia, the intervention(s) commonly used by the therapist, and outcomes that align with the reasons why patients use shiatsu and/or practitioners prescribe shiatsu. For this reason, studies of preterm infants were excluded.

Table 2 lists the conditions identified and considered in this review and specifies whether studies were identified that assessed shiatsu versus the main comparators of interest (sham or inactive control).

Included populations (no hierarchy) are listed below:

- Gynaecological cancer (survivors)
- Diabetes
- Obesity
- Neurocognitive decline (Alzheimer's disease)
- Symptoms of stress
- Insomnia or sleep problems
- Headache disorders
- Rehabilitation after stroke
- Hypertensive heart disease
- Constipation
- Chronic musculoskeletal pain (fibromyalgia, low back, neck and shoulder pain)
- Dysmenorrhoea
- Pregnancy and childbirth
- Postpartum care
- Burn injury
- Recovery after minimally invasive surgery

3 Methods

Methods used to conduct the evidence evaluation were based on that described in the *Cochrane Handbook for Systematic Reviews of Interventions* (32) and relevant sections in the Joanna Briggs Institute Reviewer's manual (33). Covidence (www.covidence.org), a web-based platform for producing SRs, was used for screening citations and recording decisions made. EndNote and Microsoft Excel were used for managing citations and data extraction, respectively. Where appropriate, RevMan 5.4 (34) 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). Up to 7 critical or important outcomes were prioritised to inform the data synthesis for the systematic review on the effects of shiatsu for preventing and treating health conditions. Throughout the 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). 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 that compared shiatsu (or acupressure) to either sham (comparison 1) or inactive control (comparison 2) and which reported on outcomes rated as critical or important by NTWC. Summary of Findings tables included up to 7 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: CRD42021243311).

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 A1 search methods
- Appendix A2 search strategy
- Appendix A3 search results
- Appendix A4 eligibility criteria (types of studies, types of participants, types of interventions, types of outcome measures)
- Appendix A5 selection of studies (inclusion decisions)
- Appendix A6 population and outcome prioritisation process
- Appendix A7 summary screening results
- Appendix B1 risk of bias process
- Appendix B2 data extraction processes
- Appendix B3 data analysis and synthesis
- Appendix B4 summary of findings and certainty of evidence and the development of evidence statements

4 Results

4.1 Description of studies

As acupressure is only included to augment the results of shiatsu, information relating to acupressure studies is presented in the supplementary materials.

4.1.1 Flow of studies

The literature was searched on 21 April 2021 to identify relevant studies published from database inception to the literature search date. The results of the search and application of the study selection criteria are provided in Appendix A1 – A5 and Appendix C1 and C2.

A PRISMA flow diagram summarising the screening results is provided in Figure 1. The flow diagram shows the number of studies at each stage of 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 which met the eligibility criteria for inclusion in the review and the number of studies which were considered in the analysis for prioritised conditions.

The search retrieved 38 citations corresponding to 26 studies that were eligible for inclusion. One additional study (one citation) was identified and included from the Department's public call for evidence (see Included studies), giving a total of 27 studies (39 citations). A further 42 studies (42 citations) are awaiting classification and 14 studies were recorded as ongoing.

4.1.2 Excluded studies

There were 468 citations screened at full text that were excluded for not meeting the reviews eligibility criteria. Of these, 407 had an intervention out of scope (e.g. not shiatsu or unable to assess shiatsu independent of other interventions), 23 had a publication type out of scope (e.g. not an interventional study), 22 had a study design out of scope (i.e. systematic review or no comparator group), 8 were in a population out of scope (i.e. healthy population not at risk), 4 were duplicate reports of the same published data, and 3 had a comparator out of scope (i.e. studies comparing different shiatsu components).

Details of citations which were thought likely to be eligible but were not, are presented in Appendix C1.1. 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

Completed studies identified as potentially eligible for inclusion that could not be retrieved, translated or provided insufficient or inadequate data, are listed in the *Characteristics of studies awaiting classification* tables (see Appendix C3.1). This includes 3 conference proceedings with incomplete information about the study (Appendix C3.1.1) and 39 studies published in languages other than English (Appendix C3.1.2) that are possibly eligible for inclusion (pending translation into English).

The 42 studies awaiting classification appeared to be comparable to those included in the evidence synthesis in terms of conditions examined, sample size, study duration and outcomes measured. There were 29 studies involving more than 1900 participants that compared shiatsu with an inactive control (no intervention). The other 13 studies compared acupoint massage or shiatsu with an active comparator.

An additional 7 studies were unable to be translated or interpreted at the title/abstract stage (see Appendix C3.1.4).

4.1.4 Ongoing studies

Ongoing studies that did not have published results at the time of the search are listed in the *Characteristics of ongoing studies* table (see Appendix C4.1). Clinical trial registries listed 2 studies as 'not yet recruiting', 3 studies as currently 'recruiting', and 5 studies as completed recruitment, but the study data not yet available. The status of 4 studies is unknown.

4.1.5 Included studies

An overview of the conditions identified and included in this review is provided in Table 2. Appendix D provides detailed descriptions of the included studies, including an overview of the Population, Intervention, Comparator, Outcome (PICO) criteria of included studies, a summary of the risk of bias assessment and results of the data synthesis for the main comparisons.

There were 27 studies (16 RCTs, 9 quasi RCTs, 2 NRSIs) identified as eligible for inclusion in the review. There were no studies found for comparison 1 (shiatsu compared with sham). For comparison 2 (shiatsu compared with no intervention, waitlist or usual care, if considered inactive), 22 studies were considered for synthesis. Studies that included NTWC prioritised critical and important outcome domains and measures (highlighted in a blue box in Appendix F1.1), were included in the final analysis. Details about the 11 studies that compared shiatsu with other (active) comparators are included in qualitative descriptions in the report, and results are listed in Appendix F2.1.

Figure 1 Literature screening results: Shiatsu

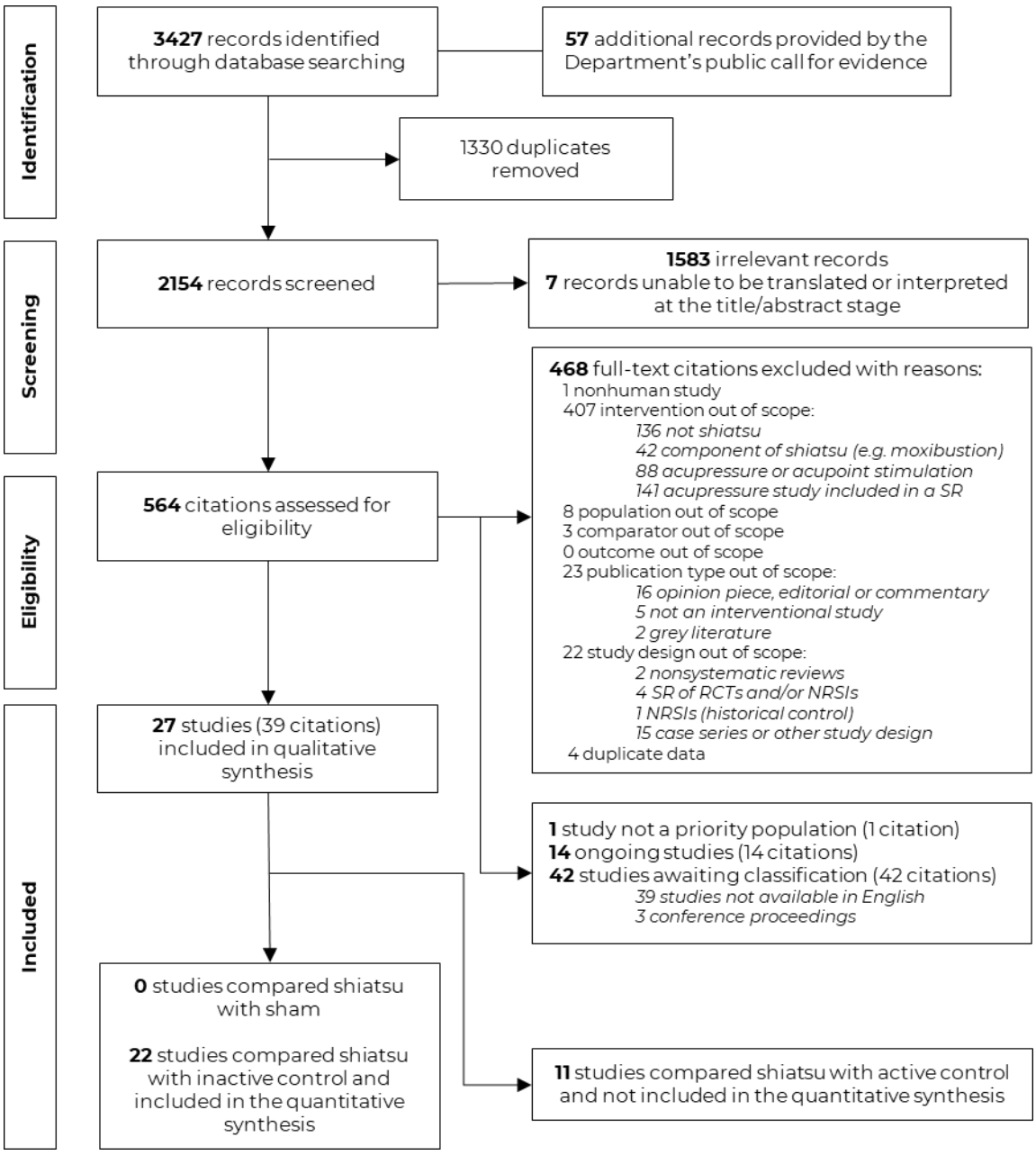


Table 2 List of conditions and population groups identified and considered in this review

ICD-11	POPULATION	# NRSIs	# RCTs & quasi RCTs	Contribute to Comparison 2#
02 Neoplasms				
	Cancer, gynaecological (survivors)	--	1	Yes
05 Endocrine, nutritional and metabolic diseases				
	Diabetes (with peripheral neuropathy)	--	1	No
	Obesity (BMI ≥ 25, or with hypertension)	--	2	Yes
06 Mental and behavioural disorders				
	Neurocognitive, Alzheimer's disease	--	1	Yes
	Symptoms of stress	1	1	Yes
07 Sleep-wake disorders				
	Insomnia, chronic †	--	1	Yes
	Sleep problems (PSQI score >/=5) †	--	1	No
08 Diseases of the nervous system				
	Headache disorders, primary (refractory)	--	1	Yes
	Stroke recovery (with deglutition disorder)	--	1	Yes
11 Diseases of the circulatory system				
	Hypertensive heart disease	--	1	Yes
13 Diseases of the digestive system				
	Functional constipation	--	2	Yes
15 Diseases of the musculoskeletal system or connective tissue				
	Fibromyalgia ††	--	1	No
	Low back pain ††	--	1	Yes
	Neck and shoulder stiffness (chronic) ††	--	1	No
16 Diseases of the genitourinary system				
	Dysmenorrhoea	--	1	Yes
18 Pregnancy, childbirth or the puerperium				
	Prenatal, third trimester ‡	1	--	Yes
	Labour induction, post-term mothers ‡	--	1	Yes
22 Injury, poisoning or certain other consequences of external causes				
	Burns (inpatient)	--	1	Yes
24 Factors influencing health status or contact with health services				
	Postpartum care	--	1	Yes
	Recovery after surgery (minimally invasive, laparoscopic) #	--	3	Yes
	Spontaneous pneumothorax after video-assisted thoracoscopic surgery#	--	1	Yes
Total (unique studies)		**2**	**25**	**22**

Abbreviations: BMI, body mass index; ICD-11, International Statistical Classification of Diseases and Related Health Problems 11th Revision; PSQI, Pittsburgh Sleep Quality Index

There were no studies found for Comparison 1: Shiatsu versus sham

-- Not applicable; Yes = study contributes to either comparison 1 or comparison 2 or both; No = study contributes to comparison 3 only (active control)

† grouped as one condition – Insomnia or sleep problems

†† grouped as one condition – Chronic musculoskeletal pain

‡ grouped as one condition – Pregnancy and childbirth

4.2 Cancer (survivors)

4.2.1 Description of the condition

4.2.1.1 Gynaecological cancer

Gynaecological cancer is an umbrella term used to describe all cancers of the female reproductive system (35). Gynaecological cancers include cancers of the vulva, vagina, cervix, uterus, fallopian tubes, placenta, and ovaries (36). In Australia, the prevalence of gynaecological cancer is increasing, with approximately 6652 females being diagnosed in 2020, equating to around 9.7% of all new cancer cases reported in females (36). According to the most recent statistics, uterine cancer is the most common diagnosed and ovarian cancer causes the highest mortality of all gynaecological cancer types in Australia (36).

Every year approximately 850 females are diagnosed with cervical cancer in Australia, which can be prevented through human papillomavirus (HPV) immunisation. HPV is a common sexually transmitted infection that can cause a range of serious illnesses (37, 38). Of all gynaecological cancers, cervical cancer is the only one that can be detected in a precancerous stage, through the National Cervical Screening Program (37). From the age of 25, it is recommended that females are tested every 5 years, an intervention that has halved cervical cancer incidence and mortality rates in Australia (39). In addition, rarer cancers of the vagina and vulva are also caused by the HPV and can be prevented by the HPV vaccine (40).

Risk for gynaecological cancers generally increases with age, but healthy lifestyle choices, particularly smoking cessation, may help reduce the likelihood of developing gynaecological cancer (40). Symptoms vary depending on the organ affected, but abnormal vaginal bleeding and discharge is common for most gynaecological cancers (41). Treatment is often complex and personalised, as it depends on the type of cancer, progression of disease, and if a woman is of child-bearing age (42). Treatments may include chemotherapy, radiation therapy or surgery, with a hysterectomy being common for cervical, uterine, and ovarian cancers (42). Complementary therapies can be used by cancer survivors to help support and manage the effect of cancer and its treatments (43). In particular, shiatsu and other touch therapies, such as massage and reflexology have been suggested to relieve symptoms such as nausea, vomiting and fatigue (44).

4.2.2 Description of studies

Five citations (45-49) corresponding to one RCT (Donoyama 2013) were identified in the literature. There was one ongoing trial, no studies awaiting classification and no additional studies 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.

Donoyama 2013 was conducted in Japan and recruited females from various medical facilities. The study enrolled 40 participants who had previously had uterine cervical, endometrial, ovarian, fallopian tube or peritoneal cancer, and were in remission for more than 3 years. Most participants had gynaecologic cancer situated in the uterine cervix. The mean age of enrolled participants was 54 years and the duration from cancer onset was between 8.3 and 8.6 years.

Donoyama 2013 compared Anma massage to no intervention, delivered as an adjunct to usual care as directed by their medical doctors. Anma massage was performed weekly over a 2-month period (total of 8 sessions). Anma was performed through clothing, with stimulation applied according to the participant's comfort. Participants in the control group met with a massage therapist on the first day of the trial to receive a semi-structured chat around self-disclosure, positive thinking and positive feedback with no massage while seated.

There were no studies found for Comparison 1: shiatsu versus sham.

Results for Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care) are provided in the Summary of Findings tables (Section 4.2.4) (and Appendix F2).

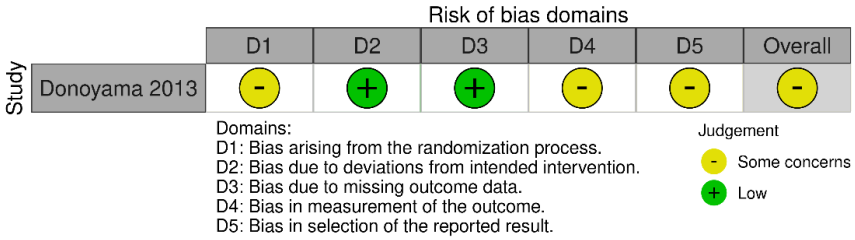
There were no studies found for Comparison 3: shiatsu versus an active comparator.

4.2.3 Risk of bias – per item

The risk of bias of the included RCT for gynaecological cancer (survivors) is summarised 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 authors' judgements about each risk of bias item for each included study: Cancer (survivors)



4.2.4 Summary of findings and evidence statements

4.2.4.1 Comparison 1 (vs sham)

No studies found.

4.2.4.2 Comparison 2 (vs inactive control)

One RCT (Donoyama 2013) was eligible for this comparison and contributed data relevant to 6 outcomes.

Shiatsu compared to control (no intervention, waitlist, usual care) for Cancer (survivors)

Patient or population: Cancer (survivors)
Setting: Community
Intervention: Shiatsu
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with shiatsu				
HRQoL (total) – not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on health-related quality of life in cancer survivors is unknown
Pain – not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on pain in cancer survivors is unknown #
Physical symptoms † assessed with: VAS (higher is worse) Scale from: 0 to 100 follow-up: 8 weeks	The mean score was **51 points**	MD **21 points lower** (35.03 lower to 6.97 lower) ^	-	40 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of shiatsu on physical symptoms in cancer survivors (gynaecological)

Shiatsu compared to control (no intervention, waitlist, usual care) for Cancer (survivors)

Patient or population: Cancer (survivors)
Setting: Community
Intervention: Shiatsu
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with shiatsu				
Physical functioning assessed with: EORTC QLQ-C30 Scale from: 0 to 100 follow-up: 8 weeks	The median physical functioning score was **93 points**	Median difference **0 points** (0.0 higher to 6.7 higher) ^	-	40 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,e,f	The evidence is very uncertain about the effect of shiatsu on physical functioning in cancer survivors (gynaecological)
Fatigue assessed with: EORTC QLQ-C30 - fatigue Scale from: 0 to 100 follow-up: 8 weeks	The median fatigue score was **33 points**	Median difference **11.1 points lower** (22.2 lower to 0.0 lower) ^	-	40 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,e,f	The evidence is very uncertain about the effect of shiatsu on fatigue in cancer survivors (gynaecological) #
Physical symptoms assessed with: EORTC QLQ-C30 – nausea and vomiting Scale from: 0 to 100 follow-up: 8 weeks	The median nausea & vomiting score was **0 points**	Median difference **0 points** (not estimable) ^	-	40 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,e,f	The evidence is very uncertain about the effect of shiatsu on physical symptoms in cancer survivors (gynaecological) #
Overall wellbeing assessed with: EORTC QLQ-C30 – global status (higher is best) Scale from: 0 to 100 follow-up: 8 weeks	The median QoL score was **67 points**	Median difference **8.3 points higher** (0.0 higher to 16.7 higher) ^		40 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,e,f	The evidence is very uncertain about the effect of shiatsu on overall wellbeing in cancer survivors (gynaecological)
Psychosocial wellbeing assessed with: HADS - anxiety (higher is worse) Scale from: 0 to 21 follow-up: 8 weeks	The median QoL was **6** points	Median difference **1.0 point lower** (2.0 lower to 1.0 higher) ^	-	40 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,e,f	The evidence is very uncertain about the effect of shiatsu on anxiety in cancer survivors (gynaecological)
Psychosocial wellbeing assessed with: HADS - depression (higher is worse) Scale from: 0 to 21 follow-up: 8 weeks	The median QoL was **4** points	Median difference **1.0 point lower** (3.0 lower to 1.0 higher)	-	40 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,e,f	The evidence is very uncertain about the effect of shiatsu on depression in cancer survivors (gynaecological).

Shiatsu compared to control (no intervention, waitlist, usual care) for Cancer (survivors)

Patient or population: Cancer (survivors)
Setting: Community
Intervention: Shiatsu
Comparison: Control (no intervention, waitlist, usual care)

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

*__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).**

† Specific physical complaints were not described, however, common physical symptoms reported in cancer survivors include fatigue, pain, stress, insomnia, weight gain, and lymphedema. The therapist focused on improving muscle tension, stiffness, induration, tenderness, knocking pain, malalignment of the spine, oedema, and area of pain/discomfort/palsy.

^ MCID is unknown. In the absence of an MCID, the effect estimate was considered on three 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; **EORTC QLQ-C30:** European Organisation for Research and Treatment of Cancer Core Quality of Life Questionnaire; **HADS:** Hamilton Anxiety and Depression scale; **HRQoL:** Health related quality of life; **IQR**: Interquartile range; **MCID:** Minimal clinically important differences; **MD:** Mean difference; **QoL:** Quality of life; **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.

There were 4 RCTs comparing acupressure with an inactive control identified by the included systematic reviews that provided evidence relating to the outcomes of pain, nausea and fatigue in people with cancer. No evidence was found for other critical or important outcomes. Refer to Supplementary material (S1.2) for further detail.

evidence in acupressure is available for this outcome as summarised below:

The evidence is very uncertain about the effect of acupressure on pain in people with cancer.

Acupressure may result in little to no difference on nausea in people with cancer.

Acupressure may result in a large reduction in fatigue in people with cancer.

Explanations

a. One RCT not at high risk of bias. Certainty of evidence not downgraded.
b. One RCT. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is generalisable to cancer survivors in Australia with some caveats. The available evidence is in women with gynaecological cancers and may not be applicable to other types of cancer. Certainty of evidence not downgraded.
d, Very serious imprecision. One RCT with wide confidence intervals (upper and lower bounds overlap with both a large and small difference). Certainty of evidence downgraded 2 levels.
e. Publication bias suspected. Evidence is limited to one small study. 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.
f. Very serious imprecision. One RCT with wide confidence intervals (upper and lower bounds overlap with both large and small (or no) important difference). Data were reported as median (IQR). Certainty of evidence downgraded 2 levels.

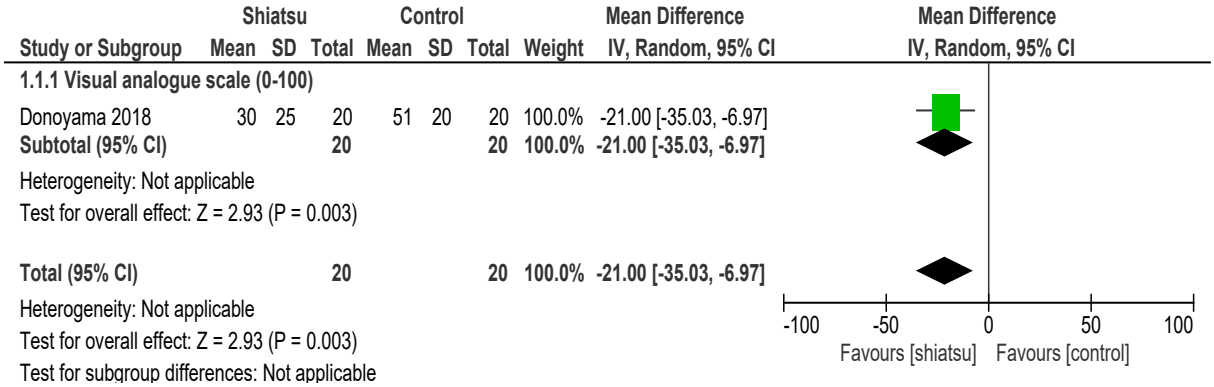
4.2.4.3 Comparison 3 (vs other including active)

No studies found.

4.2.5 Forest plots

Outcome results for gynaecological cancer (survivors) are presented in Figure 3 (physical complaints).

Figure 3 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Cancer (survivors) – physical symptoms



4.3 Diabetes

4.3.1 Description of the condition

Diabetes mellitus is a group of metabolic diseases characterised by elevated levels of blood glucose or hyperglycaemia resulting from defects in insulin secretion, insulin action, or both (50). The chronic hyperglycaemia of diabetes is associated with long-term damage, dysfunction, and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels (50). There are 3 types; type 1, type 2 and gestational diabetes.

Type 1 diabetes (previously known as juvenile diabetes) constitutes about 5% to 10% of all diabetes cases (51) and is caused by the auto-immune destruction of insulin-producing beta cells in the islets of Langerhans leading to little to no production of insulin (52, 53). The exact cause of Type 1 diabetes is unknown but risk factors include genetic predisposition and environmental triggers such as exposure to certain viruses (54, 55). Type 2 diabetes is the most common, making up 85-90% of all diabetes cases and usually occurs in adults over the age of 45 (56). It is characterised by insulin resistance and/or the gradual loss of the ability to produce enough insulin in the pancreas and is associated with modifiable lifestyle risk factors such as diet and exercise (56). Gestational diabetes is defined as an intolerance to glucose that is first diagnosed or has its onset during pregnancy. It is estimated to affect almost 5% of pregnancies in Australia and between 3% and 9% worldwide (57). Although some females will continue to have elevated glucose levels, gestational diabetes usually disappears after giving birth (58), but they remain at higher risk of type 2 diabetes.

An estimated 1.2 million Australians (4.9% of the total population) had diabetes in 2017–18, based on self-reported data from the Australian Bureau of Statistics (ABS) 2017–18 National Health Survey (59). However, this is likely to be an underestimate of the true prevalence given this does not include people with undiagnosed diabetes (59). Prevalence of diabetes in 2017-18 was higher in males (5.0%) than females (3.8%) and increases with age (59). It is also approximately twice as high among those living in the lowest socioeconomic areas (6.7% and 5.8% for males and females, respectively) compared to the highest socioeconomic areas (4.1% and 2.2% for males and females, respectively (59). Massage therapies such as shiatsu are thought to increase serum insulin action, decreasing blood glucose levels in people with type 1 diabetes and may also help to normalise blood glucose and symptoms of diabetic neuropathy in people with type 2 diabetes (60).

4.3.2 Description of studies

One citation (61) corresponding to one RCT (Jie-er 2018) was identified in the literature. There were no ongoing trials and 3 studies awaiting classification (62-64) that 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 D2.1.1.

