SHIATSU FOR PREVENTING AND TREATING HEALTH CONDITIONS

APPENDICES D TO H

prepared by

HTANALYSTS

for

National Health and Medical Research Council

NHMRC | Natural Therapies Working Committee

Canberra ACT 2601

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Report information

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Dates

This technical report and accompanying evidence evaluation report and plain language summary 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 and is published on PROSPERO (CRD42021243311).

History

NHMRC was engaged by the Department of Health and Aged Care (formerly 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 (formerly Health Technology 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 Natural Therapies Review Expert Advisory Panel (NTREAP) and NTWC were also to be included in the evidence evaluation.

This technical report has been developed by **HT**ANALYSTS in conjunction with NHMRC, NTWC, and NTREAP. It provides the appendices and supplementary data related to an evidence evaluation of the effect of shiatsu for preventing and treating health conditions. The main body of evidence is presented in the evidence evaluation report. All associated materials have been developed in a robust and transparent manner in accordance with relevant best practice standards (2-5).

Contents

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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

Appendix D Details of included studies

This appendix documents the studies that met the prespecified inclusion criteria for a systematic review on the effect of shiatsu for preventing and treating any health condition. It provides an overview of the PICO criteria of included studies, a summary of the risk of bias assessment, and results of the data synthesis for the main comparison. Similar details for the supplementary overview of acupressure are provided in the Supplement.

Additional details concerning risk of bias judgements for shiatsu are provided in Appendix E1 (shiatsu RCTs and NRSIs) and Appendix E2 (acupressure SRs). Data extraction sheets outlining the characteristics of the included studies are provided in Appendix F1 (shiatsu) and Appendix F1.2 (acupressure). Data for outcomes considered critical or important to this review are provided in Appendix F2.1 (shiatsu) and Appendix F2.2 (acupressure).

D1 Neoplasms

D1.1 Cancer (survivors)

D1.1.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-1.

Table D-1 Overview of PICO criteria of included studies: Cancer (survivors)

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham*						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Donoyama 2013 (6-10)	RCT	Gynaecological cancer survivors	Shiatsu	Control (no intervention)	Standard medical care	QoL Pain intensity Stress biomarkers
Shiatsu vs 'other' intervention**						
No studies found						

Abbreviations: RCT, randomised control trial; QoL, Quality of life

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

D1.1.2 Risk of bias per item

The risk of bias for each item in the included studies for gynaecological cancer is described below and shown graphically in Figure D-1.

Bias arising from the randomisation process

Donoyama 2013 randomised participants using block randomisation but did not provide any information on allocation concealment. Reported baseline characteristics and baseline outcomes measures appeared matched between treatment groups.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

Donoyama 2013 was judged to be at low risk of bias as no deviations from the trial protocol were reported and an appropriate analysis method was used to estimate the effect of assignment to intervention.

Bias due to missing outcome data

Donoyama 2013 was judged to be at low risk of bias for this domain as outcome data appeared to be available for nearly all participants.

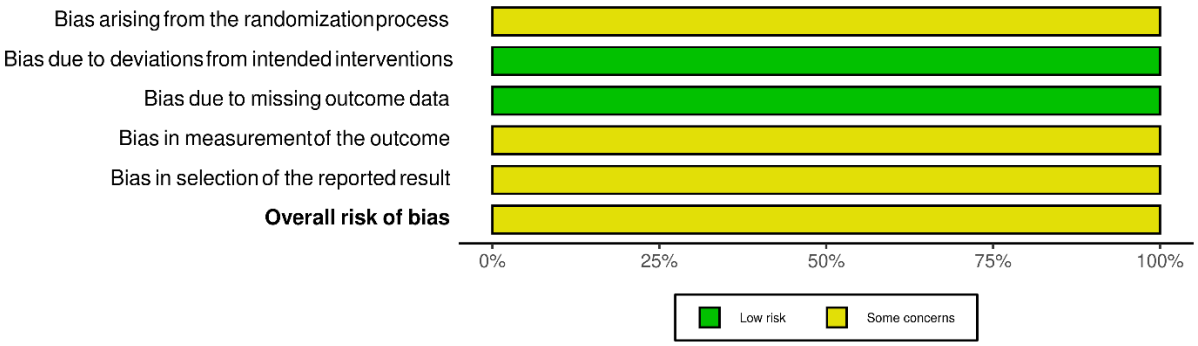
Bias in measurement of the outcome

There were some concerns of bias relating to the measurement of outcomes as both participants and outcome assessors were not blinded to treatment allocation. Many of the primary or key outcomes were subjective, results of which could be influenced by knowledge of the intervention.