Jie-er 2018 was carried out in a single centre outpatient setting in China with a sample size of 60 participants. Jie-er 2018 included people with peripheral neuropathy and met the diabetic peripheral neuropathy criteria (history of diabetes and secondary neuropathy, abnormal sputum reflex, analgesia, vibratory dysfunction or pressure dysfunction). Jie-er 2018 included people aged 30 to 70 years old.

Jie-er 2018 compared combined acupoint massage and meridian beat with mecobalamin tablets (oral) as an adjunct to routine care (diet control, exercise therapy and insulin). The duration of each session was 15 minutes, twice daily for 2 weeks.

There were no studies found for Comparison 1: shiatsu versus sham or Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care).

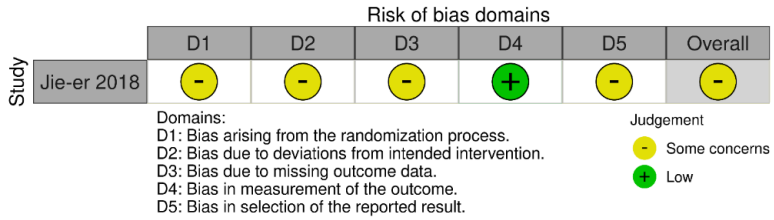
Results for one study for Comparison 3: shiatsu versus an active comparator are presented in Appendix F2.

4.3.3 Risk of bias – per item

The risk of bias of included RCTs for diabetes is summarised in Figure 4. Details are provided in Appendix D2.1.2.

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

Figure 4 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Diabetes



4.3.4 Summary of findings and evidence statements

4.3.4.1 Comparison 1 (vs sham)

No studies found.

4.3.4.2 Comparison 2 (vs control)

There were no RCTs or NRSIs found comparing shiatsu with control (no intervention, waitlist or usual care [inactive]) in people with diabetes thus the effect of shiatsu on the following outcomes for diabetes are unknown.

The following outcomes were selected (in order of importance):

- Pain
- Activities of daily living
- Psychosocial wellbeing
- Quality of life
- Comorbidities

4.3.4.3 Comparison 3 (vs other including active)

There was one RCT comparing shiatsu to an active comparator (see Appendix F2).

The study does not measure or report any outcomes considered to be critical or important to this review.

4.4 Obesity

4.4.1 Description of the condition

People who are overweight or obese have abnormal or excessive fat accumulation that presents a risk to health. A body mass index (BMI) over 25 is considered overweight, and over 30 is obese (65). Research shows that obesity is associated with increased risk of death (due to any cause) and numerous complications including diabetes, heart disease, dementia and cancer involving numerous players, including inflammation and the gut microbiome (66, 67). In addition, being overweight can hamper the ability to control or manage chronic conditions (68).

Obesity is a complex disease associated with a state of chronic low-level inflammation, orchestrated by metabolic cells in response to excess nutrients (69, 70). The inflammatory state is present in organs such as the liver, brain, pancreas and adipose tissue (fat cells) and has been implicated in immuno-metabolic disease (70). Immune cells are abundant in adipose tissue and obesity induced activation of their inflammatory response causes changes in their number and activity (71) leading to inflammation and a dysregulated immune system. This has been proposed as the central mechanism connecting obesity to its metabolic and vascular complications (71). It also helps explain increased risks of cancer (72) and infectious disease (73).

In 2014–15, nearly two-thirds (63%) of Australian adults were overweight or obese and around one-quarter of Australian children and adolescents were overweight or obese (67). The prevalence of overweight and obesity has steadily increased, up from 57% in 1995 — with obesity largely driving the rise (not overweight). The prevalence of severe obesity among Australian adults has almost doubled over this period, from 5% in 1995 to 9% in 2014–15. A greater proportion of males (42%) than females (29%) were overweight but not obese, while a similar proportion of men (28%) and females (27%) were obese.

The worldwide economic burden of managing obesity and its complications has been estimated at roughly $2 trillion annually or 2.8% of global GDP — nearly as much as smoking, armed conflict and terrorism combined (74). Locally, obesity was estimated to have cost the Australian 2011–12 economy $8.6 billion (67), being responsible for 7% of the total health burden in Australia in 2011, of which 63% was fatal burden. For people who are overweight or obese, diet and physical activity are central to bringing about change in how the body regulates appetite and energy expenditure, however obesity management goes beyond simple weight loss, with guidelines typically recommending strategies that involve some form of lifestyle change and support that focuses on improving wellbeing and reducing health risks, such as lowering blood pressure and delaying progression to type 2 diabetes (75-77). Whole-system interventions, such as shiatsu, are thought to promote improved metabolism and microcirculation leading to weight loss (78).

4.4.2 Description of studies

Two citations (78, 79) corresponding to 2 RCTs (Guo 2015, Yan 2014) were identified in the literature. There was one ongoing trial, no studies awaiting classification and no additional studies identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D2.2.1.

The 2 RCTs were carried out in outpatient settings in China (Guo 2015, Yan 2014) with the sample size ranging from 42 to 60 participants (total 102). One study (Guo 2015) included female and male participants who met the clinical diagnosis of simple obesity, who are complicated with mild and moderate hypertension. One study (Yan 2014) included female and male participants with simple obesity based on the diagnostic criteria from the Working Group for Obesity Problems in China. Participants were required to have a BMI ≥ 25.0 and aged between 18 and 50 years old. There was no age restriction in Guo 2015, however, participants ranged between 26 and 55 years old.

Both RCTs assessed the effectiveness of acupoint massage (Guo 2015) or meridian massage (Yan 2014) compared to no intervention. The primary acupoints massaged in Guo 2015 were Zunsanli, Juegu, Yongquan and Quchi. Each acupoint was massaged for at least one minute, 3 to 4 times, with massage sessions being 40 minutes in duration. The acupoint massage was administered daily for 6 weeks. Yan 2014 focused on stomach, spleen and bladder meridians massaging the Guanyuan, Qihai, Zhongwan, Daheng, Tianshil, Zusiinll, Fenglong and Ashi (position of fat accumulation) acupoints. The treatment duration was not reported but the meridian massages were carried out 3 times a week for 23 weeks.

There were no studies found for Comparison 1: shiatsu versus sham.

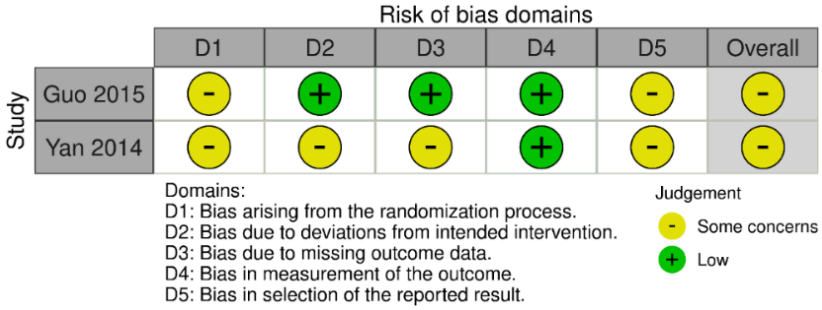
Results for Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care) are provided in the Summary of Findings tables (Section 4.4.4) (and Appendix F2).

There were no studies found for Comparison 3: shiatsu versus an active comparator.

4.4.3 Risk of bias – per item

The risk of bias of included RCTs for obesity is summarised in Figure 5. Details are provided in Appendix D2.2.2. No studies were judged to be at overall low risk of bias.

Figure 5 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Obesity



4.4.4 Summary of findings and evidence statements

4.4.4.1 Comparison 1 (vs sham)

No studies found.

4.4.4.2 Comparison 2 (vs inactive control)

Two studies (Yan 2014, Guo 2015) were eligible for this comparison and contributed data to 3 outcomes.

Shiatsu compared to control (no intervention, waitlist, usual care) for obesity

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

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with Shiatsu				
Quality of life - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on quality of life in people with obesity is unknown.
Body composition assessed with: Waist circumference (cm) (higher is worse) follow-up: 2 months	The mean waist circumference was **84.4 cm**	MD **3.1 cm lower** (6.34 lower to 0.14 lower) ^	-	54 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	Shiatsu may result in a reduction in waist circumference in people with obesity.**
Cardiometabolic disease risk assessed with: Systolic blood pressure (closer to 120 is best) follow-up: 3 months	The mean SBP **135.9 mmHg**	MD **9.9 mmHg lower** (13.6 lower to 6.2 lower)	-	42 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	Shiatsu may result in a slight reduction in systolic blood pressure in people with obesity.***
Cardiometabolic disease risk assessed with: Diastolic blood pressure (closer to 80 is best) follow-up: 3 months	The mean DBP was **90.3 mmHg**	MD **5.8 mmHg lower** (8.4 lower to 3.2 lower)	-	42 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	Shiatsu may result in a slight reduction in diastolic blood pressure in people with obesity.***
Comorbidities - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on comorbidities in people with obesity is unknown.
Psychosocial wellbeing - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on psychosocial wellbeing in people with obesity is unknown.
Functional capacity - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on functional capacity in people with obesity 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).

Shiatsu compared to control (no intervention, waitlist, usual care) for obesity

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

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with Shiatsu				

** In the absence of an MCID and no minimum/maximum to the scale, the effect estimate was considered based on Cohen's guidance, where an SMD of 0.2 is considered a small difference, 0.5 is moderate, and 0.8 is large difference (80).
*** A reduction of more than 2 mmHg in both systolic and diastolic blood pressure is considered clinically important (81).
^ SMD –0.51; 95% CI –1.05, 0.04

CI: confidence interval; **MD:** mean difference; **RCT:** randomised controlled trial

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. One RCT not at high risk of bias. Certainty of evidence not downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is generalisable to the to the target population with few caveats. The studies described the intervention as meridian massage/acupoint massage, a service component of shiatsu that could be sensibly applied to the Australian health care context. Certainty of evidence not downgraded.
d. Serious imprecision. Single study with wide confidence intervals (lower bound overlaps with small difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. 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.

4.4.4.3 Comparison 3 (vs other including active)

No studies found.

4.4.5 Forest plots

Outcome results for people with obesity are presented in Figure 6 (anthropometrics) and Figure 7 (cardiovascular disease risk).

Figure 6 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Obesity – anthropometrics

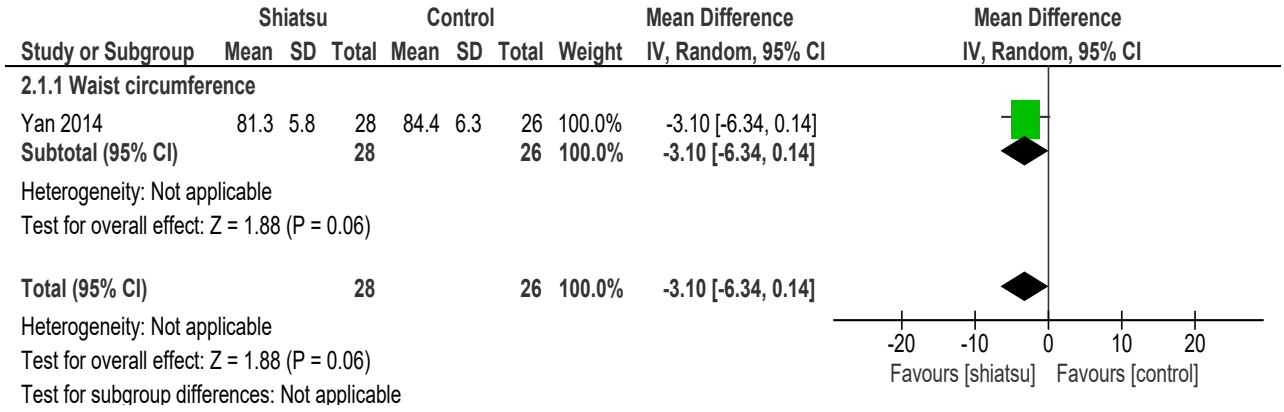
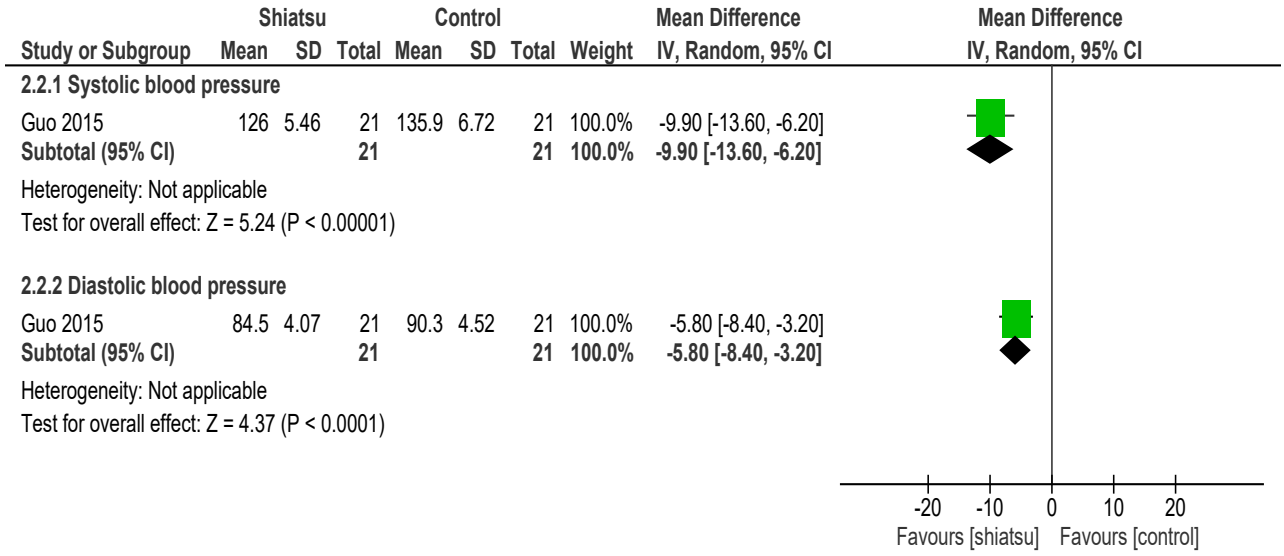


Figure 7 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Obesity – cardiometabolic disease risk



4.5 Neurocognitive decline

4.5.1 Description of the condition

4.5.1.1 Alzheimer's disease

Alzheimer's disease is the most prevalent neurocognitive disorder in the elderly population in Australia, affecting nearly 70% of people diagnosed with dementia (82). Vascular dementia, dementia with Lewy bodies, and frontotemporal dementia are other forms of dementia, the collective name for a variety of degenerative brain syndromes that affect memory, thinking, behaviour, emotions, and social functioning. Each subtype is distinguished by their underlying pathology (82). Alzheimer's disease is a progressive disease, characterised by the aggregation and accumulation of proteins (amyloid beta and neurofibrillary tangles) in the cerebral cortex and subcortical gray matter, where plaques impair synapses, so signals are unable to transmit between cells (82, 83).

Increasing age and genetics are the largest risk factors for Alzheimer's disease, impacting 3 in 10 people over the age of 85 and being twice as common among females, who generally have a longer life expectancy (84). Initially, the most common clinical manifestations are short term memory loss, impaired reasoning, language dysfunction and visuospatial dysfunction (84). Symptoms range from mild to severe, but disease progression and deterioration affect people in different ways (85).

To date, there is no cure or treatment for people living with Alzheimer's disease, but cholinergic drugs may provide temporary cognitive improvement for people with mild to moderate disease (82). Due to the limited benefit of pharmacological treatments in delaying or preventing functional decline, activity-based interventions and protective lifestyle factors are typically used as a first approach to manage secondary symptoms such as agitation, depression or sleep disturbances symptoms among people with Alzheimer's (82, 86).

4.5.2 Description of studies

One citation (87) corresponding to one RCT (Lanza 2018) was identified in the literature. There were no ongoing trials and one study (88) awaiting classification, that was 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 D3.1.1.

Lanza 2018 was conducted in an Alzheimer community centre in Italy with a sample size of 12 participants. The study included people older than 65 years with Alzheimer's disease, with a MMSE score between 16 and 25, a Clinical Dementia Rating (CDR) of less than 2, adequate visual, auditory and mobility function and who were on a stable dose regimen of cholinesterase/ memantine inhibitors for at least 6 months.

Lanza 2018 investigated shiatsu compared to no intervention delivered as an adjunct to a physical activity program. Shiatsu was performed by a senior therapist, in accordance with traditional Chinese medicine principles, by applying pressure to trigger points of the meridians (individualised for each participant). The duration of each session was 40 minutes, once a week for 10 months.

There were no studies found for Comparison 1: shiatsu versus sham.

Results for Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care) in people are provided in the Summary of Findings tables (Section 4.5.4 and Appendix F2).

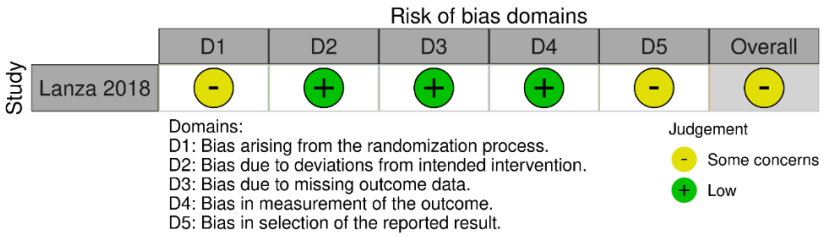
There were no studies found for Comparison 3: shiatsu versus an active comparator.

4.5.3 Risk of bias – per item

The risk of bias of included RCTs for Alzheimer's disease is summarised in Figure 8. Details are provided in Appendix D3.1.2.

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

Figure 8 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Neurocognitive decline



4.5.4 Summary of findings and evidence statements

4.5.4.1 Comparison 1 (vs sham)

No studies found.

4.5.4.2 Comparison 2 (vs inactive control)

One RCT (Lanza 2018) comparing shiatsu with no intervention in people with Alzheimer's disease was eligible for this comparison and contributed data to 3 outcomes.

Shiatsu compared to control (no intervention, waitlist, usual care) for Alzheimer's disease

Patient or population: Alzheimer's disease
Setting: Community
Intervention: Shiatsu
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Functional capacity assessed with: Activities of daily living (higher is best) Scale from: 0 to 6 follow-up: 10 months	The mean functional status was **4.7** points	MD **0.6 points higher** (0.03 higher to 1.17 higher)	-	12 (1 RCT)	⊕◯◯◯ VERY LOW [a,b,c,d,e]	The evidence is very uncertain about the effects of shiatsu on functional capacity in people living with Alzheimer's disease.**
Quality of life - not reported	-	-	-	-	(0 studies)	No studies found. The effect of shiatsu on quality of life in people with Alzheimer's disease is unknown.
Behavioural symptoms - not reported	-	-	-	-	(0 studies)	No studies found. The effect of shiatsu on behavioural symptoms in people with Alzheimer's disease is unknown.

Shiatsu compared to control (no intervention, waitlist, usual care) for Alzheimer's disease

Patient or population: Alzheimer's disease
Setting: Community
Intervention: Shiatsu
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Neurocognitive function assessed with: MMSE (higher is best) Scale from: 0 to 30 follow-up: 10 months	The mean MMSE score was **18.1** points	MD **1.9 points higher** (0.25 higher to 3.55 higher)	-	12 (1 RCT)	⊕◯◯◯ VERY LOW [a,b,c,d,e]	The evidence is very uncertain about the effects of shiatsu on neurocognitive function in people living with Alzheimer's disease.*** #
Emotional wellbeing assessed with: Geriatric depression scale (higher is worse) Scale from: 0 to 15 follow-up: 10 months	The mean emotional wellbeing was **12** points	MD **2 points lower** (3.02 lower to 0.98 lower)	-	12 (1 RCT)	⊕◯◯◯ VERY LOW [a,b,c,d,e]	The evidence is very uncertain about the effects of shiatsu on emotional wellbeing in people living with Alzheimer's disease. ****
Sleep - not reported	-	-	-	-	(0 studies)	No studies found. The effect of shiatsu on sleep in people with Alzheimer's disease 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).

** The MCID for Katz-ADDL index is approximately 0.5 points (89).
*** The MCID for MMSE in people with Alzheimer's disease is 1 to 3 points (90).
**** The MCID for GDS is around 2 points.

CI: confidence interval; **MD:** mean difference; **MMSE:** Mini Mental State Examination

There were 4 RCTs found by the included systematic reviews comparing acupressure with control (no intervention, waitlist, usual care) in people with neurocognitive disorders. One RCT assessing self-acupoint massage (delivered as an adjunct to community services) contributed data relevant to neurocognitive function. The other 3 RCTs did not measure, or report outcomes considered critical or important for this review. Refer to Supplementary material (S1.5.4) for further detail.

evidence in acupressure is available for this outcome as summarised below.

Acupressure may result in a slight improvement in neurocognitive function in people with neurocognitive decline.

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. One RCT not at high risk of bias. Certainty of evidence not downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is directly generalisable to the target population and applicable to the Australian healthcare context with few caveats. Certainty of evidence not downgraded.
d. Very serious imprecision. Small study (12 participants) with wide confidence intervals (upper and lower bounds overlap with important and no important difference). Certainty of evidence downgraded 2 levels.
e. Publication bias suspected. Evidence is limited to a small number of small trials. 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.

4.5.4.3 Comparison 3 (vs other including active)

No studies found.

4.5.5 Forest plots

Outcome results for people living with Alzheimer's disease are presented in Figure 9 (functional capacity, Figure 10 (neurocognitive function) and Figure 11 (emotional wellbeing).

Figure 9 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Alzheimer's disease – functional capacity

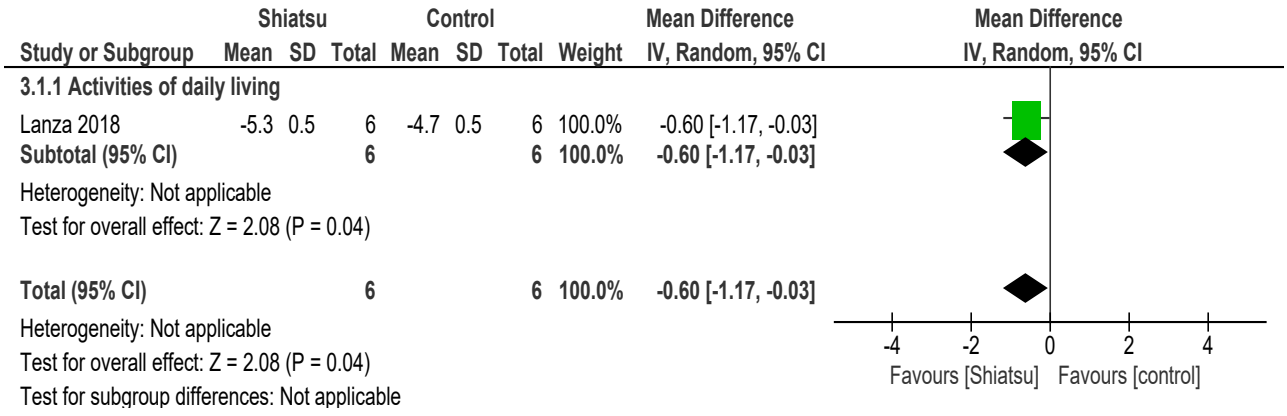


Figure 10 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Alzheimer's disease – neurocognitive function

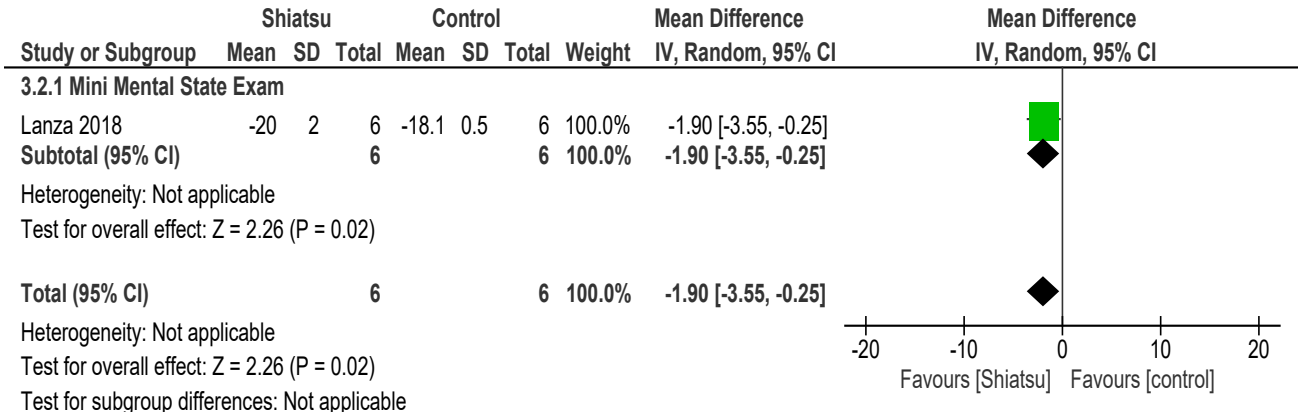
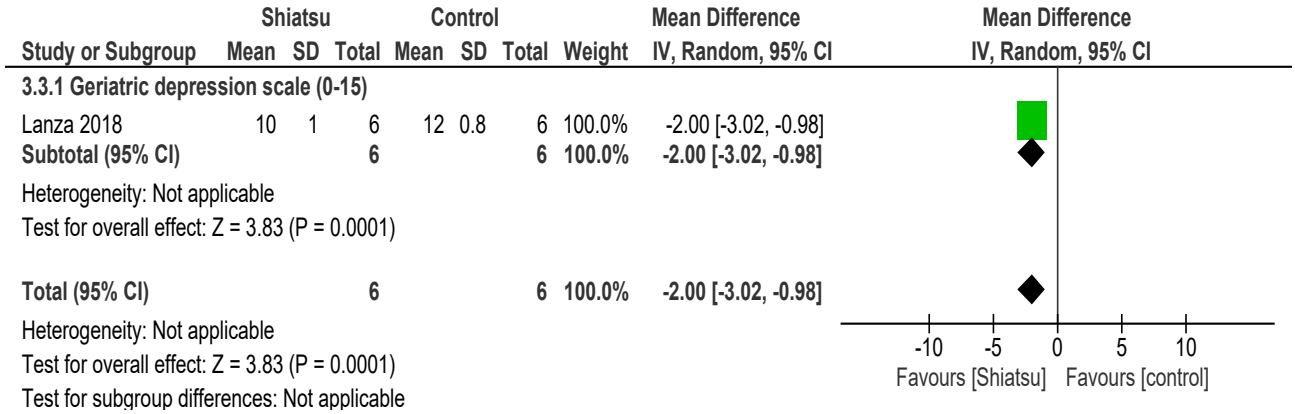


Figure 11 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Alzheimer's disease – emotional wellbeing



4.6 Symptoms of stress

4.6.1 Description of the condition

Adverse workplace environments may lead to substantial stress and burnout which can result in negative mental health outcomes such as depression (91). Families and other informal caregivers providing long-term care to older adults or persons with chronic illness and disabilities face additional stressors that can be associated with poorer mental health (92). Social inequalities such as poverty and access to education and healthcare have a clear relationship with poor mental health, particularly in children and adolescents (93).

Mental health plays a vital role in overall health and wellbeing. An estimated one in 5 Australians aged between 16 and 85 years' experience a common mental health condition each year. Among children and adolescents (aged between 4 and 17 years), approximately one in 7 meet the clinical criteria for one or more mental health conditions each year (94).

Stress is a multifactorial phenomenon that affects an individual mentally, emotionally, and physically (95). 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 (96). 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 (95). 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 (97).

Even though the majority of Australians have reported that stress impacts their physical health (72%) and mental health (64%), a very small proportion of individuals seek professional help (97). A healthy diet, exercise, sleep and relaxation techniques (yoga, meditation, deep breathing and massage) are self-care strategies used for stress management (97). It is believed that whole-body modalities such as shiatsu can aid stress management, by releasing muscles and calming the nervous system (98).

4.6.2 Description of studies

Two citations (98, 99) corresponding to one RCT (Kurebayashi 2020) and one NRSI (Lucini 2009) were identified in the literature. There were no ongoing trials, no studies awaiting classification and no additional studies identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D3.2.1.

One study (Kurebayashi 2020) was conducted in a single centre outpatient clinic in Brazil and one study (Lucini 2009) was conducted in a single centre inpatient setting in Italy. Samples sizes ranged from 70 to 101 (total 171 participants). Kurebayashi 2020 included people who scored between 37 and 119 on the Vasoncellos Stress Symptom List (LSS). Lucini 2009 included people who had chronic stress for longer than 3 months with unexplained medical symptoms.

One study (Kurebayashi 2020) compared the effects of Anma massage (with and without the addition of Reiki) to no intervention, delivered as an adjunct to usual care. Anma massage was performed to the posterior cervical, thoracic, lumbar, buttocks, thighs and feet by pressing, kneading and smoothing techniques. The duration of each session was 20 minutes, twice a week for one month. One study (Lucini 2009) examined the effects of shiatsu massage, compared with either stress education or breathing guided relaxation training. Shiatsu massage was performed by an expert technician, who used their hands to apply deep pressure focusing on spine, arms and legs, according to a personalised scheme. The duration of each session was one hour, delivered twice a week for 3 months.

There were no studies found for Comparison 1: shiatsu versus sham.

Results for Comparison 1: shiatsu versus inactive control (no intervention, waitlist or usual care) are provided in the Summary of Findings tables (Section 4.6.4) and Appendix F2.

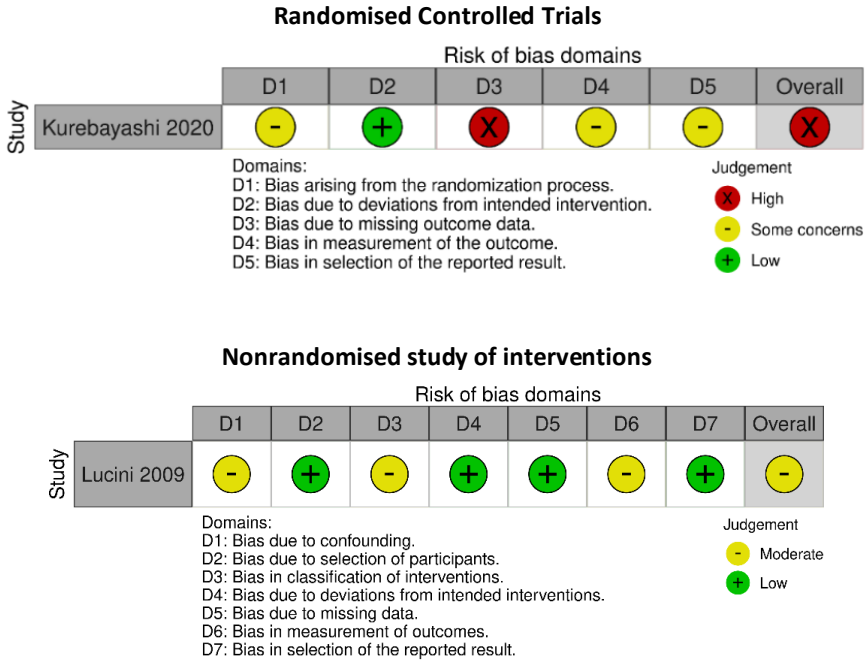
Results for Comparison 3: shiatsu versus an active comparator are presented in Appendix F2.

4.6.3 Risk of bias – per item

The risk of bias of included RCTs and NRSIs for stress are summarised in Figure 12. Details are provided in Appendix D3.2.2.

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

Figure 12 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Stress



4.6.4 Summary of findings and evidence statements

4.6.4.1 Comparison 1 (vs sham)

No studies found.

4.6.4.2 Comparison 2 (vs inactive control)

One RCT (Kurebayashi 2020) and one NRSI (Lucini 2009) in people with symptoms of stress were eligible for this comparison and contributed data to 4 outcomes.

Shiatsu compared to control (no intervention, waitlist, usual care) for stress

Patient or population: Stress
Setting: Community and/or hospital
Intervention: Shiatsu
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Quality of life assessed with: SF12 – physical component (higher is best) Scale from: 0 to 100 follow-up: 1 month	The mean QoL – physical score was **45.8**	MD **5.90 higher** (2.36 higher to 9.44 higher)	-	63 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	Shiatsu may improve quality of life (physical) in people with stress.**
Quality of life assessed with: SF12 – mental component (higher is best) Scale from: 0 to 100 follow-up: 1 month	The mean QoL – mental score was **37.2**	MD **7.3 higher** (2.56 higher to 12.04 higher)	-	63 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	The evidence suggests shiatsu improves quality of life (mental) in people with stress.**
Stress symptoms assessed with: Vasconcellos stress symptoms list (higher is worse) Scale from: 0 to 177 follow-up: 1 month	The mean stress score was **65.9** points	MD **15.5 lower** (24.46 lower to 6.54 lower)	-	63 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	Shiatsu may improve stress symptoms in people with stress.***
Psychosocial wellbeing (anxiety) - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on anxiety in people with stress in unknown.
Fatigue (tiredness) assessed with: Visual analogue scale (higher is worse) Scale from: 0 to 10 follow-up: 3 months	The mean change from baseline score was **0.68** cm	MD **2.41 lower** (3.94 lower to 0.88 lower)	-	40 (1 NRSI)	⊕◯◯◯ VERY LOW [b,c,e,f,g]	The evidence is very uncertain about the effect of shiatsu on fatigue in people with stress.***
Functional status - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on functional status in people with stress in unknown.
Cognitive function - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on cognitive function in people with stress in unknown.

Shiatsu compared to control (no intervention, waitlist, usual care) for stress

Patient or population: Stress
Setting: Community and/or hospital
Intervention: Shiatsu
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Physical health - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on physical health in people with stress in 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).

** The MCID is estimated to be between 2 to 4 points for the general population (i.e. ~0.5 of the SD) (100)
*** In the absence of an MCID, the effect estimate was considered on three 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

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. One RCT at high risk of bias (100% weight). Certainty of evidence downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. Evidence is generalisable to the target population and applicable to the Australian health care context with few caveats. Certainty of evidence not downgraded.
d. No serious imprecision. Certainty of evidence not downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. 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.
f. One NRSI with some concerns of bias (100% weight). Certainty of evidence not downgraded.
g. Very serious imprecision. Single study with wide confidence intervals (upper and lower bound overlaps with both large and small important difference). Certainty of evidence downgraded 2 levels.

4.6.4.3 Comparison 3 (vs other including active)

Results for 2 studies comparing shiatsu to active comparators are presented in Appendix F2.

4.6.5 Forest plots

Outcome results in people with symptoms of stress are presented in Figure 13 (quality of life), Figure 14 (stress symptoms) and Figure 15 (fatigue).

Figure 13 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Symptoms of stress – quality of life

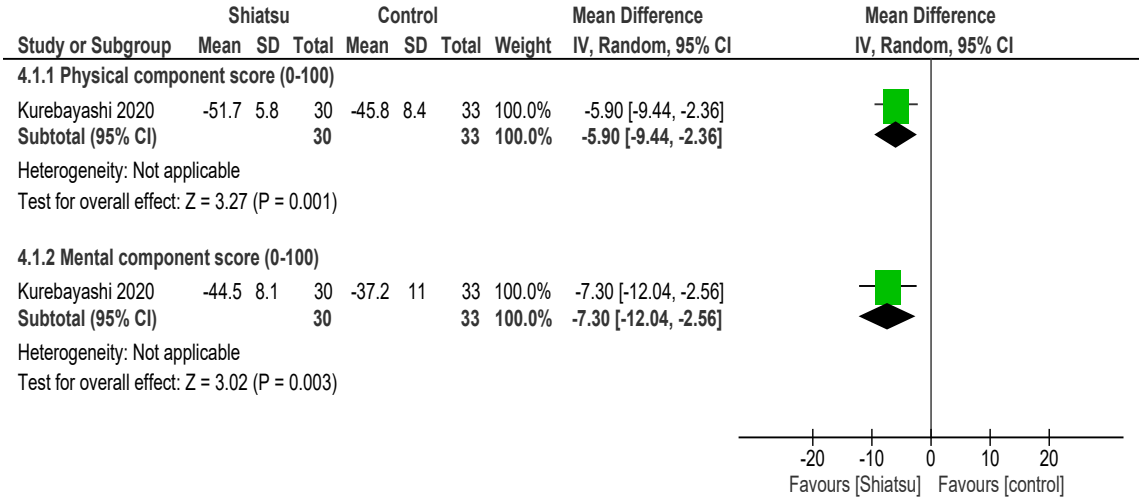


Figure 14 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Symptoms of stress – stress symptoms

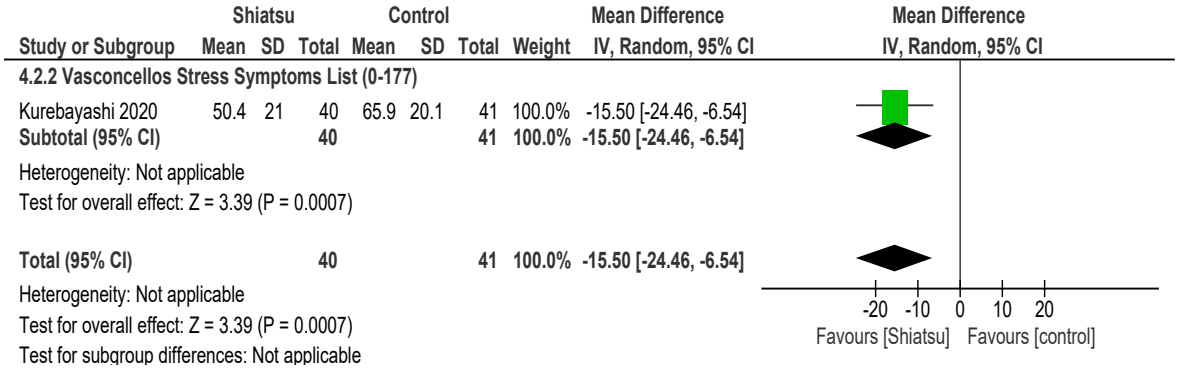
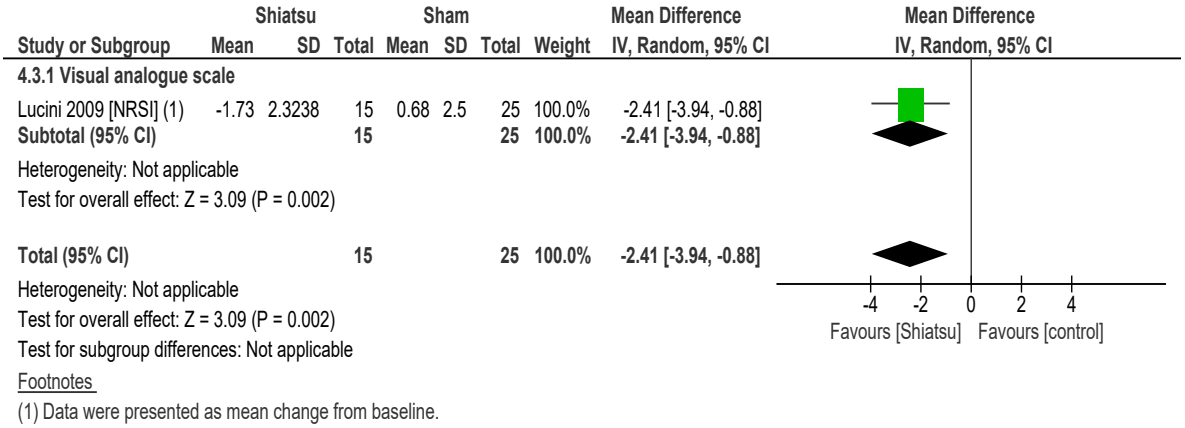


Figure 15 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Stress – fatigue (tiredness)



Footnotes

(1) Data were presented as mean change from baseline.

4.7 Insomnia or sleep problems

4.7.1 Description of the condition

Insomnia and sleep disturbances are characterised by an inability to fall asleep or lack of sleep which can cause daytime impairment. Insomnia can present in different forms and includes onset insomnia, which is difficulty initiating sleep; and maintenance insomnia, which is difficulty maintaining sleep through the night or early awakening (101). 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, people are considered to have chronic insomnia disorder by ICSD-3 criteria (102).

Sleep problems are common across the adult population in Australia and can range in severity from experiencing some sleep symptoms each week to experiencing severe symptoms results in a diagnosis of clinical insomnia (103). In Australia, 14.8% of adults are reported to have chronic insomnia and 59.4% report sleep symptoms more than 3 times a week. Females are more likely to report chronic insomnia and daytime consequences than men. In both men and females, the prevalence of chronic insomnia increases with age; adults over 75 report the highest rates of chronic insomnia (23.1%) in Australia. Older people are also significantly more likely to report maintenance insomnia. Despite these significant numbers, less than one-third of people seek treatment. Even when treatment is initiated, it can take a relatively heterogenous approach (103).

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 people with insomnia since improvements can be maintained for up to 3 years and medications are only recommended for short term usage (103, 104). However, CBT can be time consuming (4-8 weeks) and limited by accessibility of clinicians. New evidence has suggested that exercise interventions and mindfulness based interventions can be helpful in improving sleep quality (104).

4.7.2 Description of studies

Two citations (105, 106) corresponding to one RCT (Yue 2016) and one quasi-RCT (Kao 2017) were identified in the literature. There were no ongoing trials and one study awaiting classification (107) that was published in a language other than English. There were no additional studies 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.

One study (Kao 2017) was conducted at a single centre in Taiwan and one study (Yue 2016) was conducted in 7 residential community settings in China. Sample sizes ranged from 90 to 132 participants (total 222). Kao 2017 included career females aged between 24 to 55 years who attained a score of 5 or more on the Pittsburgh Sleep Quality Index. Yue 2016 included older adults who had been diagnosed with insomnia induced by other physical diseases or older adults with severe insomnia who rely on drug treatment. The mean of age of participants in Yue 2016 was 65 years.

One study (Yue 2016) examined the effect of acupoint massage compared with either Tai Chi or a combination or acupoint massage and Tai Chi. Participant's applied pressure to 4 acupoints specific for the treatment of insomnia (Baihui, An'mian, Shenmen and Neiguan) one to 2 times a day for 30 minutes in total. Each acupoint was to be massaged twice for 5 minutes each.

One study (Kao 2017) examined the effect of acupressure massage compared to 3 essential oil groups (placebo [distilled water], lavender essential oil and blended essential oil). In Kao 2017, acupressure massage was performed by an experienced masseur focusing on 17 acupuncture points, including some that enhance head circulation and sleep quality. The massage session typically lasted 45 minutes and was conducted once per week for 4 weeks.

There were no studies found for Comparison 1: shiatsu versus sham.

Results for Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care) are provided in the Summary of Findings tables (Section 4.7.4) (and Appendix F2).

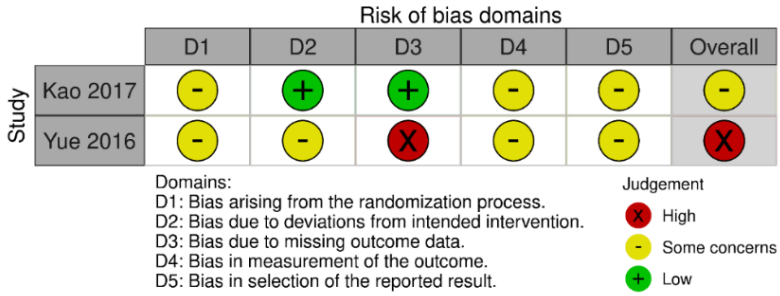
Results for Comparison 3: shiatsu versus an active comparator are presented in Appendix F2.

4.7.3 Risk of bias – per item

The risk of bias of included RCTs for insomnia is summarised in Figure 16. Details are provided in Appendix D4.1.2.

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

Figure 16 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Insomnia



4.7.4 Summary of findings and evidence statements

4.7.4.1 Comparison 1 (vs sham)

No studies found.

4.7.4.2 Comparison 2 (vs inactive control)

One RCT (Yue 2016) comparing shiatsu with no intervention (delivered as an adjunct to Tai Chi) in people with insomnia contributed data relevant to 3 outcomes.

Shiatsu compared to control (no intervention, waitlist, usual care) for insomnia or sleep problems

Patient or population: insomnia or sleep problems
Setting: community
Intervention: shiatsu
Comparison: control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Sleep quality assessed with: SPIEGEL sleep quality scale (higher is worse) Scale from: 0 to 30 follow-up: 12 weeks	The mean sleep quality was **14.86** points	MD **4.12 lower** (5.30 lower to 2.94 lower)	-	60 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of shiatsu on sleep quality in people with insomnia. #

Shiatsu compared to control (no intervention, waitlist, usual care) for insomnia or sleep problems

Patient or population: insomnia or sleep problems
Setting: community
Intervention: shiatsu
Comparison: control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Fatigue - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on fatigue in people with insomnia is unknown.
Quality of life assessed with: GQ-OLI-74 (higher is better) Scale from: Unknown follow-up: 12 weeks	The mean quality of life was **66.31**	MD **3.76 higher** (1.42 higher to 6.1 higher)	-	60 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of shiatsu on sleep quality in people with insomnia.
Cognitive function - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on cognitive function in people with insomnia is unknown.
Global clinical improvement - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on global clinical improvement in people with insomnia is unknown.
Psychosocial wellbeing assessed with: Exon Emotional stability scale (higher is worse) Scale from: 0 to 30 follow-up: 12 weeks	The mean anxiety score was **19.25**	MD **2.7 points lower** (4.27 lower to 1.13 lower)	-	60 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of shiatsu on psychosocial wellbeing (anxiety) in people with insomnia.
Cardiorespiratory health - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on cardiorespiratory health in people with insomnia 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).

CI: confidence interval; **GQ-LI-74:** 74-item life quality assessment questionnaire

Shiatsu compared to control (no intervention, waitlist, usual care) for insomnia or sleep problems

Patient or population: insomnia or sleep problems
Setting: community
Intervention: shiatsu
Comparison: control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
There were 6 RCTs comparing acupressure with control (no intervention, waitlist, or usual care) in people with insomnia (or sleep problems) that were identified by the included systematic reviews and contributed data to one critical or important outcome. Refer to Supplementary material (S1.6.4) for further detail. # evidence in acupressure is available for this outcome as summarised below. *Acupressure probably results in a slight improvement on sleep quality in people with insomnia (or sleep problems)*						

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. One study at high risk of bias (100% weight). Certainty of evidence downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. Serious indirectness. Evidence is not directly generalisable to the Australian heath care context, and it is difficult to judge if it could be sensibly applied. The study is in people with insomnia, but the intervention (acupressure massage) is self-administered, with participants in both groups also practicing Tai Chi. Certainty of evidence downgraded.
d. No serious imprecision. Certainty of evidence not downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. 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.

4.7.4.3 Comparison 3 (vs other including active)

Results for 2 studies comparing shiatsu to active comparators are presented in Appendix F2.

4.7.5 Forest plots

Outcome results for people with insomnia (or sleep problems) are presented in Figure 17 (sleep quality), Figure 18 (quality of life) and Figure 19 (psychosocial wellbeing).

Figure 17 Forest plot of comparison: shiatsu vs control (no intervention, waitlist, usual activities): insomnia (or sleep problems) – sleep quality

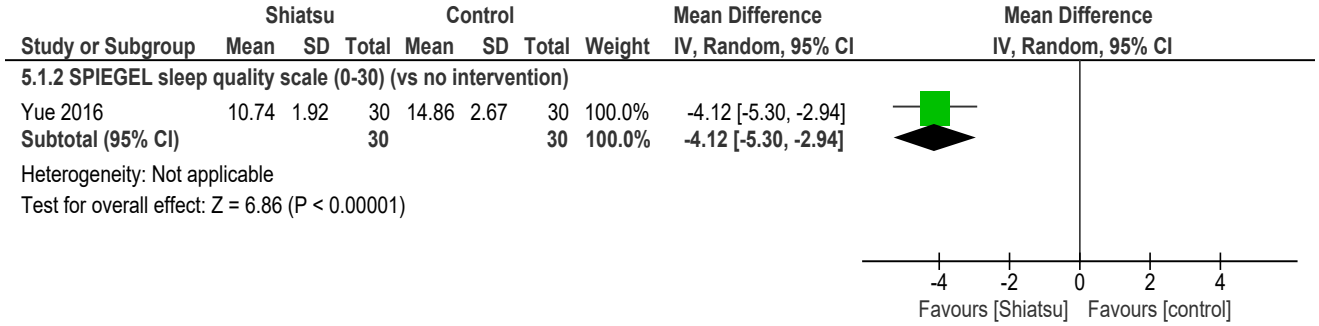


Figure 18 Forest plot of comparison: shiatsu vs control (no intervention, waitlist, usual activities): insomnia (or sleep problems) – quality of life

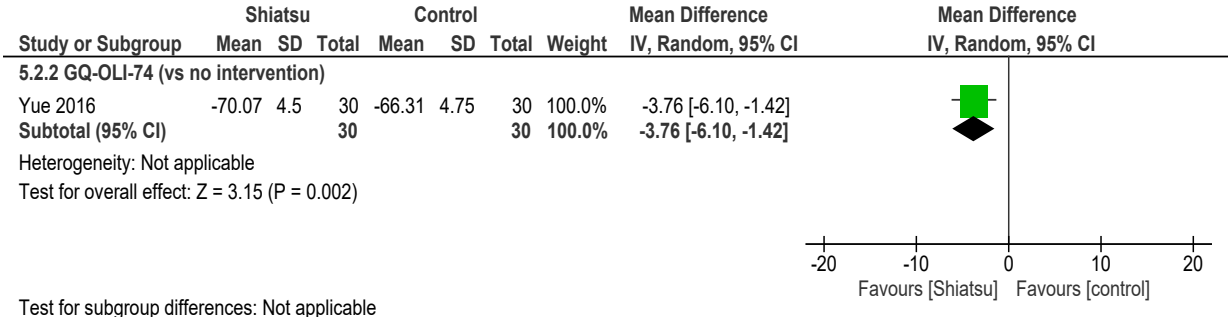
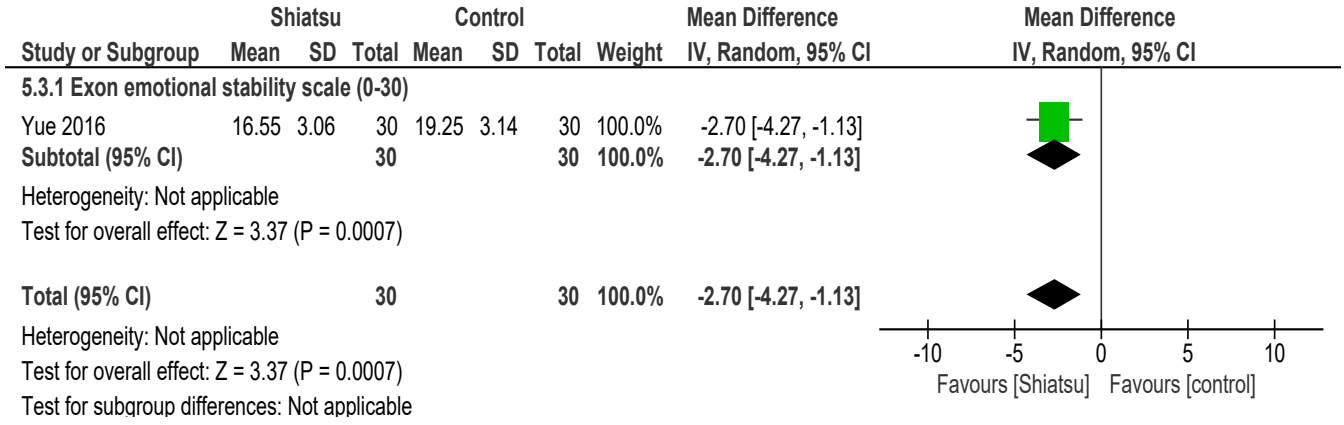


Figure 19 Forest plot of comparison: shiatsu vs control (no intervention, waitlist, usual activities): insomnia (or sleep problems) – psychosocial wellbeing



4.8 Headache disorders

4.8.1 Description of the condition

Headache disorders can be disabling chronic conditions that cause disability, suffering, loss of work productivity and reduced quality of life (108, 109). They include tension-type 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. Other symptoms may include nausea, vomiting, sensitivity to light and sound, affected vision, trouble concentrating, depression and anxiety (110-112). While it is unknown exactly what causes headaches and migraines, episodes are thought to be triggered by diet, stress, sleep and hormonal influences among others (110-112).