Bias in selection of the reported result

Donoyama 2013 reported all results specified in the published protocol, but there were some concerns relating variations in the reporting across publications.

Figure D-1 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included RCTs – Gynaecological cancer (survivors)



D1.1.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in gynaecological cancer survivors are listed in Table D-2.

Table D-2 Outcomes considered by the NTWC to be critical or important for decision-making: cancer (survivors)

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Donoyama 2013
Quality of life	EORTC QLQ-C30 – total score	Critical	No	X
Pain	Visual analogue scale (VAS)	Critical	Yes	X
Physical symptoms	VAS, EORTC QLQ-C30 – Nausea and vomiting	Critical	Yes	✓
Fatigue	EORTC QLQ-C30 - Fatigue	Critical	Yes	✓
Physical functioning	EORTC QLQ-C30 – Physical functioning	Critical	Yes	✓
Overall wellbeing	EORTC QLQ-C30 – Global health status	Critical	Yes	✓
Psychosocial wellbeing	HADS-Anxiety and HADS-Depression	Critical	Yes	✓

Abbreviations: EORTC-QLQ, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire; HADS, Hospital Anxiety and Depression score

✓ A study result is available for inclusion in the synthesis

X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators

-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results

Comparison 1 (vs sham)

There were no studies identified comparing shiatsu with sham in cancer (survivors).

Comparison 2 (vs control)

One RCT (Donoyama 2013) comparing shiatsu with no intervention in women with gynaecological cancer (survivors) was eligible for this comparison and contributed data relevant to six of the seven outcomes. None of the studies were judged to be at high risk of bias therefore no sensitivity analysis was conducted.

Physical complaints

One trial (40 participants) reported subjective physical complaints measured with a visual analogue scale (VAS) at the end of treatment (eight weeks) (Donoyama 2013). 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.

The VAS assessed physical complaints, reported by participants and measured on a continuous scale (mm) from 0 (no pain) to 100 (worst imaginable pain). The minimal clinically important difference (MCID) for this measure has not been established.

The results suggest an effect in favour of shiatsu compared with the control group (MD –21; 95% CI –35.03, –6.97; p = 0.003) *(GRADE: low).*

Quality of Life (QoL)

One trial (40 participants) reported quality of life measured with EORTC QLQ-C30 at the end of treatment (eight weeks) (Donoyama 2013). The EORTC QLQ-C30 is designed to measure physical, psychological and social functions in people with cancer, summarised on a scale from 0 (worse) to 100 (best). A validated MCID for gynaecological cancer survivors was not found. For women with ovarian cancer the MCID ranges between 3 and 14 (improvement) (11).

The data were presented as medians (IQR) for individual domains *(GRADE: very low)*. A total EORTC QLQ-C30 estimate was not provided. Results relating to critical or important domains comparing shiatsu with control (no intervention) were reported by the study authors as follows:

- Physical functioning: median difference 0.00 (95% CI 0.0, 6.7; p = 0.755)
- Fatigue: median difference –11.1 (95% CI –22.2, 0.0; p = 0.047)
- Physical symptoms: median difference 0.0 (95% CI not estimable; p = 0.506)
- Global health status: median difference 8.3 (95% CI 0.0, 16.7; p = 0.042).

Psychosocial wellbeing

One trial (40 participants) reported depression and anxiety measured with the Hospital Anxiety and Depression Scale (HADS) at the end-of-treatment (eight weeks) (Donoyama 2013). The 7-item HADS-depression scale measure symptoms of depression and is summarised on a scale from 0 (no depression) to 21 (severe). Similarly, the 7-item HADS-anxiety scale measure symptoms of anxiety and is summarised on a scale from 0 (no anxiety) to 21 (severe). For both scales, a score less than 7 indicates no depression or anxiety, score between 8-10 are considered borderline, and score greater than 11 indicate the presence of increased symptoms of depression or anxiety (12).

The data was presented as medians (IQR). The results reported by the study authors suggest no difference between the shiatsu and control groups for depression (median difference –1.0; 95% CI –3.0, 1.0; p = 0.282) *(GRADE: very low)* or anxiety (median difference –1.0; 95% CI –2.0, 1.0; p = 0.256) *(GRADE: very low).*

Median scores were less than 7 for both anxiety and depression in both groups.