International studies show that 36% of men and 42% of females experience tension-type headaches, which translates to around 7 million Australians (110). Migraines are estimated to affect between 1.4 and 4.9 million Australians (112, 113). Affecting females approximately 3 times more than men, migraine is the 14th largest non-fatal contributor to burden of disease for females in Australia (114).

Effective management of headaches and migraines includes both acute and preventative treatments to reduce the frequency of attacks. Treatments include pain relief medication (such as amitriptyline), avoiding trigger factors, exercise, and relaxation techniques (110-112). Non-pharmaceutical treatment options include a variety of complementary and alternative medicines such as relaxation techniques, aromatherapy, deep breathing, hypnotherapy, biofeedback, yoga, Tai Chi, and neck and shoulder massage (110-112).

4.8.2 Description of studies

One citation (115) corresponding to one RCT (Villani 2017) was identified in the literature. There were no ongoing trials and 2 studies awaiting classification that were published as conference abstract (92(116) or in a language other than English (117). 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 D5.1.1.

Villani 2017 was carried out in a single centre setting in Italy with a sample size of 41 participants. The study included people with a diagnosis of migraine with or without aura, tension type headaches or chronic migraine without overuse according to the second version of the International Headache Criteria (ICHD-II). Participants were also required to have a lack of response to at least 2 different prophylactic drugs (other than amitriptyline) for 3 or more months. Villani 2017 included participants aged 18 to 55 years old.

Villani 2017 examined the effects of shiatsu delivered alone or in combination with amitriptyline with a control group that received amitriptyline only. The duration of each shiatsu session was 45 minutes per week for 12 weeks. Oral amitriptyline was started at a dosage of 5 mg daily and was increased up to 10 mg daily after one week. In case of side effects, participants were instructed to reduce the dosage to 5 mg daily. Post intervention follow up also occurred at 16 weeks.

There were no studies found for Comparison 1: shiatsu versus sham.

Results for Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care) are provided in the Summary of Findings tables (Section 4.8.4) (and Appendix F2).

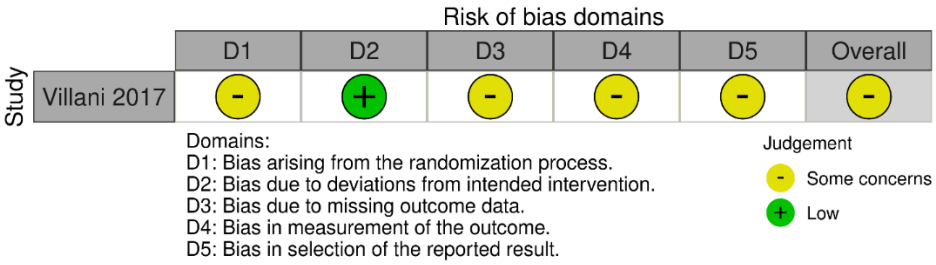
Results for Comparison 3: shiatsu versus an active comparator are presented in Appendix F2.

4.8.3 Risk of bias – per item

The risk of bias of included RCTs for headache disorders is summarised in Figure 20. Details are provided in Appendix D5.1.2.

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

Figure 20 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Headache disorders



4.8.4 Summary of findings and evidence statements

4.8.4.1 Comparison 1 (vs sham)

No studies found.

4.8.4.2 Comparison 2 (vs inactive control)

One quasi-RCT (Villiani 2017) comparing shiatsu with no intervention (delivered as an adjunct to amitriptyline) in people with headache disorders contributed data relevant to 3 outcomes (see below).

Shiatsu compared to control (no intervention) for headache disorders

Patient or population: headache disorders
Setting: community
Intervention: shiatsu
Comparison: control (no intervention)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Symptom severity - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on frequency of headaches in people with headache disorders is unknown.
Headache frequency assessed with: daily diary (per month) follow-up: 12 weeks	The mean number of days with headache was **7.6**	MD **0.5 more** (4.33 fewer to 5.33 more)	-	24 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of shiatsu on headache frequency in people with headache disorders.
Pain assessed with: VAS (higher is worse) Scale from: 0 to 10 follow-up: 12 weeks	The mean pain score was **6.2**	MD **0.2 lower** (1.48 lower to 1.08 higher)	-	24 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of shiatsu on pain in people with headache disorders.**

Shiatsu compared to control (no intervention) for headache disorders

Patient or population: headache disorders
Setting: community
Intervention: shiatsu
Comparison: control (no intervention)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Clinical efficacy assessed with: % with more than 50% reduction in headache frequency follow-up: 12 weeks	462 per 1000	**411 per 1000** (203 to 817)	**RR 0.89** (0.44 to 1.77)	24 (1 RCT)	⊕◯◯◯ VERY LOW [a,b,c,d,e]	The evidence is very uncertain about the effect of shiatsu on clinical efficacy in people with headache disorders.***
Quality of life - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on quality of life in people with headache disorders is unknown.
Psychosocial wellbeing - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on psychosocial wellbeing in people with headache disorders is unknown.
Functional capacity (activities of daily living) - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on activities of daily living in people with headache disorders 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).

** The MCID for pain (VAS for people with headache is around 2.7 cm.
*** A 25% relative improvement was considered important (i.e. RR > 1.25).

CI: confidence interval; **MD:** mean difference; **OR:** odds ratio; **QoL:** quality of life; **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. One study not at high risk of bias. Certainty of evidence not downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The available evidence is in people with headache disorders who are also receiving amitriptyline. This may not be generalisable to all people in Australia with headache but could be sensibly applied. Certainty of evidence not downgraded.
d. Serious imprecision. One small study (24 participants) with wide confidence intervals (upper and lower bound overlap with little or no important difference). Certainty of evidence downgraded 2 levels.
e. Publication bias suspected. Evidence is limited to a small number of small trials. 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.

4.8.4.3 Comparison 3 (vs other including active)

Results for the one study comparing shiatsu to active comparators are presented in Appendix F2.

4.8.5 Forest plots

Outcome results for people with headache disorders are presented in Figure 21 (headache frequency), Figure 22 (pain intensity) and Figure 23 (clinical efficacy).

Figure 21 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): headache disorders – headache frequency

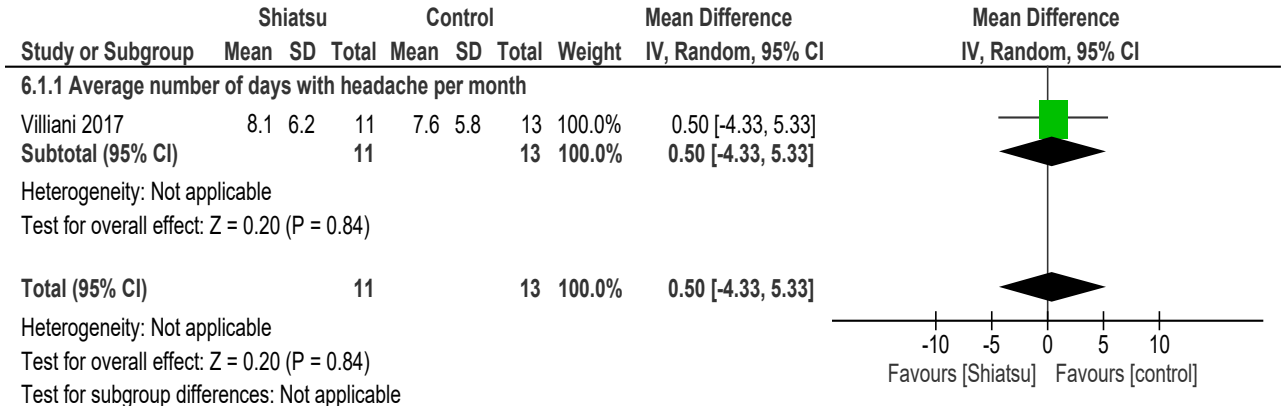


Figure 22 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): headache disorders – pain intensity

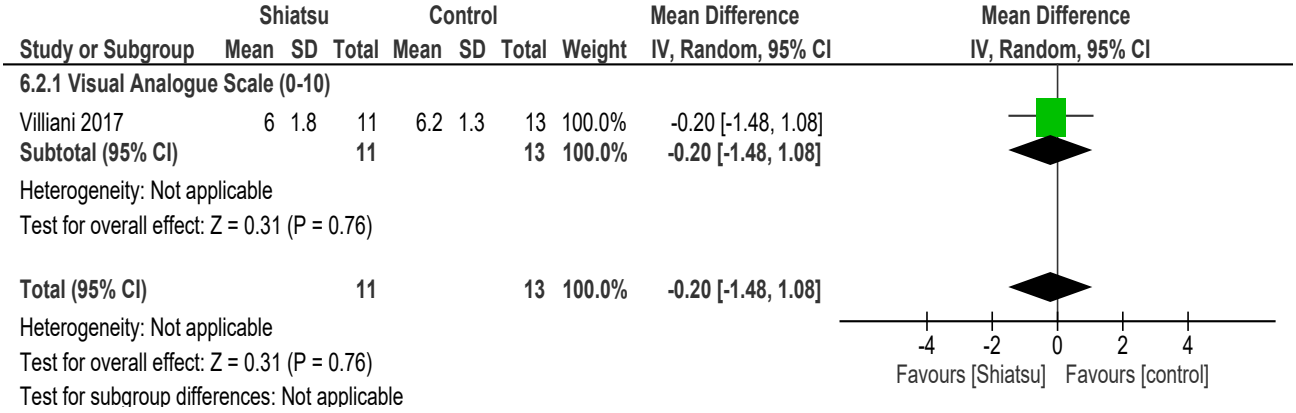
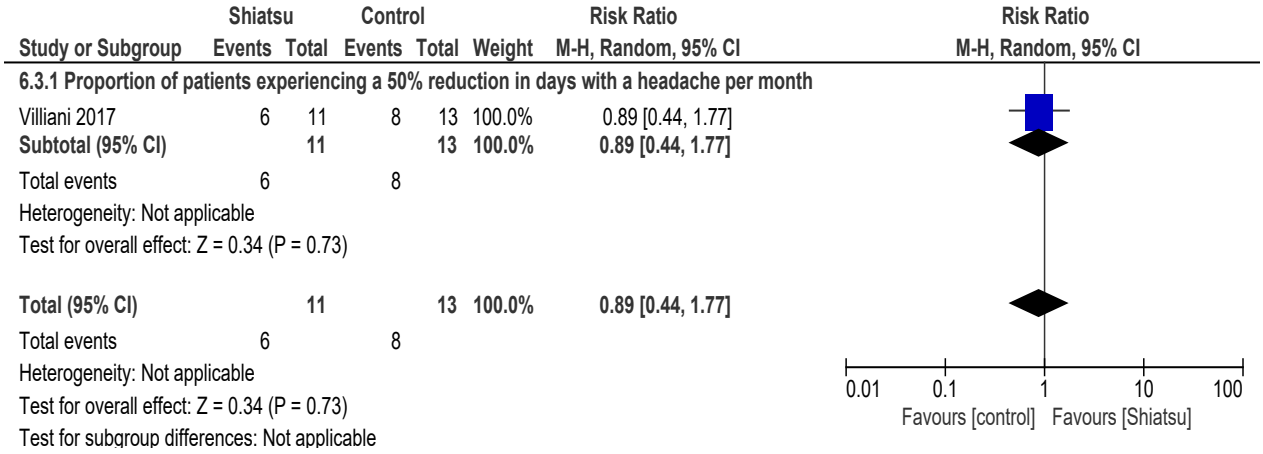


Figure 23 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): headache disorders – clinical efficacy



4.9 Rehabilitation after stroke

4.9.1 Description of the condition

Stroke occurs when blood supply to the brain either suddenly becomes blocked (ischaemic stroke) or a blood vessel ruptures and begins to bleed (haemorrhagic stroke) (118). In Australia, there were more than 100 stroke events every day in 2017 and stroke accounted for 5.3% of all deaths in 2018 (118). Every stroke is different depending on where in the brain stroke occurs and the severity. As a result of stroke, part of the brain may die which can lead to the impairment of various functions, including partial paralysis and difficulties with speech, swallowing, vision and thinking (119). Dysphagia or difficulty swallowing and eating, for example, is common, affecting 13 to 94% of people post stroke (120). Dysphagia is associated with an increased risk of aspiration, dehydration, nutritional problems and pneumonia (120, 121).

People with chronic stroke are hospitalised during the acute or sub-acute phase and go on to receive rehabilitation treatment in the months following (122). Australian Clinical Guidelines for Stroke Management (123) suggest holistic rehabilitation beginning the first day after stroke with the aim of maximising the participation of the person with stroke in the community. An important part of the rehabilitation process is improving muscle strength, coordination as well as improving swallowing function. To treat dysphagia, speech and language therapists often administer compensatory and rehabilitative interventions. Compensatory approaches include modification of fluid and food. Rehabilitative methods include exercises, as well as physical stimulation and acupuncture techniques (121).

4.9.2 Description of studies

One citation (124) corresponding to one quasi-RCT (Tian 2020) was identified in the literature. There was one ongoing trial and 3 studies awaiting classification, including one conference abstract (125) and 2 studies (126, 127) 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 D5.2.1.

One study (Tian 2020) was carried out among inpatients at a single hospital in China. The study enrolled 60 participants aged between 41 and 70 years old that met the diagnostic criteria for stroke and had dysphagia after stroke as diagnosed by the water swallowing test. Participants were required to have an incomplete loss of swallowing function (not reliant on nasal feeding) and relatively stable vital signs with a mini mental state examination score of 21 or more.

One study (Tian 2020) compared acupoint massage with electrical stimulation or acupoint massage delivered in combination with electrical stimulation. Participants in all groups received standard medical care that included routine rehabilitation for swallowing. Acupoint massage focused on the Jiache (ST 6), Xiaguan (ST 7) and Chengjiang (CV 24) on the face and Lianquan (CV 23), Renying (ST 9), Tiantu (CV 22), Yamen (GV 15), Dazhui (GV 14) and Fengchi on the neck. The participant took a supine position and manipulations mainly included finger digital An-pressing, An-pressing, Rou-kneading and Tui pushing. Acupoint massage was given once a day for 6 days, with a rest of one day for 4 weeks.

There were no studies found for Comparison 1: shiatsu versus sham.

Results for Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care) are provided in the Summary of Findings tables (Section 4.9.4) (and Appendix F2).

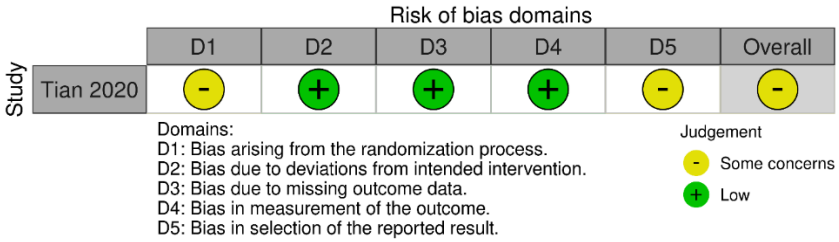
Results for Comparison 3: shiatsu versus an active comparator are presented in Appendix F2.

4.9.3 Risk of bias – per item

The risk of bias of included RCTs for stroke recovery is summarised in Figure 24. Details are provided in Appendix D5.2.2.

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

Figure 24 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Stroke recovery



4.9.4 Summary of findings and evidence statements

4.9.4.1 Comparison 1 (vs sham)

No studies found.

4.9.4.2 Comparison 2 (vs inactive control)

One RCT (Tian 2020) comparing shiatsu plus electrical stimulation with electrical stimulation (delivered as an adjunct to standard medical care) in people recovering after stroke was eligible for this comparison and contributed data relevant to one of the 6 critical or important outcomes.

Shiatsu compared to control (no intervention) as an adjunct to amitriptyline for rehabilitation after stroke

Patient or population: rehabilitation after stroke
Setting: community
Intervention: shiatsu
Comparison: control (no intervention)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Activities of daily living - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on activities of daily living in people recovering after stroke is unknown.
Disability assessed with: Food intake levels scale Scale from: 0 to 10 follow-up: 4 weeks	The mean food intake levels score was **6.33**	MD **1.36 higher** (0.92 higher to 1.80 higher)	-	40 (1 RCT)	⨁⨁◯◯ LOW [a,b,c,d,e]	Shiatsu may result in an improvement in swallowing function in people recovering after stroke.**
Motor function - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on motor function in people recovering after stroke is unknown.

Shiatsu compared to control (no intervention) as an adjunct to amitriptyline for rehabilitation after stroke

Patient or population: rehabilitation after stroke
Setting: community
Intervention: shiatsu
Comparison: control (no intervention)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Quality of life - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on quality of life in people recovering after stroke is unknown.
Cardiorespiratory health - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on cardiorespiratory health in people recovering after stroke is unknown.
Pain - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on pain people recovering after stroke 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).

**In the absence of an MCID, the effect estimate was considered based on three levels: small (MD less than 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; **OR:** odds ratio; **QoL:** quality of life; **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. One RCT not at high risk of bias. Certainty of evidence not downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. Serious indirectness. The evidence is not applicable to all people rehabilitation after stroke or to shiatsu as delivered in Australia. The available evidence is in people with dysphagia after stroke and the intervention (acupressure massage) is delivered in combination with electrical stimulation. Certainty of evidence downgraded.
d. No serious imprecision. Certainty of evidence not downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. 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.

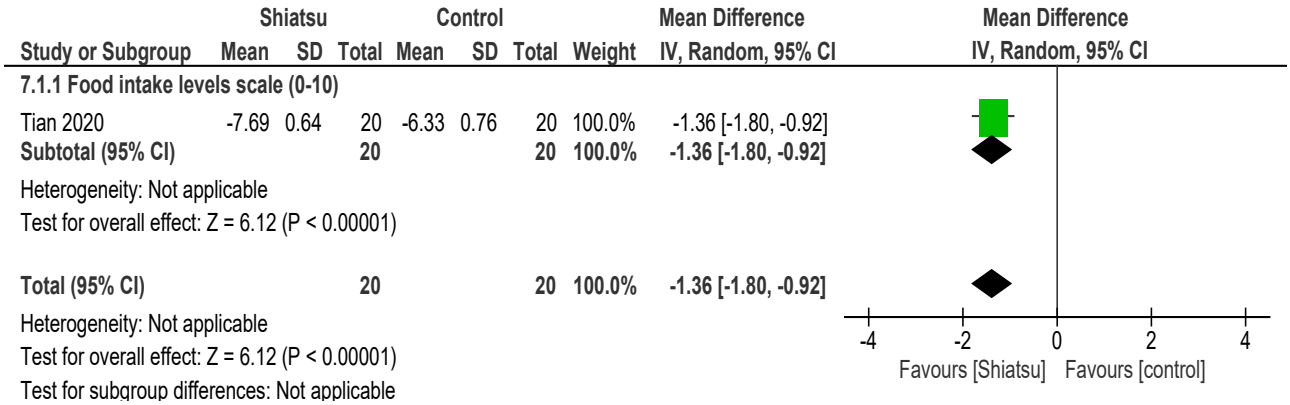
4.9.4.3 Comparison 3 (vs other including active)

Results for the one study comparing shiatsu to active comparators are presented in Appendix F2.

4.9.5 Forest plots

Outcome results for people rehabilitating after stroke are presented in Figure 25 (disability).

Figure 25 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): stroke recovery – disability (dysphagia)



4.10 Hypertensive heart disease

4.10.1 Description of the condition

Elevated blood pressure (BP) is a significant contributor to global burden of cardiovascular disease (CVD) and mortality (128). 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) (129). As an independent risk factor for stroke, heart failure, chronic kidney disease and premature death, uncontrolled hypertension poses a significant burden to Australia's healthcare system (130). Structural changes to the left atrial, 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 (131).

Different categories and grades are used to assist in the diagnosis and management of BP (130). 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. 3 grades of hypertension are classified 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 progressive resistance exercises demonstrated to reduce blood pressure (132) and regular physical activities improving cardiovascular function in those with cardiovascular disease (e.g. heart failure) (133). 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 (130).

4.10.2 Description of studies

One citation (134) corresponding to one quasi-RCT (Lei 2015) was identified in the literature. There were no ongoing trials and no studies awaiting classification. 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.

One study (Lei 2015) was conducted at a single centre in China. Lei 2015 enrolled 68 participants who were aged between 61 to 80 years and had primary hypertension (i.e. no severe internal diseases of the heart, liver, kidney, or mental diseases). Participants with secondary hypertension (i.e. high blood pressure caused by another condition or disease) were excluded.

Lei 2015 compared self-acupoint massage to no intervention (control), delivered as an adjunct to routine health education. Nurses taught and supervised participants in the intervention arm to perform acupoint massage (head, face, and body acupoints) on themselves 4 times a day for 3 months. This included An-pressing and Rou-kneading Anmian (Extra), Neiguan (PC 6), and Sanyingjiao (SP 6), An-pressing Taiyang (EX-HN 5) and circular Gua-scraping the 2 orbits, and An-pressing Shenmen (HT 7) and Fengchi (GB 20). Nurses also provided all participants with mental health guidance and sleep education (intended to provide participants with an understanding of disease progression) once per week.

There were no studies found for Comparison 1: shiatsu versus sham.

Results for Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care) are provided in the Summary of Findings tables (Section 4.10.4) (and Appendix F2).

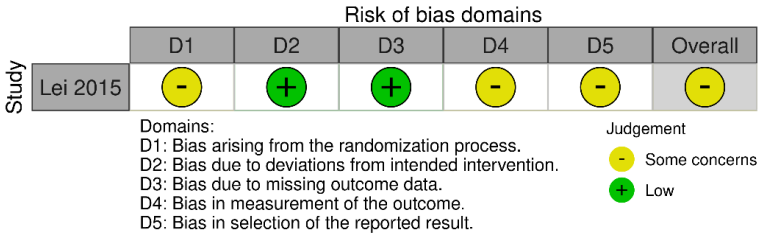
There were no studies found for Comparison 3: shiatsu versus an active comparator.

4.10.3 Risk of bias – per item

The risk of bias of included RCTs for hypertension is summarised in Figure 26. Details are provided in Appendix D6.1.2.

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

Figure 26 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Hypertensive heart disease



4.10.4 Summary of findings and evidence statements

4.10.4.1 Comparison 1 (vs sham)

No studies found.

4.10.4.2 Comparison 2 (vs inactive control)

One quasi-RCT (Lei 2015) comparing shiatsu to control (no intervention) in participants with primary hypertension contributed data relevant to one outcome.

Shiatsu compared to control (no intervention, waitlist, usual care) for hypertensive heart disease

Patient or population: hypertensive heart disease
Setting: community, outpatient
Intervention: shiatsu
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with shiatsu				
Cardiovascular health assessed with: Systolic blood pressure (closer to 120 is best)	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on systolic blood pressure in people with hypertensive heart disease is unknown. #
Cardiovascular health assessed with: Diastolic blood pressure (closer to 80 is best)	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on diastolic blood pressure in people with hypertensive heart disease is unknown. #

Shiatsu compared to control (no intervention, waitlist, usual care) for hypertensive heart disease

Patient or population: hypertensive heart disease
Setting: community, outpatient
Intervention: shiatsu
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with shiatsu				
Cognitive function assessed with: MMSE (higher is best) Scale from: 0 to 30 follow-up: 4 weeks	The mean MMSE score was **24.67 points**	MD **2.11 points higher** (1.02 higher to 3.2 higher)	-	68 (1 RCT)	⨁⨁◯◯ LOW [a,b,c,d,e]	Shiatsu may result in a slight improvement in cognitive function in people with hypertensive heart disease.**

*__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).

**In the absence of an MCID, the effect estimate was considered based on three levels: small (MD less than 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; **MMSE**: Mini-Mental State Examination

There was one RCT comparing acupressure with control (routine care) identified by the included systematic reviews in people with hypertensive heart disease that was eligible for this comparison, but reported data were incomplete. Refer to supplementary material (S1.7.4) for further detail.

evidence in acupressure is available for this outcome as summarised below.