Comparison 3 (vs other)

There were no studies identified comparing shiatsu with 'other' interventions in gynaecological cancer survivors.

D2 Endocrine, nutritional or metabolic diseases

D2.1 Diabetes

D2.1.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-3.

Table D-3 Overview of PICO criteria of included studies: Diabetes

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
No studies found						
Shiatsu vs 'other' intervention**						
Jie-er 2018 (13)	Quasi RCT	Diabetes (with peripheral neuropathy)	Acupoint massage	Mecobalamin tablets	Routine care (diet control, exercise therapy, insulin)	Disease markers Comorbidities General health

Abbreviations: RCT, randomised control trial

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

D2.1.2 Risk of bias per item

The risk of bias for each item in the included studies for diabetes is described below and shown graphically in Figure D-2.

Bias arising from the randomisation process

Jie-er 2018 was judged to have some concerns for this domain as details relating to method of randomisation and allocation concealment were not provided. Baseline differences between intervention groups did not suggest a problem with the randomisation process.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

Concerns were raised with Jie-er 2018 due to a lack of information regarding any deviations from the intended deviation.

Bias due to missing outcome data

Concerns were raised with Jie-er 2018 due to a lack of information regarding missing outcome data.

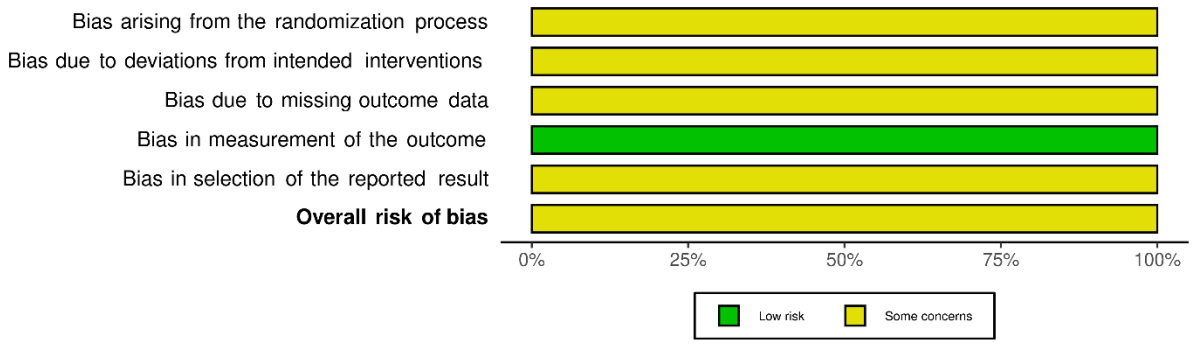
Bias in measurement of the outcome

Jie-er 2018 was judged to be at low risk of bias regarding the measurement of outcomes. The study did not blind the participants and it is unclear if the outcome assessors were blinded. However, objectives measure such as glycaemic control (glycated haemoglobin, blood glucose levels), cardiovascular risk (blood pressure), therapeutic and clinical effect as well as observed effect (ankle brachial index) are not likely to be biased because of knowledge of treatment.

Bias in selection of the reported result

Jie-er 2018 was judged to have some concerns of bias due to a lack of information.

Figure D-2 Risk of bias graph: review authors' judgement about each risk of bias item presented as percentages across all included RCTs - Diabetes



D2.1.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in people with diabetes are listed in Table D-4.

Table D-4 Outcomes considered by the NTWC to be critical or important for decision-making: diabetes

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?
Pain	No measures reported in eligible studies	Critical	No
Activities of daily living	No measures reported in eligible studies	Critical	No
Psychosocial wellbeing	No measures reported in eligible studies	Critical	No
Quality of life	Diabetes-specific quality of life scale	Critical	No
Comorbidities	Hyperlipidaemia	Critical	No

Abbreviations: EORTC-QLQ, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire

Comparison 1 (vs sham)

There were no studies identified comparing shiatsu with sham in people with diabetes.

Comparison 2 (vs control)

There were no studies identified comparing shiatsu with inactive control in people with diabetes.

Comparison 3 (vs other)

One study (Jie-er 2018) comparing shiatsu with 'other' interventions in people with diabetes (with peripheral neuropathy) was eligible for this comparison, but the study did not contribute data to any of the critical or important outcomes.

Available data are presented in Appendix F2.1 Supplementary outcome data.