> *The evidence is very uncertain about the effect of acupressure on systolic or diastolic blood pressure in people with hypertensive heart disease*

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. One RCT not at high risk of bias. Certainty of evidence not downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is directly generalisable to the Australian population with some caveats. The available evidence is in people aged over 60 years and may not be applicable to people aged under 60 years. The intervention is described as acupoint massage, a component of shiatsu, that could be sensibly applied in Australia. Certainty of evidence not downgraded.
d. Serious imprecision. Wide confidence intervals (Lower bound overlaps with moderate difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. 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.

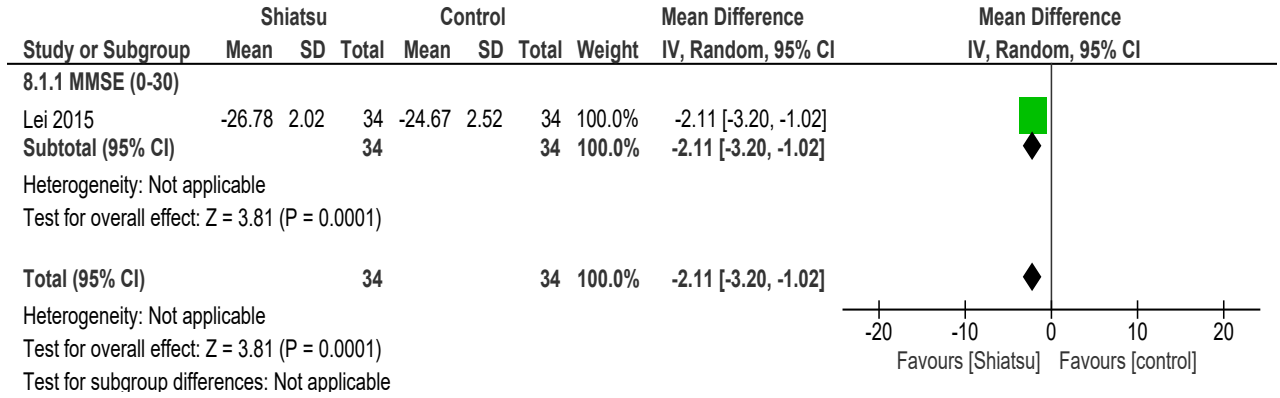
4.10.4.3 Comparison 3 (vs other including active)

No studies found.

4.10.5 Forest plots

Outcome results related to cognitive function for people with primary hypertension are presented in Figure 27.

Figure 27 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual care): hypertensive heart disease – cognitive function



4.11 Constipation

4.11.1 Description of the condition

Constipation occurs when stools become hard and dry, making bowel movements infrequent and difficult to pass (135). It is commonly caused by a low fibre diet, dehydration, lack of exercise, pregnancy, side effects of certain medications, mental illness, and delaying the urge to pass a bowel movement (135). This can result in a variety of symptoms, ranging from mild to serve, including but not limited to abdominal pain, bloating, nausea, and vomiting (136). Constipation can also be a symptom of an underlying medical condition, such as an anal fissure, abdominal obstruction, hernia, tumour, irritable bowel syndrome and diseases of the endocrine and central nervous system (136). If left untreated, constipation can lead to additional illnesses and complications, including haemorrhoids, rectal prolapse, faecal impaction and incontinence of both faeces and urine (136).

In Australia, constipation is a common gastrointestinal disorder that affects both children and adults, with a prevalence rate of 20% amongst the general population (137). Its incidence is highest amongst the elderly population, particularly females, who are more likely to experience chronic constipation (137). Chronic constipation is diagnosed when constipation lasts for greater than 3 months and it can have significant impact on a person's quality of life (138).

From a healthcare perspective, considerable costs are associated with the diagnosis, treatment and management of constipation, as it affects approximately 1 in 5 people in Australia (139, 140). Constipation is often a temporary issue that can be treated by stimulating bowel motility through dietary changes, increased fluid intake, fibre supplements, exercise, and laxatives (136). Stool softeners and laxatives are the first line of treatment for chronic constipation, a common intervention in nursing homes, where it is estimated that around 74% of nursing home residents use laxatives daily (137). In more severe cases, a surgical intervention may be required to reverse an obstruction, rectocele, or stricture, or to address an underling medical condition, such as an abdominal hernia (136, 141). In addition, it is thought that shiatsu massage may also relieve constipation by promoting peristalsis, which helps moves food through the digestive tract (142).

4.11.2 Description of studies

Two citations (143, 144) corresponding to 2 quasi-RCTs (Chen 2021, Ho 2020) were identified in the literature. There were no ongoing studies and 5 studies awaiting classification (145-149) that 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 D7.1.1.

One study (Chen 2021) was conducted in a hospital setting in China and one study (Ho 2020) involved 2 aged care facilities in Taiwan. Both studies enrolled participants with chronic functional constipation. In Chen 2021, there were 104 adult participants (44 males and 55 females) with a mean age of 59 to 60 years. Participants had to have symptoms for at least 6 months, hadn't had a colonoscopy in the preceding 6 months, or drugs that may cause constipation in the preceding 3 months of the study. Ho 2020 enrolled 90 elderly participants (number of males and females not directly reported) with a mean age ranging from 75 to 79 years across the intervention and comparator groups. Participants were included if they had fewer than 2 bowel movements per week within a month of the study and hadn't had abdominal surgery in the preceding 6 months.

One study (Chen 2021) compared 12 weeks of acupoint massage therapy with no intervention. No description of acupoint massage therapy, nor the details about the frequency of the intervention was provided. One study (Ho 2020) examined the effects of acupoint pressure therapy alone or in combination with abdominal massage compared with no intervention. Participants in all 3 groups received standard medical care (laxatives). Acupoint pressure therapy was delivered over 10 days and was performed by trained registered nurses on 5 acupoints (Tianshu (ST25), Zhongdu (GB32), Shenmen (TF4), Zusanli (ST36) and Sanyinjiao (SP6), who pressed 3 to 5 centimetres into each acupoint for a duration of one minute, once a day for 10 consecutive days.

There were no studies found for Comparison 1: shiatsu versus sham.

Results for Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care) are provided in the Summary of Findings tables (Section 4.11.4) (and Appendix F2).

Results for Comparison 3: shiatsu versus an active comparator are presented in Appendix F2.

4.11.2.1 Acupressure

Two RCTs comparing acupressure with sham, control or an active intervention were found that provided evidence for the outcome of health-related quality of life and symptom severity. No evidence was found for other critical or important outcomes.

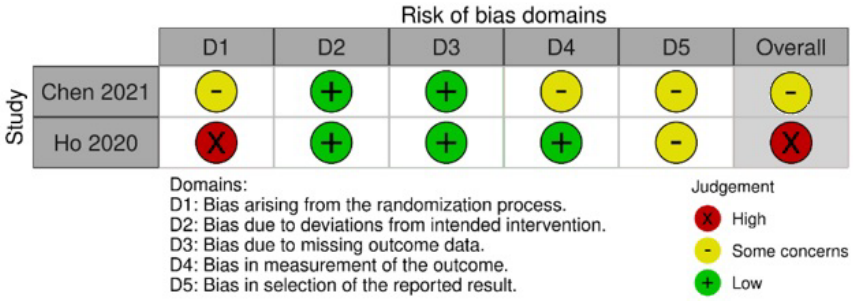
Refer to Supplementary material (S1.8) for further detail.

4.11.3 Risk of bias – per item

The risk of bias of included RCTs for constipation is summarised in Figure 28. Details are provided in Appendix D7.1.2.

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

Figure 28 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Constipation



4.11.4 Summary of findings and evidence statements

4.11.4.1 Comparison 1 (vs sham)

No studies found.

4.11.4.2 Comparison 2 (vs inactive control)

There were 2 studies (Chen 2021, Ho 2020) comparing shiatsu with no intervention in people with constipation that were eligible for this comparison. One study contributed data relevant to one outcome.

Shiatsu compared to control (no intervention, waitlist, usual care) for functional constipation

Patient or population: functional constipation
Setting: hospital, aged-care
Intervention: shiatsu
Comparison: control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence Statement
	Risk with control	Risk with shiatsu				
Symptom severity – not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on symptom severity in adults with functional constipation is unknown. #
Quality of life assessed with: PAC-QoL (higher is worse) Scale from: 0 to 112 follow-up: 12 weeks	The mean quality of life score was **81.67**	MD **10.98 lower** (17.12 lower to 4.84 lower)	-	101 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	Shiatsu may result in a large improvement in quality of life in adults with functional constipation..** #
Clinical efficacy – not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on clinical efficacy in adults with functional constipation 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).

** A reduction of more than 1 in the total PAC-QoL score is suggested to be clinically meaningful in people with chronic non-cancer pain and opioid induced constipation (150).
*** In the absence of an MCID, the effect estimate was considered based on three levels: small (MD less than 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; **PAC-QoL:** Patient Assessment of Constipation – Quality of life

There were 4 RCTs comparing acupressure with control (no intervention, waitlist, or usual care) in people with functional constipation that were identified by the included systematic reviews. Two RCTs contributed data to 3 critical or important outcomes. Refer to supplementary material (S1.8.4) for further detail.

evidence in acupressure is available for this outcome as summarised below.

Acupressure may reduce symptom severity in adults with functional constipation.

Acupressure may result in little to no improvement in quality of life in adults with functional constipation.

The evidence is very uncertain about the effect of acupressure of clinical efficacy in adults with functional constipation.

Shiatsu compared to control (no intervention, waitlist, usual care) for functional constipation

Patient or population: functional constipation
Setting: hospital, aged-care
Intervention: shiatsu
Comparison: control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence Statement
	Risk with control	Risk with shiatsu				

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. One RCT not at high risk of bias. Certainty of evidence not downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. The evidence is directly generalisable to the Australian population with some caveats. The study is in older adults with functional constipation, which may not be applicable to infants or children with constipation. The intervention is described as acupoint massage therapy, a component of shiatsu therapy that could be sensibly applied to the Australian healthcare context. Certainty of evidence not downgraded.
d. Serious imprecision. One RCT with wide confidence intervals (upper and lower bound overlap with both large and small important differences). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. 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.

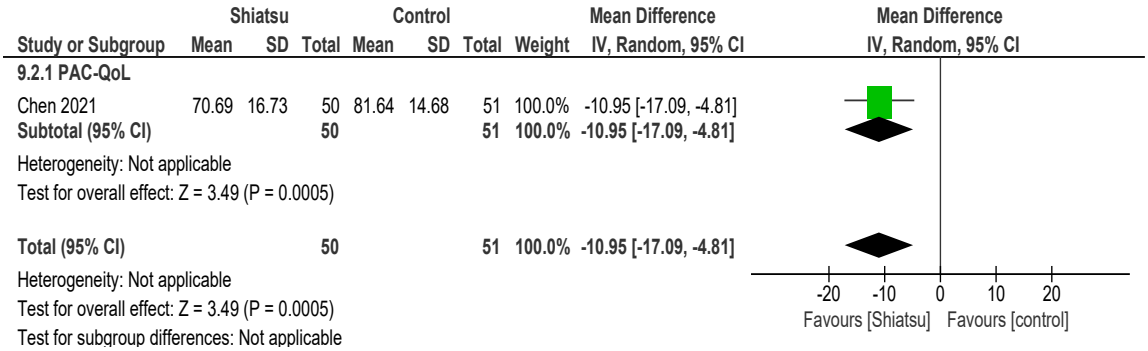
4.11.4.3 Comparison 3 (vs other including active)

Results for the one study comparing shiatsu to active comparators are presented in Appendix F2.

4.11.5 Forest plots

Outcome results for people with constipation are presented in (symptom severity) and Figure 29 (quality of life).

Figure 29 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual care): Constipation – quality of life



4.12 Chronic musculoskeletal pain

4.12.1 Description of the conditions

4.12.1.1 Chronic widespread pain (fibromyalgia)

Chronic widespread pain is a multifactorial pain syndrome that may be influenced by biological, psychological and social factors (151, 152). It is characterised as a diffuse pain that occurs in at least 4 of 5 body regions lasting for a minimum of 3 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) (151, 153).

One condition characteristically associated with chronic widespread pain is fibromyalgia, which is defined by the American College of Rheumatology[1] (154) as widespread and prolonged pain persisting for more than 3 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) as well headaches (155). 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 (156). In a North American survey, approximately half of participants surveyed had consulted 3 to 6 healthcare professionals before receiving their diagnosis (157).

Fibromyalgia is a chronic and disabling condition that can affect all aspects of life, including work, family and leisure (158). In developed countries, fibromyalgia is estimated to affect approximately 2 to 5% of the population, predominantly young to middle-aged females (156). 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. Sedentary lifestyles for people diagnosed with fibromyalgia can increase their risk for several chronic diseases (159). International guidelines therefore encourage physical therapy, exercise and massage therapy as part of a multi-modal approach to optimise overall health and quality of life (160, 161).

4.12.1.2 Low back pain

Low back pain (LBP) is the most encountered musculoskeletal problem in general practice in Australia and the leading cause of disability globally (162-164). National data reports approximately 16% of Australians experienced back pain in 2017-18 (165). 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 (163). Direct and indirect costs of LBP are reportedly $1 billion and $8 billion, respectively (166). 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 (164). In most cases there is no specific cause of LBP and is subsequently labelled nonspecific LBP. 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 (164).

[1] the most frequently used criteria by clinicians to diagnose fibromyalgia.

International guidelines consistently recommend the consideration of alternative diagnosis; however, spinal imaging should not be routinely ordered (162, 163). Advice to stay active and return to normal activities as soon as possible is a core recommendation across international guidelines (162). Furthermore, the international guidelines recommend some various forms of exercise as therapy, but no one approach is superior to another (162). However, evidence-based guidelines are not consistently translated into clinical practice and medications including opioids are overprescribed (167). Help seeking behaviours are primarily driven by characteristic factors of pain, impaired daily activities and an ability to carry out normal work (168). Providers commonly sought include physiotherapists, chiropractors, massage therapists and acupuncturists and as per guidelines, exercise is commonly prescribed for people experiencing LBP (168). Various nonpharmacological therapies that may be beneficial for LBP include rehabilitation, spinal manipulation, exercise therapy and mind-body interventions (169).

4.12.1.3 Neck and shoulder pain

Neck and shoulder pain are common complaints that can impact a person's ability to carry out normal daily activities (170) and lead to considerable disability and economic burden (171). Neck and shoulder pain often prompt a person to consider seeking help. There are multiple origins of neck and shoulder pain. Pain can arise from musculoskeletal conditions including cervical spondylitis and subacromial bursitis (170), shoulder disorders such as rotator cuff tendonitis, acromio-clavicular bursitis and frozen shoulder (172). However, in many cases the pathophysiological mechanisms underlying pain are unclear (170). Risk factors for neck and shoulder pain include individual factors (sex, mental distress, low physical capacity, history of neck or back pain) and workplace factors (physical workload, organisational structure and psychosocial factors) and person's general physical health and well-being is thought to be associated with neck and shoulder pain (173).

Prevalence of neck and shoulder pain is high. In Australia, the number of incident cases of neck pain were reportedly 190,000 in 2017 (171). 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 (174). In some situations, neck and shoulder pain may occur concurrently and are therefore treated as a single diagnostic entity. It may also be accompanied by pain in other anatomical sites. Other times pain isolated to the neck or shoulder may be reflective of local pathology (170).

Nonpharmacologic therapies such as touch (shiatsu, reflexology) or mind-body therapies (Pilates, yoga, tai chi) are thought to improve outcomes for people with neck and shoulder pain. However, studies investigating the benefits of touch or mind-body therapies exercises on neck and shoulder pain are limited (16).

4.12.2 Description of studies

Six citations (175-180) corresponding to 2 RCTs (Faull 2005, Kobayashi 2019), one cluster RCT (Yuan 2013) and one crossover quasi-RCT (Donoyama 2010) were identified in the literature. There was one ongoing trial and 2 studies awaiting classification (181, 182) that 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 D8.1.1.

Three studies were carried out in single centre settings in New Zealand (Faull 2005) or Japan (Donoyama 2010, Koboyashi 2019). One study (Yuan 2013) was carried out in a multicentre setting in Brazil. Sample sizes ranged from 17 to 59 participants. Faull 2005 included participants aged over 18 years, diagnosed by a rheumatologist with fibromyalgia and no open wounds. Yuan 2013 included participants aged 30 to 65 years old diagnosed with fibromyalgia by a rheumatologist or an orthopaedist, fulfilling the American College of Rheumatology criteria. In both trials, most participants were female (range 97% to 100%) and middle aged (mean age ranged between 46.3 to 52.0 years). Koboyashi 2019 enrolled 59 adult participants with chronic low back pain defined as a score of 4 or more on the Roland-Morris Disability Questionnaire lasting for at least 12 weeks. The mean age of participants enrolled in the study was 67.8 years and the majority (64.4%) were female. Donoyama 2010 enrolled 17 adult participants with chronic neck and shoulder stiffness. Participants were included if they felt chronic muscle stiffness around their neck and shoulders, to have no disease requiring medical intervention, be over the age of 50 years and feel no current symptoms of menopause. The mean age of participants enrolled in the study was 55.4 years and all participants were female (100%).

One study (Koboyashi 2019) compared shiatsu with an inactive control (no intervention) delivered as an adjunct to pain relief. All participants received pain relief for 8 weeks by compress or oral medicine based on the WHO relief ladder. Shiatsu therapy sessions lasted for one-hour, once a week for 4 weeks. Post treatment evaluation at 8 weeks was also carried out.

The other 3 studies compared shiatsu with an active intervention. Donoyama 2010 compared Anma therapy with an attention control (rest on a massage table). The Anma therapy sessions occurred once on the first day and lasted for 40 minutes. Participants then received the rest intervention 3 days after. Participants in the control group received the rest intervention on the first day and Anma therapy 3 days after.

Faull 2005 compared Watsu to Aix and Yuan 2013 compared shiatsu to stretching exercises and educational advice about managing fibromyalgia, delivered as an adjunct to usual medical care. Watsu sessions (Faull 2005) were carried out in a therapy pool with warm mineral water for 40 minutes in duration, twice a week for 2 weeks. Shiatsu sessions (Yuan 2013) were 49 minutes in duration, twice a week for 8 weeks.

There were no studies found for Comparison 1: shiatsu versus sham.

Results for Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care) are provided in the Summary of Findings tables (Section 4.12.4) (and Appendix F2).

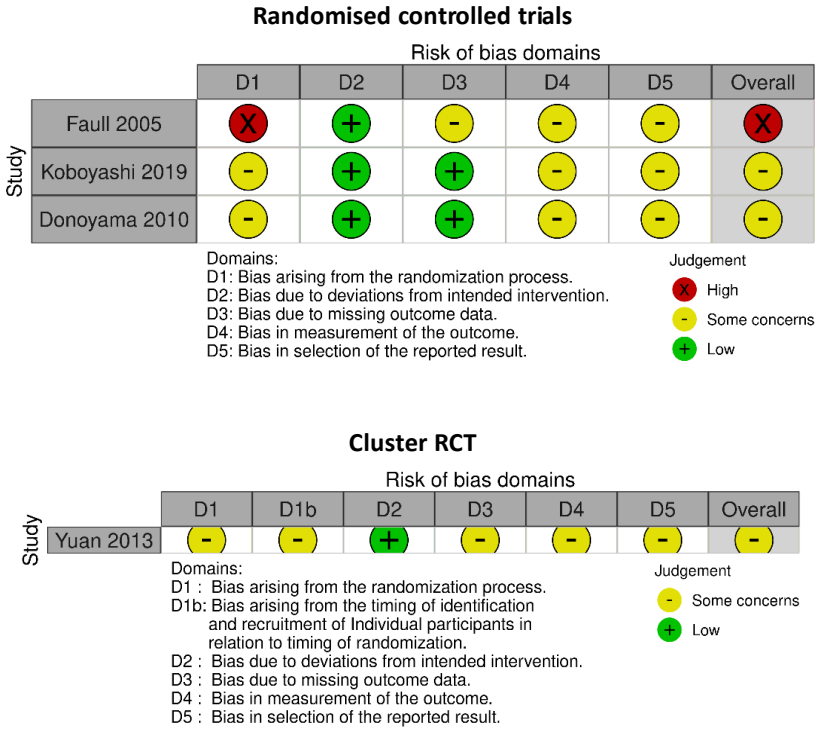
Results for 3 studies for Comparison 3: shiatsu versus an active comparator are presented in Appendix F2.

4.12.3 Risk of bias – per item

The risk of bias of included studies for chronic musculoskeletal pain (fibromyalgia, low back, neck and shoulder) is summarised in Figure 30. Details are provided in Appendix D8.1.2.

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

Figure 30 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Chronic musculoskeletal pain (fibromyalgia, low back, neck and shoulder)



4.12.4 Summary of findings and evidence statements

4.12.4.1 Comparison 1 (vs sham)

No studies found.

4.12.4.2 Comparison 2 (vs inactive control)

One RCT (Koboyashi 2019) comparing shiatsu with control (no intervention) in people with chronic low back pain was eligible for this comparison and contributed data relevant to 3 outcomes.

Shiatsu compared to control (no intervention, waitlist, usual care) for chronic musculoskeletal pain

Patient or population: chronic musculoskeletal pain
Setting: community
Intervention: shiatsu
Comparison: control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Pain assessed with: MPQ-SF (higher is worse) Scale from: 0 to 45 follow-up: 4 weeks	The mean change in pain score was **1.7**	MD **0.3 more** (1.96 more to 1.36 fewer)	-	59 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	Shiatsu may result in little to no difference in pain in people with chronic low back pain.** #

Shiatsu compared to control (no intervention, waitlist, usual care) for chronic musculoskeletal pain

Patient or population: chronic musculoskeletal pain
Setting: community
Intervention: shiatsu
Comparison: control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Functional capacity - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on functional capacity in people with chronic musculoskeletal pain is unknown.
Disability assessed with: ODI (higher is worse) Scale from: 0 to 100 follow-up: 4 weeks	The mean change in disability was **1.2** points	MD **1.2 more** (3.52 more to 1.12 fewer)	-	59 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	Shiatsu may result in little to no difference in disability in people with chronic low back pain. *** #
Quality of life assessed with: EQ-5D (higher is worse) follow-up: 4 weeks	The mean change in quality of life was **0.018** points	MD **0.06 more** (0.11 more to 0.00 more)	-	59 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	Shiatsu may result in little to no difference in quality of life in people with chronic low back pain. **
Stress - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on stress in people with chronic musculoskeletal pain is unknown.
Fatigue - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on fatigue in people with chronic musculoskeletal pain is unknown. #
Psychosocial wellbeing - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on psychosocial wellbeing in people with chronic musculoskeletal 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).

** MCID not established. In the absence of an MCID, the effect estimate was considered based on three levels: small (MD less than 10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale.
*** MCID for ODI in people with low back pain is 12.88 (183).

CI: confidence interval; **MD:** mean difference; **MPQ-SF:** short-form McGill Pain Questionnaire; **ODI:** Oswestry disability index

Shiatsu compared to control (no intervention, waitlist, usual care) for chronic musculoskeletal pain

Patient or population: chronic musculoskeletal pain
Setting: community
Intervention: shiatsu
Comparison: control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
There were 2 RCTs comparing acupressure with control (no intervention or usual care) in people with chronic musculoskeletal pain that were identified by the included systematic reviews that contributed data to 3 outcomes. Refer to supplementary material (S1.9.4) for further detail). # evidence in acupressure is available for this outcome as summarised below. *The evidence is very uncertain about the effect of acupressure on pain in people with chronic musculoskeletal pain.* *The evidence is very uncertain about the effect of acupressure on disability in people with chronic musculoskeletal pain.* *The evidence is very uncertain about the effect of acupressure on fatigue in people with chronic musculoskeletal pain.*						

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. One RCT not at high risk of bias. Certainty of evidence not downgraded.
b. Singe study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is generalisable to the Australian population with some caveats. The study is in older adults with chronic low back pain, which may not be generalisable to all people with chronic musculoskeletal pain. Certainty of evidence not downgraded.
d. Serious imprecision. One RCT with wide confidence intervals (upper and lower bounds overlap with both small and no important difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. 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.

4.12.4.3 Comparison 3 (vs other including active)

Results for 3 studies comparing shiatsu to active comparators are presented in Appendix F2.

4.12.5 Forest plots

Outcome results related to chronic musculoskeletal pain are presented in Figure 31 (pain), Figure 32 (disability) and Figure 33 (quality of life).