D2.2 Obesity

D2.2.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-5

Table D-5 Overview of PICO criteria of included studies: Obesity

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Guo 2015 (14)	RCT	Obesity (with hypertension)	Acupoint massage	Control (no intervention)	Captopril tablets	Anthropometrics Cardiometabolic disease risk
Yan 2014 (15)	RCT	Obesity (BMI ≥25)	Meridian massage	Control (no intervention)	Dietary and exercise program	Anthropometrics
Shiatsu vs 'other' intervention**						
No studies found						

Abbreviations: BMI, body mass index; RCT, randomised controlled trial

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

D2.2.2 Risk of bias per item

The risk of bias for each item in the included studies for obesity is described below and shown graphically in Figure D-3.

Bias arising from the randomisation process

Both studies (Guo 2015, Yan 2014) were judged to have some concerns for this domain due to a lack of information. Both studies randomised participants into groups either using a random digit table (Guo 2015) or a statistical analysis software (Yan 2014). Neither study provided information on if the allocation sequence was concealed, causing some concerns. Baseline differences between intervention groups for both studies, however, did not suggest a problem with the randomisation process.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

Guo 2015 was judged to be at low risk of bias as no deviations from the trial protocol were reported. Yan 2014 was judged to have some concerns for this domain due deviations from the intervention that occurred because of knowledge of the trial context. Further details on the breakdown to assess if the reasons were unbalanced was not provided.

Bias due to missing outcome data

Guo 2015 was judged to be at low risk of bias for this domain as outcome data appeared to be available for all (or nearly all) participants. Yan 2014 had some concerns raised as missingness of the data appeared to differ slightly across intervention groups.

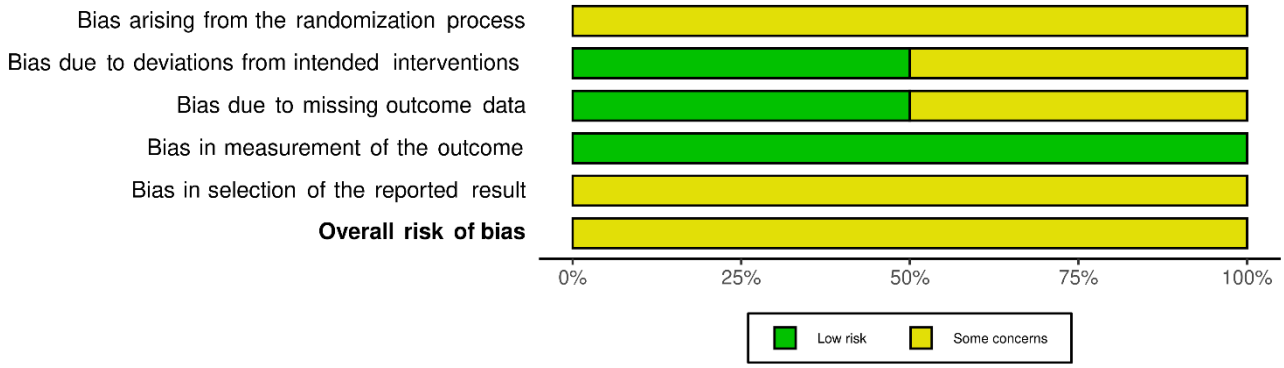
Bias in measurement of the outcome

Both studies (Guo 2015 and Yan 2014) were judged to be at low risk of bias regarding the measurement of outcomes. The studies did not blind the participants and it is unclear if the outcome assessors were blinded. However, measure of glycaemic control (glycated haemoglobin, blood glucose levels), cardiovascular risk (blood pressure) and anthropometrics (BMI, weight, waist and hip circumference) are not likely to be biased because of knowledge of treatment.

Bias in selection of the reported result

Both studies (Guo 2015 and Yan 2014) had concerns raised due to a lack of information regarding prespecified intentions for outcome measurements and analyses, reducing confidence that all intended outcome measures are reported.

Figure D-3 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included RCTs – Obesity



D2.2.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in people with obesity are listed in Table D-6.

Table D-6 Outcomes considered by the NTWC to be critical or important for decision-making: Obesity

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Guo 2015	Yan 2014
Quality of life	No measures reported in eligible studies	Critical	No	--	--
Comorbidities	No measures reported in eligible studies	Critical	No	--	--
Psychosocial wellbeing	No measures reported in eligible studies	Critical	No	--	--
Functional capacity	No measures reported in eligible studies	Critical	No	--	--
Anthropometrics/ body composition	Waist circumference	Important	Yes	X	✓
Cardiometabolic disease risk	Blood pressure (systolic, diastolic)	Important	Yes	✓	?

Abbreviations: BP, blood pressure

✓ A study result is available for inclusion in the synthesis

X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators

-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results

? No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

Comparison 1 (vs sham)

There were no studies identified comparing shiatsu with sham in people with obesity.

Comparison 2 (vs control)

Two studies (Yan 2014, Guo 2015) comparing shiatsu with no intervention in people with obesity were eligible for this comparison and contributed data to two of the seven outcomes.

None of the studies were judged to be at high risk of bias therefore no sensitivity analysis was conducted.

Anthropometrics

One trial (54 participants) measured and reported waist circumference (cm) at the end of treatment (8 weeks) (Yan 2014). Waist circumference for adults is a good indicator of total body fat and a better predictor of chronic conditions, such as diabetes. A waist circumference above 88 cm for women and above 102 cm for men is associated with a substantially increased risk of chronic conditions (16). Because each person's weight loss journey is unique, an MCID for waist circumference has not been established.

The results showed an effect in favour of shiatsu compared with the control group (MD –3.10; 95% CI –6.34, –0.14; p = 0.06) *(GRADE: Very Low)*.

Cardiometabolic disease risk

One trial (42 participants) measured cardiovascular disease risk using systolic and diastolic blood pressure at the end of treatment (3 months) (Guo 2015).

Systolic and diastolic blood pressure assess different cardiac functions, with systolic blood pressure (SBP) measuring the maximum pressure the heart exerts during when the heart beats (to pump blood out to the rest of the body) and diastolic blood pressure (DBP) measures the pressure in the arteries when the heart is at rest (between beats) (17). In the general adult population, an SBP below 120 mmHg is considered normal, whereas an SBP between 120 to 129 mmHg indicates high/elevated or prehypertension (66). Normal DBP is around 80 mmHg, and between 85 to 89 mmHg indicates high/elevated DBP (66). The closer the score to 120/80 mmHg, the more stable the cardiorespiratory health. Typically, reductions of > 2 mmHg in both systolic and diastolic blood pressure have been linked to improved coronary heart disease and reduced stroke risk (18).

The results showed an effect in favour of shiatsu compared with the control group in both SBP (MD –9.90; 95% CI –13.60, –6.20; p = 0.00001) *(GRADE: Very Low)* and DBP (MD –5.80; 95% CI –8.40, –3.20; p = 0.0001) *(GRADE: Very Low)*.

Comparison 3 (vs other)

There were no studies identified comparing shiatsu with 'other' interventions in people with obesity.

D3 Mental and behavioural disorders

D3.1 Neurocognitive decline (Alzheimer's disease)

D3.1.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-7.

Table D-7 Overview of PICO criteria of included studies: Alzheimer's disease

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Lanza 2018 (19)	RCT	Alzheimer's disease	Shiatsu	No intervention (control)	Physical activity	Neurocognitive function Emotional wellbeing Functional status
Shiatsu vs 'other' intervention**						
No studies found						

Abbreviations: RCT, randomised control trial

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

D3.1.2 Risk of bias per item

The risk of bias for each item in the included studies for Alzheimer's disease is described below and shown graphically in Figure D-4.

Bias arising from the randomisation process

Lanza 2018 was judged to have some concerns in this domain due to the lack of information provided regarding allocation concealment and an unequal sex distribution between groups.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

Lanza 2018 was judged to be at low risk of bias for this domain, as no deviations from the trial protocol were reported. Due to the nature of the intervention, participants in both studies were aware of their allocated interventions.

Bias due to missing outcome data

Lanza 2018 was judged to be at low risk of bias for this domain as outcome data appeared to be available for all (or nearly all) participants.