Figure 31 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Chronic musculoskeletal pain – Pain

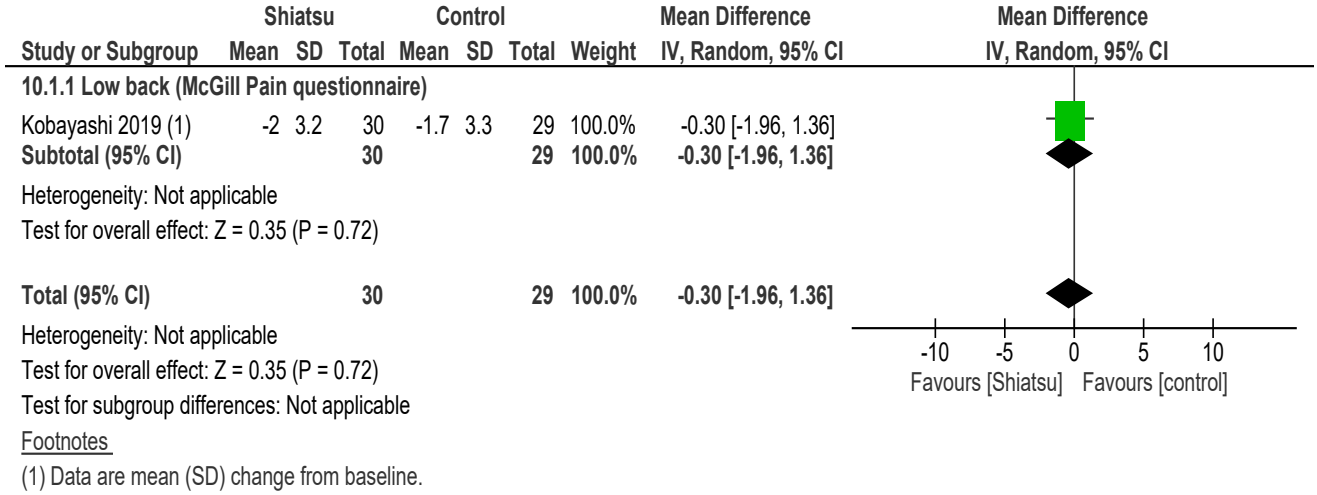


Figure 32 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Chronic musculoskeletal pain – Disability

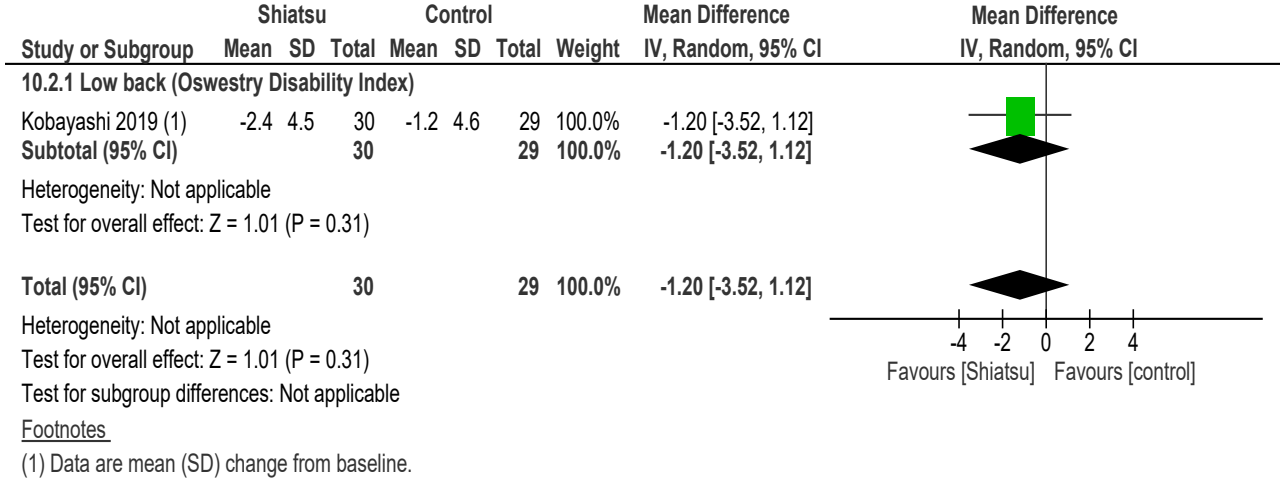
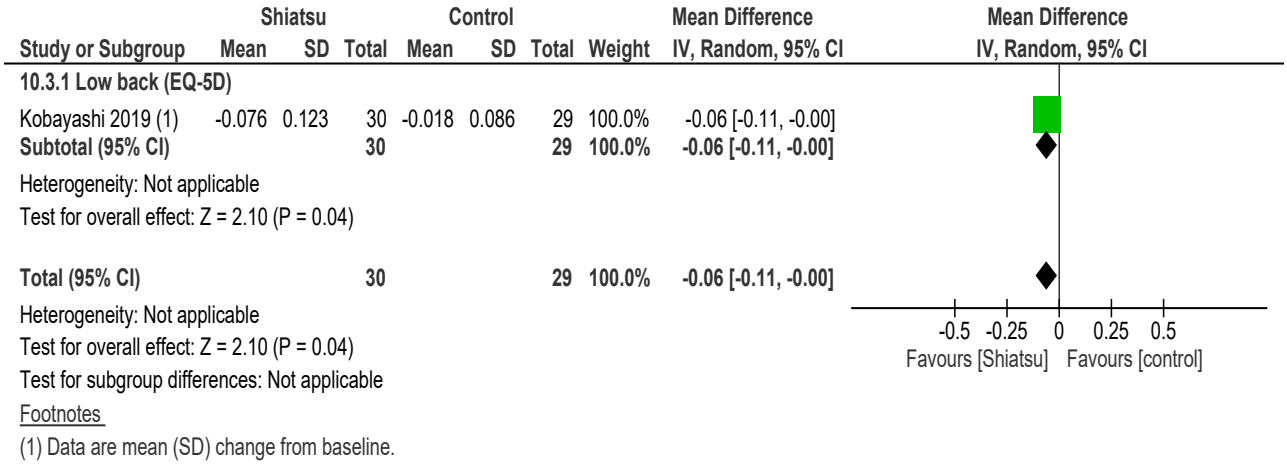


Figure 33 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Chronic musculoskeletal pain – Quality of life



Footnotes

(1) Data are mean (SD) change from baseline.

4.13 Primary dysmenorrhoea

4.13.1 Description of the condition

Dysmenorrhoea, otherwise referred to as painful periods is chronic, cyclic pelvic pain associated with menstruation (184). Primary dysmenorrhoea is pain from your first period or shortly after, and without a known cause (185). Secondary dysmenorrhoea is period pain caused by an underlying pelvic abnormality, such as endometriosis, and can be either new-onset or a change in the nature of dysmenorrhoea over time (186). Primary dysmenorrhoea in particular is a common complaint for females (186). It is especially common in young females in their teens and early adulthood with approximately 90% of Australian adolescents affected (187).

Symptoms of primary dysmenorrhoea include cramps, colicky spasms or pain in the lower abdomen, occurring within 8 to 72 hours of menstruation. In addition, many females experience other menstrual related symptoms including back and thigh pain, headaches, diarrhoea, nausea and vomiting (188). Primary dysmenorrhoea is also associated with a decrease in quality of life (189, 190), absenteeism from work or school (186, 191), reduced participation in sport and social activities (192), altered pain perception and sleeping problems (193). Pain associated with secondary dysmenorrhoea can have an impact on fertility and propensity for invasive surgical procedures in the future. In addition, there is often a delay in diagnosis of endometriosis averaging 4 to 7 years due to females and doctors not recognising the possible significance of menstrual pain (184). Most females do not seek medical advice when they experience dysmenorrhoea as they often consider the pain as normal and part of menstruation. Others, particularly teenagers, are embarrassed to discuss anything related to menstruation (184).

Consensus guidelines (194) suggest non-steroidal anti-inflammatory medications (NSAIDs) are an effective first line treatment for primary dysmenorrhoea; however, 25% of females have pain that is refractory to NSAIDs (188). Over the counter medications such as paracetamol and nonpharmacologic therapies are also used. Non-pharmacological interventions such as mind-body therapies (Pilates, yoga, tai chi), heat, massage and acupressure are thought to alleviate pain and reduce the need for analgesics (184, 188).

4.13.2 Description of studies

One citation (195) corresponding to one quasi-RCT (Soliman 2017) was identified via the Department's public call for evidence. There were no citations identified in the literature, no ongoing trials and no studies awaiting classification. An overview of the PICO criteria of included studies is provided in Appendix D9.1.1.

Soliman 2017 was conducted in a single centre setting in Egypt. The study enrolled 82 student nurses aged between 20 and 22 years who have regular menstrual cycles of 21 to 35 days and suffer from menstrual pain and discomfort. The mean duration of each menstrual period was between 5.5 and 5.7 days.

Soliman 2017 compared shiatsu with an inactive control (health education about the usual care of menstruation). Enrolled participants were taught by the researchers how to carry out shiatsu therapy, where participants self-stimulated the 'sea of energy' point located in the abdominal area with light pressure, manipulation or light massage by the fingers for one to 2 minutes, 3 times daily during menstruation for 2 consecutive menstrual cycles.

There were no studies found for Comparison 1: shiatsu versus sham.

Results for Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care) are provided in the Summary of Findings tables (Section 4.13.4) (and Appendix F2).

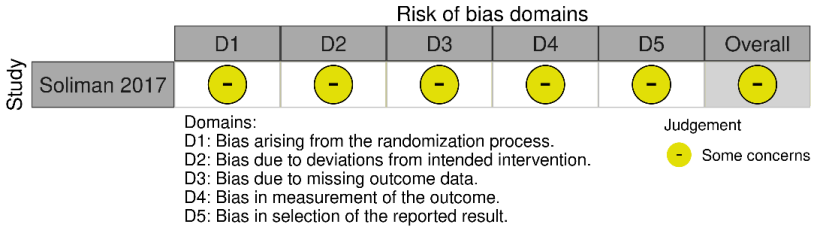
There were no studies found for Comparison 3: shiatsu versus an active comparator.

4.13.3 Risk of bias – per item

The risk of bias of included RCTs for primary dysmenorrhoea is summarised in Figure 34. Details are provided in Appendix D9.1.2.

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

Figure 34 Risk of bias summary: review authors' judgements about each risk of bias item for each included RCT: Primary dysmenorrhoea



4.13.4 Summary of findings and evidence statements

4.13.4.1 Comparison 1 (vs sham)

No studies found.

4.13.4.2 Comparison 2 (vs inactive control)

One quasi-RCT (Soliman 2017) comparing shiatsu to control (usual care) in females with primary dysmenorrhoea was eligible for this comparison and contributed data relevant to 2 outcomes.

Shiatsu compared to control (no intervention, waitlist, usual care) for Dysmenorrhoea

Patient or population: Dysmenorrhoea
Setting: Community
Intervention: shiatsu
Comparison: control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Overall symptom severity assessed with: VAS (higher is worse) follow-up: immediately after treatment	-	SMD **1.61 lower** (2.12 lower to 1.11 lower)	-	82 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	Shiatsu may result in a large improvement in overall symptom severity in females with dysmenorrhoea. ** #
Quality of life - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on quality of life in females with dysmenorrhoea is unknown.
Pain intensity assessed with: VAS (higher is worse) Scale from: 0 to 10 follow-up: immediately after (2 menstrual cycles)	The mean pain score was **2.3 cm**	MD **0.7 cm lower** (1.04 lower to 0.36 lower)	-	82 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,e,f]	Shiatsu may result in little to no difference in pain intensity in females with dysmenorrhoea. *** #
Anxiety – not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on anxiety in females with

Shiatsu compared to control (no intervention, waitlist, usual care) for Dysmenorrhoea

Patient or population: Dysmenorrhoea
Setting: Community
Intervention: shiatsu
Comparison: control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
						dysmenorrhoea is unknown. #
Emotional function - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on emotional function in females with dysmenorrhoea is unknown.
Depression - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on depression in females with dysmenorrhoea is unknown.
Sleep quality - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on sleep quality in females with dysmenorrhoea 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).

** MCID unknown. In the absence of an MCID and clarity about the outcome measure, the effect estimate was considered based on Cohen's guidance, where an SMD of 0.2 is considered a small difference, 0.5 is medium, and 0.8 is large difference (80).
*** MCID for pain (VAS) is 1.0 cm (196).

CI: confidence interval; **MD:** mean difference; **VAS:** visual analogue scale

There were 8 RCTs identified by the included systematic reviews comparing acupressure with control (no intervention, usual care) in people with primary dysmenorrhoea that contributed data to 3 of the 7 critical or important outcomes.

evidence in acupressure is available for this outcome as summarised below (refer to supplementary material (S1.10.4) for further detail).

Acupressure may result in little to no effect on symptom severity in people with dysmenorrhoea.

Acupressure may result in a reduction in pain intensity in people with dysmenorrhoea.

The evidence is very uncertain about the effect of acupressure on anxiety in people with dysmenorrhoea.

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. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is generalisable to the Australian population with some caveats. The available evidence is in self-care shiatsu applied to the 'sea of energy' point. Certainty of evidence not downgraded.

d. Serious imprecision. One study that does not reach the optimal information size. Certainty of evidence downgraded.
e. Publication bias suspected. The evidence is limited to a small number of small trials. 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.
f. Serious imprecision. One study with wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded.

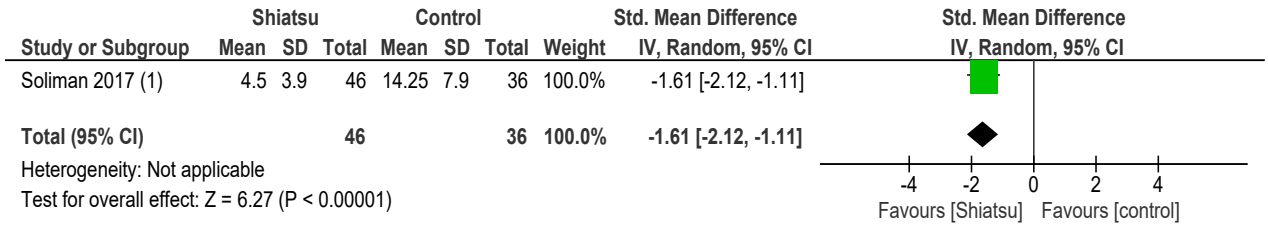
4.13.4.3 Comparison 3 (vs other including active)

No studies found.

4.13.5 Forest plots

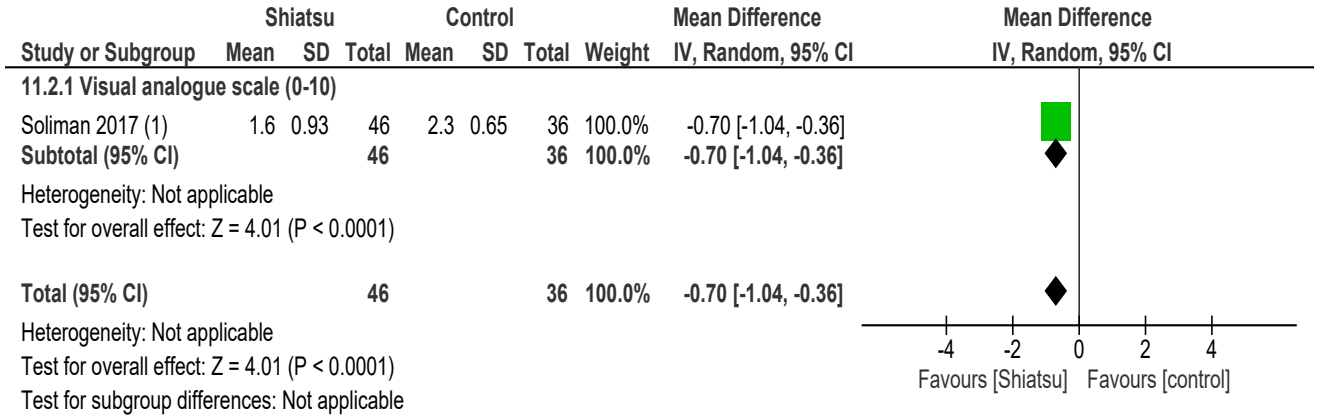
Outcome results related to dysmenorrhoea are presented in Figure 35 (symptom severity) and Figure 36 (pain).

Figure 35 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual care): Dysmenorrhoea – Symptom severity



Footnotes
(1) Measure details unclear.

Figure 36 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual care): Dysmenorrhoea – Pain



Footnotes
(1) Measure details unclear.

4.14 Pregnancy and childbirth

4.14.1 Description of the condition

4.14.1.1 Prenatal period

The prenatal period describes the phase of embryo and foetal development and includes 3 main stages, the germinal period (fertilisation – 2 weeks), embryonic period (3-8 weeks), and the foetal period (8 weeks until birth) (197). By the end of the embryonic period, the embryo has developed basic brain, peripheral and central nervous system structures (198). Once this stage is complete, the embryo enters the final foetal stage, where body systems and physical features are developed (197). This stage corresponds to a female's third trimester (29 – 40 weeks), where many physical and psychological symptoms manifest. Common third trimester complications include low back pain, shortness of breath, heart burn, anaemia, frequent urination, diabetes or weight gain as well as prenatal depression, that affects nearly 20% of females in Australia (199).

Diminished maternal physical and mental wellbeing during pregnancy increases the risk of worse pregnancy outcomes and can also adversely influence the growing foetus. It is thought that in utero effects can provoke epigenic changes induced by foetal exposure to increased levels of stress hormones, inflammatory cytokines, and other factors that lead to an increased the risk of adverse health outcomes in adult life (200-202). Complementary therapies, such as shiatsu, are proposed as solutions to assist with changes females experience as their bodies adapt to the development of a baby, by easing physical and emotional distress, improve body awareness and strengthen the mother-child relationship (203).

4.14.1.2 Labour induction

In most pregnancies, labour commences between 37-40 weeks, but if labour has not commenced after that time, it may need to be induced (204). Post-term pregnancy is defined as a pregnancy that extends beyond 42 weeks of gestation, which increases the risk of foetal and neonatal complications (205). Labour induction in post-term pregnancy is considered a conventional aspect of pregnancy care (204, 206) and aims to prevent stillbirths and perinatal morbidity, as well as reducing post-term maternal risks, such as postpartum haemorrhage and perineal tears (207). According to the most recent Australian statistics in 2016, 0.6% of babies were born post-term, of which labour was induced in 60% of females, spontaneous in 35% of females, and 5% of females had no labour (207). Among the post-term babies, the perinatal death rate was 2.2 per 1000 births, which is higher than the death rate of 1.5 per 1000 births for babies born at 37 to 41 weeks (204, 206).

The method of labour induction depends on the extent of cervical dilation, but is typically comprised of a combination of surgical and pharmacological techniques such as prostaglandin, oxytocin, balloon catheter, and artificial rupture of membranes (204, 208). Complementary therapies, such as herbal preparations, massage and acupuncture may also be used to encourage labour induction.

4.14.2 Description of studies

Two citations (209, 210) corresponding to one RCT (Teimoori 2014) and one NRSI (Schitter 2015) were identified in the literature. There were no ongoing trials and 2 studies (211, 212) awaiting classification that 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 D10.1.1.

One study (Schitter 2015) was conducted at a University Hospital in Switzerland and one study (Teimoori 2014) was conducted in a hospital in Iran. Schitter 2015 enrolled 17 pregnant females (average 32 years) who were at more than 34 weeks gestational weeks and had pregnancy-related complaints. Teimoori 2014 enrolled 288 females (aged between 16 and 42 years) who presented with post-term pregnancy, had reliable estimated due date, non-consequence pregnancy and cephalic presentation (baby is head down and facing the mother's back).

Both studies examined the effect of shiatsu compared to no intervention (control). In Schitter 2015, Watsu (water shiatsu) was performed by specialised therapists, on days one and 4 for 20 minutes in a 35-degree therapy pool. The females were slowly floated back and forth in large circular motions, whilst being supported in supine position by both therapists and floating devices. Participants were instructed to drink 500mLs of water after each session. An ultrasound was performed 20 minutes before and after each session and on day 8 of the study. In Teimoori 2014 shiatsu was conducted for 30 seconds on 3 acupoints (GB21, L14, SP6) by an experienced midwife using hands, thumbs, and an Acu-health device. If labour did not start after 24 hours, the technique was repeated.

There were no studies found for Comparison 1: shiatsu versus sham.

Results for Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care) are provided in the Summary of Findings tables (Section 4.14.4) (and Appendix F2).

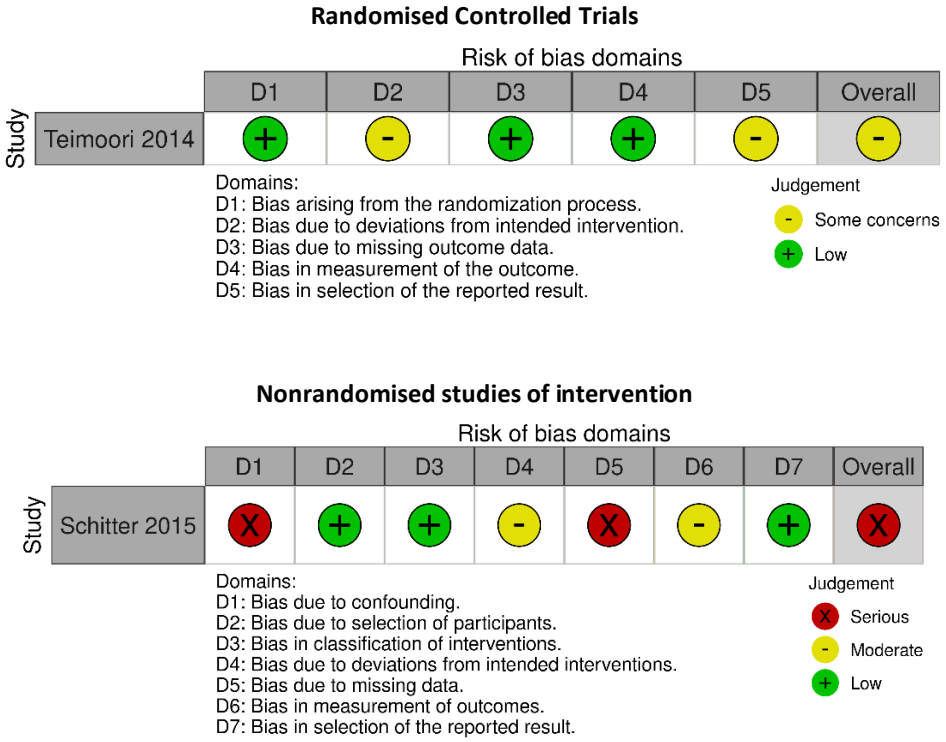
There were no studies found for Comparison 3: shiatsu versus an active comparator.

4.14.3 Risk of bias – per item

The risk of bias of included studies for pregnancy and childbirth is summarised in Figure 37. Details are provided in Appendix D10.1.2.

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

Figure 37 Risk of bias summary: review authors' judgement about each risk of bias item for each included study: Pregnancy and childbirth



4.14.4 Summary of findings and evidence statements

4.14.4.1 Comparison 1 (vs sham)

No studies found.

4.14.4.2 Comparison 2 (vs inactive control)

One RCT (Teimoori 2014) and one NRSI (Schitter 2015) comparing shiatsu to control (no intervention) in pregnant females contributed data relevant to the 3 outcomes.

Shiatsu compared to control (no intervention) for pregnancy and childbirth

Patient or population: Pregnancy and childbirth
Setting: Hospital
Intervention: Shiatsu
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with Control	Risk with Shiatsu				
Birth experience assessed with: Duration of labour (hrs) (higher is worse) follow-up: within 24-hours of intervention	The mean duration of labour was **13.2** hours	MD **2.2 hours more** (NR to NR)	-	288 (1 RCT)	⊕◯◯◯ VERY LOW[a,b,c,d,e]	The evidence is very uncertain about the effect of shiatsu on duration of labour in pregnant females. #
Quality of life assessed with: SF-36 - physical component score (higher is better) Scale from: 0 to 100 follow-up: 8 days	The mean change in physical component score was **0.20**	MD **1.80 lower** (7.99 lower to 4.39 higher)	-	17 (1 NRSI)	⊕◯◯◯ VERY LOW[b,e,f,g,h]	The evidence is very uncertain about the effect of shiatsu on quality of life (physical) in pregnant females.
Quality of life assessed with: SF-36 - mental component score (higher is better) Scale from: 0 to 100 follow-up: 8 days	The mean change in mental component score was **3.1**	MD **0.20 higher** (3.41 lower to 3.81 higher)	-	17 (1 NRSI)	⊕◯◯◯ VERY LOW[b,e,f,g,h]	The evidence is very uncertain about the effect of shiatsu on quality of life (mental) in pregnant females.
Pain - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on pain in pregnant females is unknown. #
Perceived stress assessed with: VAS (higher is worse) Scale from: 0 to 100 follow-up: 8 days	The mean change in perceived stress score was **0.9**	MD **3.0 lower** (5.64 lower to 0.36 lower)	-	17 (1 NRSI)	⊕◯◯◯ VERY LOW[b,e,f,g,h]	The evidence is very uncertain about the effect of shiatsu on perceived stress in pregnancy.
Functional capacity - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on functional capacity in pregnant females is unknown.

Shiatsu compared to control (no intervention) for pregnancy and childbirth

Patient or population: Pregnancy and childbirth
Setting: Hospital
Intervention: Shiatsu
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with Control	Risk with Shiatsu				
Maternal morbidity - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu during pregnancy on maternal morbidity is unknown.
Fetal health - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu during pregnancy on fetal health at birth 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).

CI: confidence interval; **MD:** mean difference

There were 18 RCTs identified by the included systematic reviews that compared acupressure with control (usual care) in pregnant females (requiring labour induction or in labour) that were eligible for this comparison, of which 14 RCTs contributed data relevant to 2 outcomes. Refer to supplementary material (S1.11.4) for further details.

evidence in acupressure is available for this outcome as summarised below.:

Acupressure may result in a reduction in the duration of labour in pregnant females.

Acupressure may result in a slight reduction in labour pain in pregnant females.

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 not at high risk of bias. Certainty of evidence not downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. Serious indirectness. The evidence is applicable to the target population with some caveats. The available evidence is in post-term mothers with the application of shiatsu to 3 acupoints for 30 seconds to induce labour within 24-hours. It is not clear if the evidence is applicable to non-complicated pregnancies undergoing spontaneous labour. Certainty of evidence downgraded.
d. Serious imprecision. In the absence information to make a judgement about confidence intervals, imprecision is suspected. Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to one study with insufficient reporting of data. 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.
f. Very Serious risk of bias. One NRSI at serious risk of bias relating to likelihood of residual confounding. Certainty of evidence downgraded 2 levels.
g. No serious indirectness. The evidence is applicable to the target population with some caveats. The intervention is as Watsu, a service component of shiatsu that could be sensibly applied. Certainty of the evidence not downgraded.
h. Serious imprecision. Small study (17 participants) with wide confidence intervals (lower bounds overlap with no important difference). Certainty of evidence downgraded.

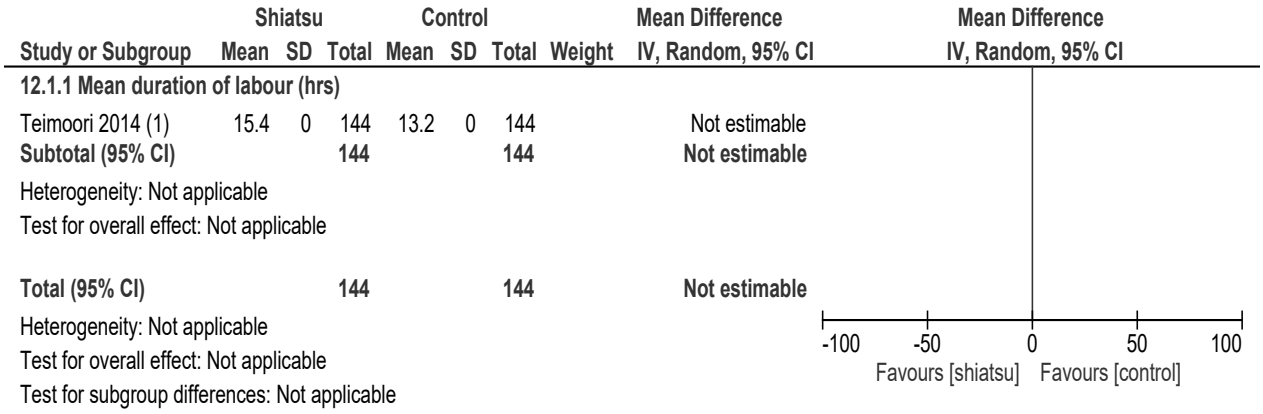
4.14.4.3 Comparison 3 (vs other including active)

No studies found.

4.14.5 Forest plots

Outcome results related to pregnancy are presented in Figure 38 (birth experience), Figure 39 (quality of life) and Figure 40 (perceived stress).

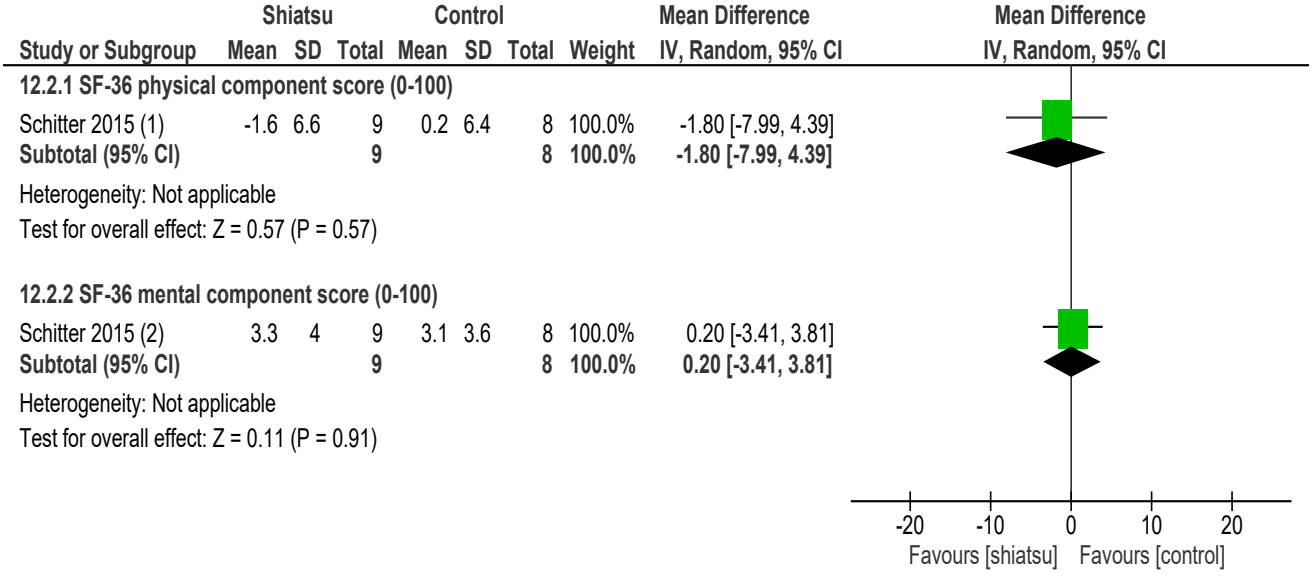
Figure 38 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Pregnant females – Birth experience



Footnotes

(1) Authors state the difference is not significant (p>0.05). No other data reported.

Figure 39 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Pregnant females – Quality of life

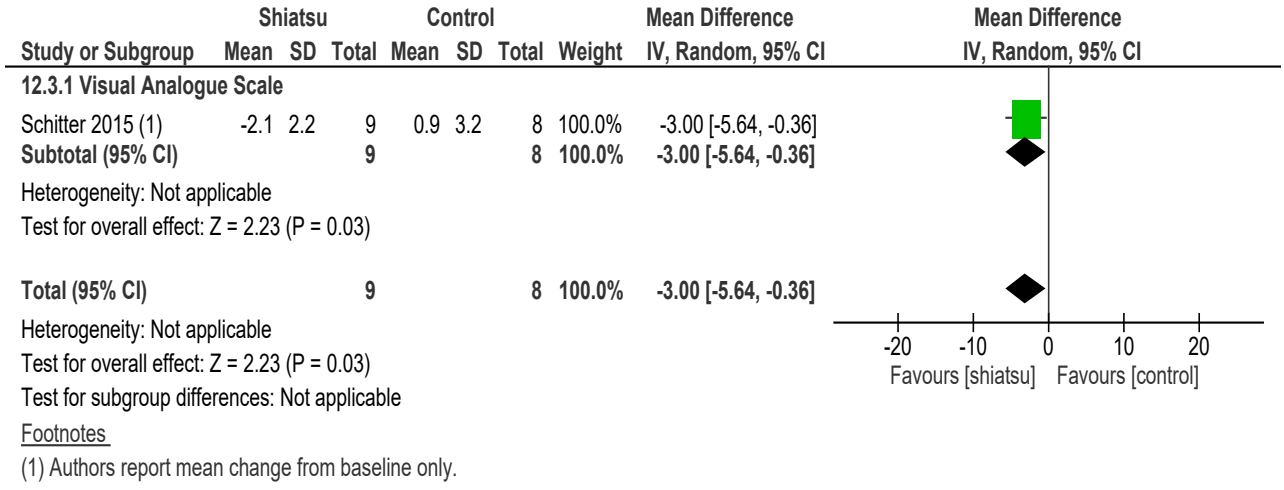


Footnotes

(1) Authors report mean change from baseline only.

(2) Authors report mean change from baseline only.

Figure 40 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual activities): Pregnant females – Perceived stress



Footnotes

(1) Authors report mean change from baseline only.

4.15 Postpartum care

4.15.1 Description of the condition

Maternity care relates to the provision of care to women in the antenatal, intrapartum and postnatal period (up to six weeks after birth) to manage conditions associated with the fetus, or to issues associated with labour and birth (213). In 2018 there were 303,029 babies born to 298,630 mothers in Australia. The health of both mother and baby can have significant short and long-term implications (214). Breastfeeding is also considered essential for newborn care, providing sufficient nutrition to support growth and development (218-220).

The mechanical stress on the body experienced in childbirth, has long been considered risk factors for the development of pelvic floor injury and dysfunction, such as stress urinary incontinence (222). Health promoting behaviours before and during pregnancy, as well as following birth, may reduce the likelihood of negative outcomes for both mothers and babies, improving positive outcomes and experiences. Such behaviours include regular physical activity (223), nutrition (224), support networks (225) and stress management (226). Breast massage (e.g. shiatsu) and acupoint stimulation have also been suggested to be effective in increasing milk expression for mothers of newborns, by increasing blood circulation and facilitating the flow of milk supply (210).

4.15.2 Description of studies

One citation (210) corresponding to one RCT (Sheng 2021) was identified in the literature. There were no ongoing trials, one study awaiting classification (213) that was published in a language other than English and no additional studies identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D10.3.1.

One study (Sheng 2021) was conducted at a hospital in China. The study enrolled 33 females aged older than 18 years who had a preterm newborn (gestation age of younger than 34 weeks) in the neonatal intensive care unit. Mothers were excluded if they were unable to breastfeed, reluctant to express milk, had pregnancy complications that may affect expression, or had postpartum depression. The mean age of participants was around 30 to 31 years, with 13 out of 33 (39%) having undergone caesarean section. Of the newborns, the mean birthweight was 1.58 kilograms in the control group and 1.73 kilograms in the intervention group[2], with 10 (21%) born from multiple pregnancies.

Sheng 2021 compared breast massage and acupoint stimulation to no intervention (control), delivered as an adjunct to education and support. The intervention was initially performed by a nurse, who taught the mothers and family members to perform the intervention. Breast massage was performed less than 24 hours after delivery, prior to expression (6 to 8 times per day), for 15 to 20 minutes (each breast). The massage intervention was performed by massaging the breast in a circular motion with fingers and palm (20 minutes), touching and shaking breast gently (20 times), patting the breast with 4 finger pulps from the periphery to centre (20 times), and combing the breast with 5 fingers from the root to the nipple (20 times). Acupoint stimulation was performed less than 24 hours after delivery, 3 times a day, for 3 to 5 minutes per acupoint (Rugen ST18, Tanzhong CV17, Hegu LI4, and Shaoze SI1).

There were no studies found for Comparison 1: shiatsu versus sham.

Results for Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care) are provided in Summary of Finding (Section 4.15.4) (and Appendix F2).

There were no studies found for Comparison 3: shiatsu versus an active comparator.

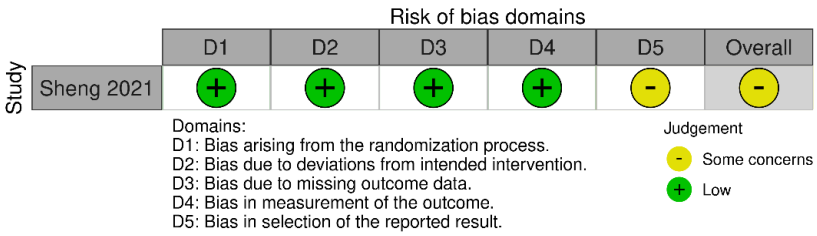
4.15.3 Risk of bias – per item

The risk of bias of included RCTs for newborn mothers is summarised in Figure 41. Details are provided in Appendix D10.3.2.

[2] The original report lists the mean birthweights as 1.58 and 1.73 grams. Given the mean birthweight of a preterm infant is typically < 2500 g (or 2.5 kg), this was assumed to be in error, and should be kilograms.

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

Figure 41 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Postpartum care



4.15.4 Summary of findings and evidence statements

4.15.4.1 Comparison 1 (vs sham)

No studies found.

4.15.4.2 Comparison 2 (vs inactive control)

There was one study found comparing shiatsu with control (no intervention, waitlist, usual care) in newborn mothers but the study did not measure or report any outcomes considered critical or important for this review, thus the effect of shiatsu on the following outcomes in newborn mothers is unknown.

The following outcomes were selected (in order of importance):

- Birth experience
- Pelvic floor muscle function
- Pelvic pain and dysfunction
- Quality of life

4.15.4.3 Comparison 3 (vs other including active)

No studies found.

4.16 Burn injuries

4.16.1 Description of the condition

Burn related injuries account for approximately 50,000 hospital admissions in Australia annually, with around 2500 people requiring specialist burn management (214). A burn occurs when the skin is damaged by heat, radiation, radioactivity, electricity, friction, or chemicals, causing the skin cells to die (215). Burns are most likely to occur in the home or workplace, and injuries range from mild to life-threatening (216). Each degree (first, second, third or fourth) is classified by the severity of the burn, with first degree burns being superficial (erythema to the epidermis layer of the skin), second degree burns being partial thickness (erythema and blistering to the epidermis and dermis), third degree burns being full thickness (loss of sensation and white/blackened dermis) and forth degree burns going deeper than the skin to affect muscles and bones (217).

First and second-degree burns are usually treated with first aid – running cool water over the affected area, simple analgesia, and wound care – that includes application of a dressing to cover the wound, with or without antimicrobial properties (218). Burns greater than 3 inches in width and burns to the face, neck, joints, hands, feet and groin may require additional medical treatment that includes regular dressing changes and debridement (removal of dead skin from the burn area) (218). Third- and fourth-degree burns may be life-threatening and require urgent medical attention, as they are associated with an increased risk of infection, dehydration, systemic shock, hypothermia, hypovolaemia and death (218).

Complementary and alternative therapies associated with burn injury management include topical application of herbal ointments, such as aloe vera or calendula to sooth and heal (219), mind-body therapies (e.g. massage, shiatsu) to promote relaxation and reduce pain, itching and anxiety associated with wound care (220, 221) or to minimise hypertrophic scarring (222).

4.16.2 Description of studies

Two citations (223, 224) corresponding to one quasi-RCT (Ardabili 2014) were identified in the literature. There were no ongoing trials, no studies awaiting classification and no additional studies identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D12.1.1.

Ardabili 2014 was conducted in a single inpatient setting in Iran. The study enrolled 120 participants with burn injuries covering between 10% to 45% total body surface area, who had anxiety associated with dressing changes. Baseline characteristics of participants were not reported, but the authors mention that male and females were included.

Ardabili 2014 examined the effect of shiatsu massage with no intervention (control). 3 shiatsu massage groups were included: hand and leg, hand only, or leg only. Shiatsu massage was performed on healthy skin for a total of 20 minutes. The study does not report how many sessions participants underwent, but it's assumed to be one session before wound dressing change. It is unclear if analgesics were used as a co-intervention.

There were no studies found for Comparison 1: shiatsu versus sham.

Results for Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care) are provided in the Summary of Findings tables (Section 4.16.4) (and Appendix F2).

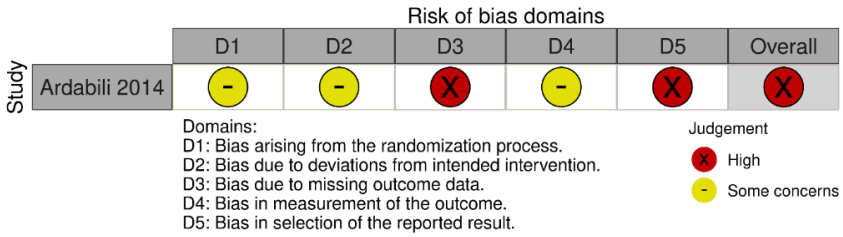
There were no studies found for Comparison 3: shiatsu versus an active comparator.

4.16.3 Risk of bias – per item

The risk of bias of included RCTs for burn injuries is summarised in Figure 42. Details are provided in Appendix D12.1.2.

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

Figure 42 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Burn injuries



4.16.4 Summary of findings and evidence statements

4.16.4.1 Comparison 1 (vs sham)

No studies found.

4.16.4.2 Comparison 2 (vs inactive control)

One quasi-RCT (Ardabili 2014) in people with burn injuries was eligible for this comparison and contributed data relevant to one outcome.

Shiatsu compared to control (no intervention, waitlist, usual care) for Burn injuries

Patient or population: burn injuries
Setting: hospital
Intervention: shiatsu
Comparison: control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Pain intensity assessed with: VAS (higher is worse) Range from: 0 to 100 Follow-up: immediately after treatment	The pain intensity score in the shiatsu group was lower than that of the control group. No further *data* were presented.			120 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of shiatsu on pain in people with burn injuries.
Quality of life - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on quality of life in people with burn injuries is unknown.
Functional capacity - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on functional capacity in people with burn injuries is unknown.

Shiatsu compared to control (no intervention, waitlist, usual care) for Burn injuries

Patient or population: burn injuries
Setting: hospital
Intervention: shiatsu
Comparison: control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Sleep quality - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on sleep quality in people with burn injuries is unknown.
Burden of care - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on burden of care in people with burn injuries is unknown.
Scar issues - not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on scar issues in people with burn injuries 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).

CI: confidence interval; **QoL:** quality of life; **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. One RCT (100% weight) at high risk of bias. Certainty of evidence downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is applicable to the target population with some caveats. The available evidence is in people with burns to 10% to 45% total body surface area (age, sex not reported) so may not be directly applicable to all people with burns injury but could be sensibly applied. Certainty of evidence not downgraded.
d. Serious imprecision. Small study with wide confidence intervals. Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. 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.

4.16.4.3 Comparison 3 (vs other including active)

No studies found.

4.17 Recovery after minimally invasive surgery

4.17.1 Description of the condition

Recovery after surgery is dependent on numerous factors, including a person's age, the type of surgery, and pre-operative physical and mental health. Post-operative complications may be general or specific to the type of surgery performed, but excessive bleeding, fever, atelectasis (complete or partial collapse of a lung), infection, embolism and deep vein thrombosis are common (225). In addition, surgical complications can arise from anaesthesia (226). Specifically, anaesthetic medications can cause chills, agitation, and short-term post-operative gastrointestinal dysfunction, frequently causing abdominal distension and nausea and vomiting, which is commonly managed by hydration, fasting and anti-emetics (227).

Minimally invasive surgery has gradually become the intervention of choice for many surgical procedures, as it is associated with fewer post-operative complications than conventional, open surgery (226, 228). Comparatively, minimally invasive surgery is characterised by smaller wounds, fewer stiches, reduced pain or soreness around the incision site, and a faster recovery time, due to less injury to tissues and organs (226, 228-230). This is advantageous for elderly and high-risk populations, who benefit from reduced surgical trauma and a shorter time in hospital (228). The indications for minimally invasive surgery continues to expand, but it is routinely used for gastrointestinal, gynaecological, neurological, thoracic, urologic, otolaryngology and orthopaedic procedures (226).

Pharmacological interventions are typically administered to manage post-operative pain, nausea and vomiting; however, relaxation techniques, acupuncture and other complementary methods are increasingly used to help promote both physical and mental recovery after surgery.

4.17.2 Description of studies

Four citations (229-232) corresponding to 4 RCTs (Ruan 2021, Sui 2019, Xia 2014, Zhenqing 2019) were identified in the literature. There were no ongoing trials and 2 studies awaiting classification (233, 234) that 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 D13.1.1.

All 4 studies were conducted in a hospital setting in China. Two (2) studies enrolled participants after laparoscopic surgery. Ruan 2021 enrolled 160 participants aged between 21 and 58 years who were recovering after laparoscopic surgery for gynaecological indications. During surgery the pneumoperitoneum had been insufflated with 10 to 20 litres of carbon dioxide. Zhenqing 2019 enrolled 98 participants aged between 30 and 60 years who were recovering after a laparoscopic cholecystectomy for gallbladder disease. One study (Xia 2014) enrolled 92 participants recovering after ureteroscopic homium laser lithotripsy to treat ureteral calculus. The mean age of participants was 32 years. One study (Sui 2019) enrolled 398 participants who had video assisted thoracoscopic surgery (VATS) due to spontaneous pneumothorax. Participants were aged between 18-57 years.

All 4 studies examined the effect of acupoint massage compared to no intervention (control) delivered as adjunct to standard post-operative nursing care. In one study (Ruan 2021) acupoint massage was performed 6 hours post-operatively to 4 acupoints (Zusanli, Neiguan, Zhongyu, Sanyinjiao), with each being massaged 3 times a day until first anal exhaust. In Xia 2014, acupoint massage was performed for 3 minutes on 4 acupoints (Shenshiu, Gaohuang, Feishu, Tiantu) at 2-3 hours, 6 hours, 10 hours and 20 hours post-surgery. Acupoint massage was performed by pressing the acupoints with a thumb, gradually increasing the strength and then gradually releasing the pressure, with aim to inflict pain and numb sensations. In both studies (Ruan 2021, Xia 2014) the authors do not specify who delivered the intervention.

In Sui 2019, a nurse performed post-operative acupoint stimulation on days 1, 3, 5 and 30. The authors state that '20 actions' were completed per round, by hitting the acupoints with empty palms and pressing them 5 times with a forefinger. In Zhenqing 2019, an experienced physician conducted acupoint massage 3 hours prior to anaesthesia according to standard protocols of World Federation of Acupuncture Moxibustion Societies. The intervention was performed for 10 minutes and repeated 3 times. Subsequently, acupressure application was performed with acupressure wrist bands at specific acupoints.

There were no studies found for Comparison 1: shiatsu versus sham.

Results for Comparison 2: shiatsu versus inactive control (no intervention, waitlist or usual care) are provided in the Summary of Findings tables (Section 4.17.4) (and Appendix F2).

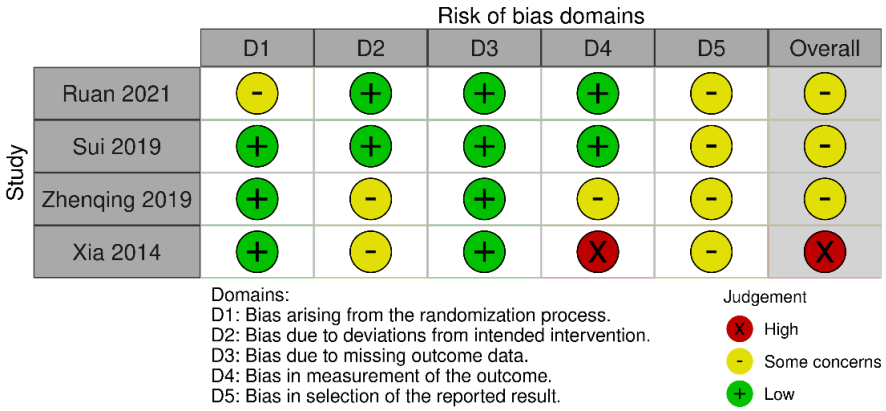
There were no studies found for Comparison 3: shiatsu versus an active comparator.

4.17.3 Risk of bias – per item

The risk of bias of included RCTs in people recovering after minimally invasive surgery is summarised in Figure 43. Details are provided in Appendix D13.1.2.

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

Figure 43 Risk of bias summary: review authors' judgement about each risk of bias item for each included study: Recovery after minimally invasive surgery



4.17.4 Summary of findings and evidence statements

4.17.4.1 Comparison 1 (vs sham)

No studies found.

4.17.4.2 Comparison 2 (vs inactive control)

Four studies (Ruan 2021, Sui 2019, Xia 2014, Zhenqing 2019) comparing acupoint massage with no intervention in people recovering after minimally invasive surgery were eligible for this comparison and contributed data to three outcomes.

Shiatsu compared to control (no intervention, waitlist, usual care) for Recovery after minimally invasive surgery?

Patient or population: recovery after minimally invasive surgery
Setting: hospital
Intervention: shiatsu
Comparison: control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Clinical recovery – not reported	-	-	-	(0 studies)	-	No studies found. The effect of shiatsu on clinical recovery in people recovering after minimally invasive surgery is unknown.
Postoperative nausea and vomiting – total episodes (higher is worse) Follow-up: 6-days	490 per 1000	**225 per 1000** (122 to 407) ARD **264 fewer per 1000** (367 fewer to 83 fewer)	**RR 0.46** (0.25 to 0.83)	98 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	Shiatsu may reduce postoperative nausea and vomiting in people recovering after minimally invasive surgery.**
Postoperative pain - number with pain (higher is worse) Follow-up: 24 hours to 6 days	400 per 1000	**128 per 1000** (72 to 224) ARD **272 fewer per 1000** (328 fewer to 176 fewer)	**RR 0.32** (0.18 to 0.56)	190 (2 RCTs)	⊕⊕◯◯ LOW [b,d,e,f,g]	Shiatsu may reduce postoperative pain people recovering after minimally invasive surgery.**
Bowel recovery assessed with: time between first and last defecation (higher is worse)	The mean bowel recovery time was **45.96** hours	MD **11.95 hours less** (14.33 less to 9.57 less) ^	-	160 (1 RCT)	⊕⊕⊕◯ MODERATE [a,b,e,h,j]	Shiatsu probably improves bowel recovery time in people recovering after minimally invasive surgery. ***
Pulmonary function assessed with: Oxygen saturation (higher is best) Scale from: 0 to 100 follow-up: end of surgery	The mean $Sp0_2$ was **95.2%**	MD **2.20% higher** (2.54 higher to 1.86 higher)	-	98 (1 RCT)	⊕⊕◯◯ LOW [a,b,d,e,i]	Shiatsu may result in a slight improvement in immediate postoperative oxygen saturation in people undergoing minimally invasive surgery.****

Shiatsu compared to control (no intervention, waitlist, usual care) for Recovery after minimally invasive surgery?

Patient or population: recovery after minimally invasive surgery
Setting: hospital
Intervention: shiatsu
Comparison: control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with control	Risk with shiatsu				
Pulmonary function assessed with: Oxygen saturation (higher is best) Scale from: 0 to 100 follow-up: 30 days	The mean Sp02 was **97.01%**	MD **0.55% higher** (1.29 higher to 0.19 lower)	-	398 (1 RCT)	⊕⊕⊕◯ MODERATE a,b,e,i,j	Shiatsu probably results in little to no difference in oxygen saturation in people recovering after minimally invasive surgery due to spontaneous pneumothorax. ****

*__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).

** A 25% relative reduction was considered important (i.e. RR < 0.75).
*** Effect estimate was considered based on Cohen's guidance, where an SMD of 0.2 is considered a small difference, 0.5 is medium, and 0.8 is large difference (80).
**** the MCID for $Sp0_2$ is estimated to be 4% (235).

^ SMD –1.55; 95% CI –1.90, –1.19

ARD: absolute risk difference; **CI:** confidence interval; **MD:** 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 not at high risk of bias. Certainty of the evidence not downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is applicable to the target population with some caveats. The available evidence is in people recovering after a laparoscopic cholecystectomy for gallbladder disease with acupoint massage and application prior to anaesthesia. This may not be applicable to all people recovering from surgery but could be sensibly applied. Certainty of evidence not downgraded.
d. Serious imprecision. Single study with wide confidence intervals (upper and lower bound overlap with both large and small important difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. There is a strong suspicion of non-reporting likely to be related to *p* value, direction, or magnitude of effect. Certainty of evidence downgraded.
f. No serious risk of bias. One RCT at high risk of bias contributing 40% of data. Removal of this study does not materially change the result. Certainty of the evidence not downgraded.
g. No serious indirectness. The evidence is applicable to the target population with some caveats. The available evidence is in people recovering after a laparoscopic cholecystectomy for gallbladder disease or ureteroscopic homium laser lithotripsy to treat ureteral calculus. This may not be applicable to all people recovering from surgery but could be sensibly applied. Certainty of evidence not downgraded.
h. No serious indirectness. The evidence is applicable to the target population with some caveats. The available evidence is in people recovering after laparoscopic surgery for gynaecological indications. This may not be applicable to all people recovering from surgery but could be sensibly applied. Certainty of evidence not downgraded.
i. No serious indirectness. The evidence is applicable to the target population with some caveats. The available evidence is in patients who had video assisted thoracoscopic surgery (VATS) due to spontaneous pneumothorax with acupoint stimulation applied after surgery. This may not be applicable to all people recovering from surgery but could be sensibly applied. Certainty of evidence not downgraded.
j. No serious imprecision. Certainty of the evidence not downgraded.

4.17.4.3 Comparison 3 (vs other including active)

No studies found.

4.17.5 Forest plots

Outcome results related to recovery after minimally invasive surgery are presented in Figure 44 (nausea and vomiting), Figure 45 (postoperative pain), Figure 46 (bowel recovery) and Figure 47 (respiratory function).

Figure 44 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual care): Recovery after minimally invasive surgery – postoperative nausea and vomiting

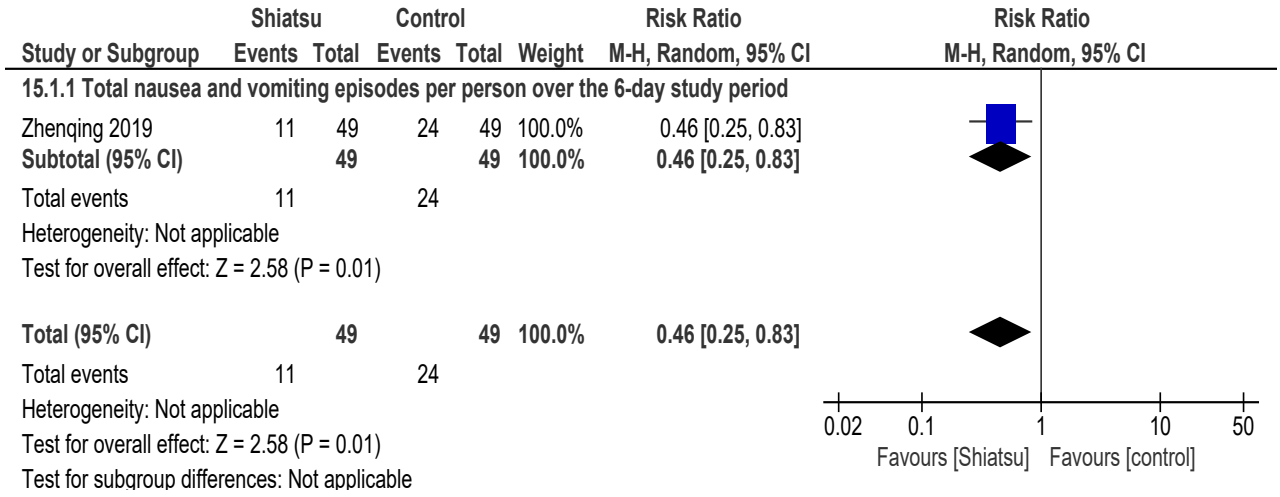


Figure 45 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual care): Recovery after minimally invasive surgery – post-operative pain

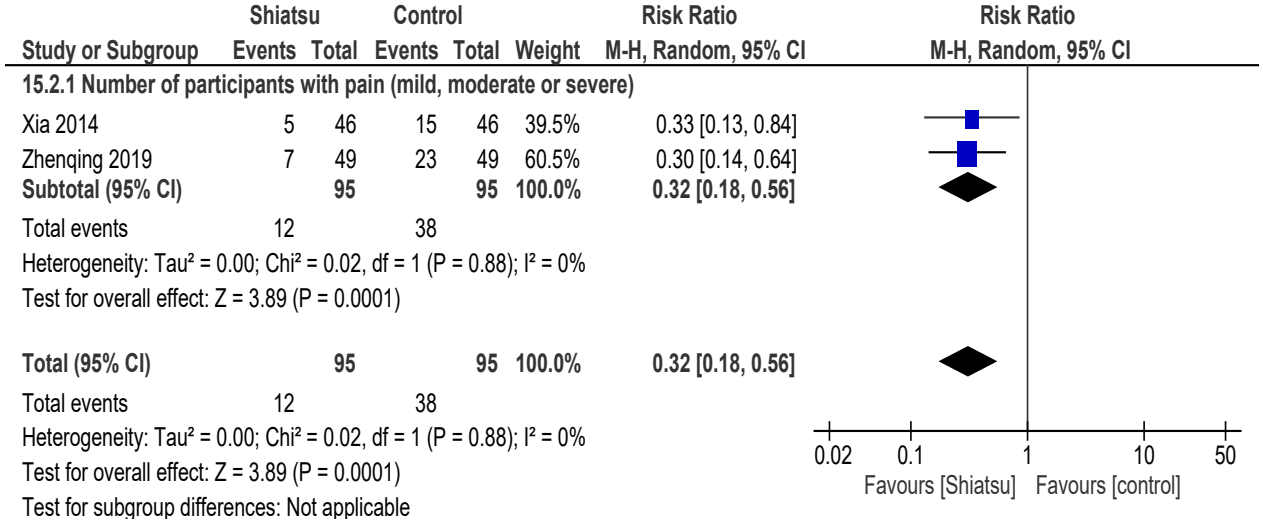


Figure 46 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual care): Recovery after minimally invasive surgery – Bowel recovery

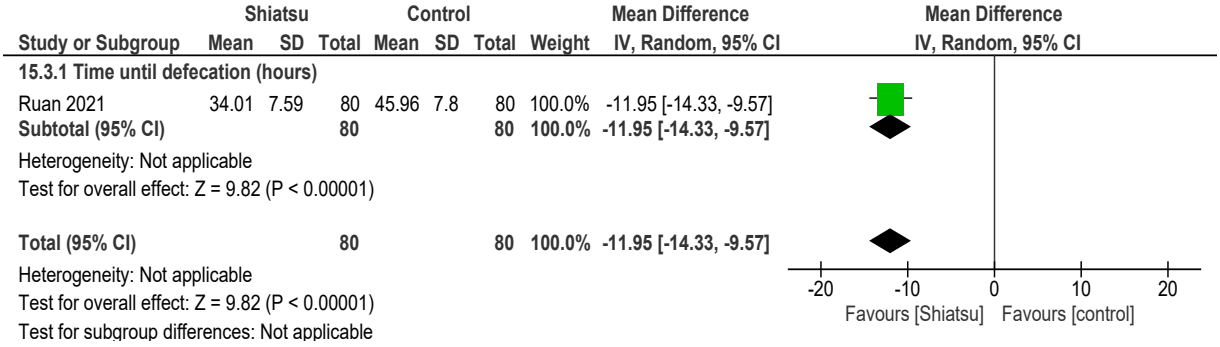
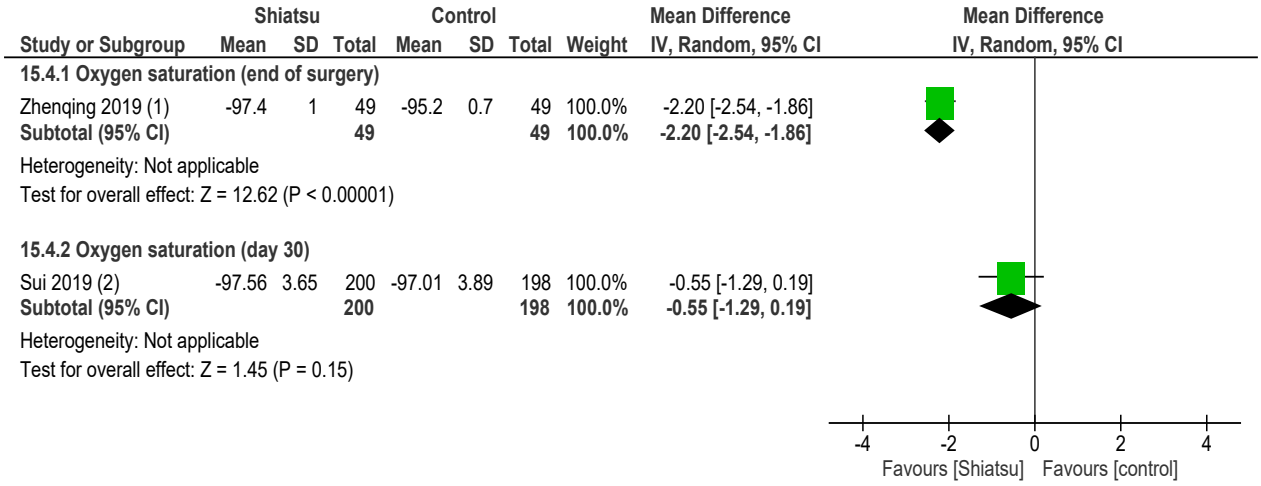


Figure 47 Forest plot of comparison: Shiatsu vs control (no intervention, waitlist, usual care): Recovery after minimally invasive surgery – Pulmonary function



Footnotes

(1) values inverted for graphing purposes only.

(2) values inverted for graphing purposes only.

5 Discussion

5.1 Summary of main results

We conducted a systematic review of RCTs and NRSIs to evaluate the effectiveness of shiatsu for 17 clinical or preclinical conditions identified in the literature. We identified 27 studies that were included in the results. Of these studies, 16 studies that included either critical or important outcomes were included in the final analysis and are presented in the summary of findings tables. The 2 comparators of interest were sham and 'inactive' control. There were no studies found for Comparison 1: shiatsu versus sham. For the synthesis, there were 16 RCTs covering 16 conditions that compared shiatsu with an inactive control (no intervention, waitlist or usual care).

Results for studies with active comparators are presented in Appendix F2 and narratively described in the results section. However, 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.

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.

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

This review identified 16 conditions for which the evidence provided moderate or low certainty about the effect of shiatsu on an outcome considered critical or important by NTWC.

Compared with a sham intervention, the effect of shiatsu is unknown.

Compared with an inactive control (no intervention, waitlist or usual care), the evidence provides:

- moderate certainty that shiatsu probably results in:
  - a moderate (10-20%) improvement in bowel recovery (1 RCT, 160 participants) in people recovering after minimally invasive surgery.
- low certainty that shiatsu may result in:
  - a large (> 20%) improvement in quality of life (1 RCT, 101 participants) in people with functional constipation
  - a large (> 20%) reduction in symptom severity in people with dysmenorrhoea (1 RCT, 82 participants)
  - a moderate (10-20%) reduction in waist circumference (1 RCT, 54 participants) in people with obesity
  - a moderate (10-20%) improvement in quality of life (1 RCT, 63 participants) and a moderate (10-20%) reduction in symptoms of stress (1 RCT, 63 participants) in people with stress
  - a moderate (10-20%) reduction in disability in people rehabilitating after stroke (1 RCT, 40 participants)
  - a moderate (10-20%) improvement in post-operative nausea and vomiting (1 RCT, 98 participants) and a moderate (10-20%) improvement post-operative pain (2 RCTs, 190 participants) in people recovering after minimally invasive surgery

  - a slight (<10%) improvement in cognitive function (1 RCT, 68 participants) in people with hypertension
  - a slight (<10%) improvement in systolic and diastolic blood pressure (1 RCT, 42 participants) in people with obesity
  - a slight (< 10%) improvement in post-operative respiratory function (1 RCT, 98 participants) in people recovering after minimally invasive surgery.

- low certainty that shiatsu may result in little (to no) change in:
  - pain, disability or improving quality of life (1 RCT, 59 participants) in people with chronic musculoskeletal pain
  - pain intensity (1 RCT, 82 participants) in people with dysmenorrhoea
  - labour duration (1 RCT, 288 participants) in pregnant females.

Compared with an inactive control, the evidence provides very low certainty of the effect of shiatsu for 21 out of the 100 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 100 outcomes prioritised as critical or important in this review, 60 were not addressed by any studies comparing shiatsu to inactive control, and therefore the effect of shiatsu compared to inactive control on these 60 outcomes is unknown.

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

Overall, shiatsu may provide people who receive it with some benefit for a small number of relevant outcomes across 7 conditions (between one and 4 for a given condition) when compared with an inactive control. In many cases the true size of the effect estimate was uncertain (21 outcomes) or unknown (60 outcomes). Many of the effect estimates were based on results from fewer than 2 RCTs (range 15 to 288 total participants) which can impact the precision of the results. For several outcomes, a clinically important difference was not observed (possibly relating to study design, size or duration).

This review identified 8 conditions for the supplementary overview of acupressure that were also identified in the systematic review for the effectiveness of shiatsu, and for which there was evidence about the effect of acupressure on an outcome considered critical or important by NTWC. We are unable to comment about the consistency of results reported in studies in acupressure and the role it plays when used as part of the overall practice of shiatsu. Compared with an inactive control (no intervention) the results for acupressure were inconsistent with the effect reported for shiatsu for 4 outcomes[3] or the certainty of evidence was very low or unknown for either shiatsu or acupressure such that a clear judgement about consistency of the effect could not be made.

5.2 Overall completeness and applicability of evidence

This review aimed to identify the available evidence on the effectiveness of shiatsu. Most studies identified were RCTs and very few NRSIs. There were no studies found comparing shiatsu with a sham therefore only studies that assessed shiatsu versus inactive control (no intervention, waitlist, usual care) were included in the synthesis. Eleven (11) studies comparing shiatsu 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. Notably, there were no (or very few studies) found for several conditions (or symptoms) commonly cited by practitioners as being of importance to Australians including, mental health (e.g., anxiety, depression), musculoskeletal pain, and fatigue (8).

To supplement the evidence for shiatsu, systematic reviews examining the effectiveness of acupressure in conditions identified in shiatsu were also considered. There were 131 systematic reviews covering numerous conditions not prioritised for analysis. These reviews were listed in an inventory titled *Systematic reviews of acupressure not included in the synthesis (no analogous shiatsu population)* (Appendix C5, Table C-16).

[3] functional constipation (quality of life); dysmenorrhoea (symptom severity, pain); pregnancy (labour duration)].

Databases in languages other than English were not searched. Studies identified through English databases but published in a language other than English were not translated and were not included in the synthesis. These studies (and reviews) were listed in an inventory for completeness (Appendix C3.1.2 and Appendix C3.2.2). There were 39 studies for shiatsu and 12 reviews of acupressure identified in a language other than English.

The available evidence for shiatsu was predominantly from China. Other countries represented included Taiwan, Iran, Egypt, Italy, Japan, Brazil, Switzerland and New Zealand. There were no studies from Australia. Based on their descriptions, all studies examined shiatsu delivered in a manner that would be considered generally applicable to the Australian context. The treatment provider was often an experienced therapist or nurse trained in shiatsu massage. Shiatsu, acupoint or meridian massage was typically applied using pressure to specified trigger points, although in some cases this was individualised to the participant. The application of pressure varied from 20 seconds to between 3 and 5 minutes (or not specified), with treatment sessions being between 15 and 60 minutes in duration and treatment administered between one and 3 times per week. Outcomes were typically measured at the beginning and end of treatment, which varied from between 10 days and 10 months. No studies provided any longer-term data (more than 10-months).

For acupressure, details about the intervention applied within the eligible studies (such as the acupoints, timing, pressure intensity etc.) were not investigated in this review and were rarely described in detail in the included systematic reviews. This means different applications of acupressure have not been considered as a potential effect modifier in the overview (e.g. no subgroup analyses based on intervention components). For example, acupressure could be self-applied, delivered via an acupressure device (e.g. wrist band) or by a researcher certified in acupressure. The acupoint pressure could last between 2 to 5 seconds or up to 30 to 40 minutes with the focus being on one to numerous acupoints (e.g. SP6, L14). The intensity of pressure applied to the acupoint also varied, with most reviews not providing any information about this detail, but some reviews noted the pressure being adapted to the participants pain threshold, until the skin changed colour, or was measured electronically.

In general, the included studies provided a clear description of the condition and outcome measured. However, for each population, the evidence synthesis was typically comprised of one or 2 studies and was limited to a small number of outcomes. For the studies comparing shiatsu with an inactive control, 60 out of the 100 outcomes prioritised as critical or important, were not measured or reported. The results for 2 conditions (diabetes, postpartum care) could not be determined, as no studies were found with outcomes that were considered critical or important for this review.

For the studies comparing acupressure with either a sham intervention or an inactive control, 74 out of the 100 outcomes prioritised as critical or important, were not measured or reported in the reviews. More than one-third of the studies included in the synthesis for acupressure (34 RCTs) were conducted in pregnant females and there were no studies found for 7 conditions (diabetes, obesity, stress, headache disorders, stroke recovery, postpartum care, and burn injuries).

Studies included in this review are those published up until on 21 April 2021. At the time of the search, for shiatsu, an additional 42 studies were awaiting classification (39 of these were in a language other than English) and an additional 14 studies (~1000 target participants) were recorded as ongoing (registered but not published). These studies (awaiting classification and ongoing) appear comparable to those included in the evidence synthesis in terms of population, sample size, study duration and outcomes measured. For acupressure, an additional 25 reviews were awaiting classification, and an additional 11 reviews were recorded as ongoing (protocol registered but not complete). Given the large amount of evidence for acupressure that was not yet evaluated at the time of the search (131 reviews in conditions not identified in shiatsu) it is unknown whether studies included within those reviews would provide evidence about the benefits (or lack thereof) of acupoint massage in populations not identified in the review of shiatsu.

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) and suspected publication bias (relating to the likelihood that studies with negative outcome results were not published at the time of the search).

For shiatsu, a proportion of the studies included in this review had some (but not serious) concerns with bias. 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. An absence of information about the randomisation procedure and allocation concealment contributed to higher risk of bias assessments for some studies, as did a failure to report baseline characteristics or account for missing outcome data. Risk of bias reporting by the included systematics reviews varied considerably, making it difficult to consider bias on a per outcome basis. For this reason, we did not downgrade acupressure studies for bias unless clearly specified by review authors.

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. Where possible, we have applied a methodological approach consistent with the Cochrane Handbook for Systematic Reviews of Interventions and other best practice methods.

To capture the majority of studies assessing the effectiveness of shiatsu, we did not apply date, language or population restrictions in our search. In addition, we comprehensively searched multiple databases and did not limit by study design (RCTs, quasi RCTs, and NRSIs were included). We included detailed documentation of the inclusion criteria to avoid inconsistent application of study selection and used standardised procedures for data collection and critical appraisal. 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.

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**.

Decisions regarding prioritisation of critical or important outcomes were made by NTWC, with input from NTREAP, who were blinded to the number and details of the studies found.

We did not 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) impact 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 shiatsu published up until June 2023 that assess comparable populations.

There was one systematic review found in the literature that specifically assessed the effectiveness of shiatsu for any clinical condition. The review by Robinson 2011 (16) was considered in this review (for acupressure), with authors concluding the evidence for shiatsu is poor and that more research is needed. Similar to this review, Robinson 2011 noted that acupressure may be beneficial for reducing pain (dysmenorrhoea, labour pain), reducing post-operative nausea and vomiting, and improving sleep quality in institutionalised elderly.

As observed in the systematic review of systematic reviews of acupressure, most systematic reviews that assess the effectiveness of shiatsu consider the intervention alongside other mind-body therapies from traditional Chinese medicine, or alongside other interventions that focus on acupoint stimulation such as auricular acupressure and acupuncture, or alongside other massage or non-pharmaceutical interventions such as reflexology, heat therapy, music therapy, cognitive behaviour therapy, meditation and aromatherapy (188, 236-246). It is therefore difficult to assess agreements or disagreement with other reviews.

One review (236) examining the application and effects of water shiatsu (watsu) noted beneficial effects for pain, physical function, and mental issues across some conditions (including pregnancy-related pain, cerebral palsy). However, most reviews note findings similar to this review with inconclusive or mixed-results that justify further research, especially in the following areas: nausea and vomiting (237, 238), pain, length of labour and improving women's sense of control and emotional experience of labour (239), alleviating symptoms of cancer (240) or primary dysmenorrhoea (188, 244, 245), improving gastrointestinal motility and reduce abdominal discomfort or reducing pain after surgery (241, 246), or reducing sleep problems in women or people with insomnia (242, 243).

5.6 Limitations

5.6.1 At the 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 for most conditions, which reduce the statistical precision of the effect estimate and prevented any subgroup or sensitivity analyses. Given the limited evidence base, many of the estimates of effect were limited to one or two small studies, with total participants ranging from 15 to 288 participants for most outcomes.

5.6.2 At the review level

This review was designed 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 use shiatsu, or the reasons practitioners prescribe shiatsu and was not intended to inform individual choices about using shiatsu. Furthermore, the evidence synthesis for acupressure was limited to assessment of the evidence for conditions identified in shiatsu to inform the Australian Government about health policy decisions for private health insurance rebates.

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. It was out of scope of the review to assess safety.

The 2 main comparators of interest were shiatsu compared to sham or inactive control (no intervention, waitlist or usual care) with the outcomes assessed limited to those deemed critical or important by NTWC for each condition. The evidence was often limited to between one and 3 critical or important outcomes. Studies with active comparators were not included in the synthesis or summary of findings tables, as the range of comparators and outcomes did not allow for synthesis as planned in the protocol. Results of these studies for shiatsu are listed in Appendix F2. It is unlikely the results of these 11 studies would impact the overall conclusions of this review.

An additional limitation of this review is that there were a larger proportion of studies awaiting classification than that included in the evidence synthesis. This is because, as per the protocol, studies published in a language other than English, although eligible for the review, were not translated. There were 16 studies (~1400 participants) comparing shiatsu with inactive control (no intervention) included in the results and evidence synthesis, with 29 studies (~2100+ participants) awaiting classification. There is no reason to suspect that the results of the studies awaiting classification would differ substantially from those published in English or change the reviews overall conclusions; however, given many of the studies awaiting classification examined the effect of shiatsu across similar populations and outcomes, it is possible that the inclusion of these studies could modify the certainty of evidence across some outcomes.

A final limitation is that the literature search was last conducted in April 2021, it is possible that there may be additional evidence published after this date that may (or may not) impact the overall conclusions of this review.

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 shiatsu. As such, specific recommendations are not provided.

There is an absence of high certainty evidence examining the effectiveness of shiatsu compared with sham or control (no intervention, waitlist or inactive control) for the 16 conditions considered in this review.

There was one condition (recovery after minimally invasive surgery) for which the evidence provides moderate certainty of benefit for one outcome (bowel recovery) and 7 conditions for which the evidence provides low certainty of benefit: functional constipation (quality of life), dysmenorrhoea (symptom severity), obesity (waist circumference, blood pressure), stress (quality of life, symptoms of stress), rehabilitation after stroke (disability), recovery after minimally invasive surgery (nausea and vomiting, post-operative respiratory function) and hypertension (cognitive function).

In contrast, there were 3 conditions where the evidence provides low certainty that shiatsu provides little (to no) benefit: chronic musculoskeletal pain (pain, disability, quality of life), dysmenorrhoea (pain intensity), and childbirth (labour duration). The effect of shiatsu remains uncertain or is unknown in 81 outcomes across the 16 conditions.

6.2 Implications for research

There is a need for more robust trials evaluating the effectiveness of shiatsu compared with sham or an inactive control (no intervention, usual care). The available evidence could be enhanced by larger studies (more participants enrolled), improved registering and reporting of the methods use, and analysis of results from all randomised participants (or better transparency of missing data), as well as measuring and reporting outcomes that are considered critical or important for decision-making. Many of the studies focused on treatment over a short-time period (12 weeks or less, with only one study continuing for 10 months). Information about the sustainability of the effect would also be valuable, with no studies providing any data about what happens if you stop shiatsu.

There were only 14 studies (1000+ total target participants) identified in our search that were listed as ongoing, with 3 studies (~240 target participants) having a sham control group and 8 studies (~640 target participants) having an inactive comparator group. Of these ongoing studies, 5 were still in recruitment phase (or not yet recruiting), and 5 had completed recruitment but the trial was not yet complete. Evidence reported in these ongoing studies are expected to contribute to future updates where studies are completed, and results published.

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