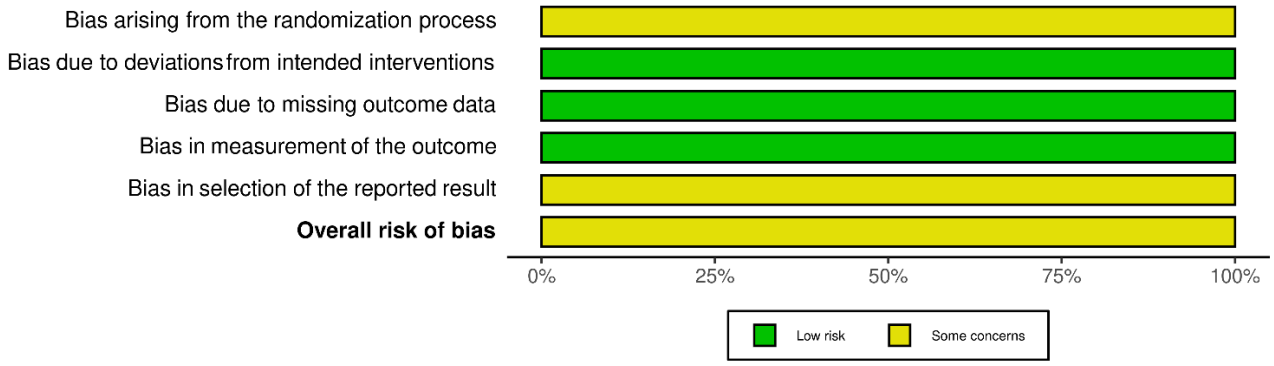
Bias in measurement of the outcome

Lanza 2018 was assessed to be at low risk of bias in this domain, as outcomes were measured appropriately, and investigators were blinded to treatment allocation.

Bias in selection of the reported result

Lanza was judged to have some concern of bias in this domain due to a lack of information of the pre-specified analysis plan.

Figure D-4 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included RCTs – Alzheimer's disease



D3.1.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in people with Alzheimer's disease are listed in Table D-8.

Table D-8 Outcomes considered by the NTWC to be critical or important for decision-making: Alzheimer's disease

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Lanza 2018
Functional capacity	Activities of daily living	Critical	Yes	✓
Quality of life	SF-36	Critical	No	--
Behavioural symptoms	Neuropsychiatric inventory	Critical	No	--
Neurocognitive function	Mini Mental State Examination	Critical	Yes	✓
Emotional wellbeing	Geriatric Depression Scale	Important	Yes	✓
Sleep	PSQI	Important	No	--

Abbreviations: PSQI, Pittsburgh Sleep Quality Index; SF-36, 36-item short form survey

✓ A study result is available for inclusion in the synthesis

X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators

-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results

? No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

Comparison 1 (vs sham)

There were no studies identified comparing shiatsu with sham in people with Alzheimer's disease.

Comparison 2 (vs 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 three out of six critical or important outcomes.

Functional capacity

One trial (12 participants) measured functional capacity using the Katz Index of Independence in Activities of Daily Living (ADL) at the end of treatment (10 months) (Lanza 2018). The instrument assesses functional status in the elderly population by their ability to perform activities of daily living independently, in the six functions of bathing, dressing, toileting, transferring, continence and feeding (20). A score of 6 indicates full independence, 4 moderate impairment and 2 or less severe functional impairments (20). The tool is limited in its ability to detect small increments of change and is therefore sensitive to deterioration. The MCID of Katz-ADL index is approximately 0.5 points (21).

The results showed an effect in favour of shiatsu compared with the control group (MD –0.60; 95% CI –1.17, –0.03; *p* = 0.04) *(GRADE: very low)*.

Neurocognitive function

One trial (12 participants) reported neurocognitive function measured with MMSE at the end of treatment (10 months) (Lanza 2018). The MMSE is a widely used screening test for cognitive impairment designed to measure orientation, short and long-term memory, registration, recall, constructional ability, language and the ability to understand and follow commends in the elderly population (22). The MMSE is conducted by healthcare professionals and results are summarised on a scale from 0 (worse) to 30 (best). A difference of 1 to 3 points is reported as the MCID for MMSE in people with Alzheimer's disease (23), with a score below 25 considered abnormal (22, 24).

The results showed an effect in favour of shiatsu compared with the control group (MD –1.90; 95% CI –3.55, –0.25; *p* = 0.02) *(GRADE: very low)*.

Emotional wellbeing

One trial (12 participants) reported emotional wellbeing using the Geriatric Depression Scale at the end of treatment (10 months) (Lanza 2018). The 15-item short form questionnaire in which participants respond by answering yes or no in reference to how they've felt during the preceding week, is commonly used to measure depression (not suicidality) in the elderly population. Scores of 0-4 are considered normal, 5-6 indicate mild depression, 9-11 moderate depression and 12-15 severe depression (25). Any two-point change on the Geriatric Depression Scale has been found to represent a MCID (population not identified) (21).

The results showed an effect in favour of shiatsu compared with the control group (MD –2.00; 95% CI –3.02, –0.98; *p* = 0.0001) *(GRADE: very low)*.

Comparison 3 (vs other)

There were no studies found comparing shiatsu with 'other' interventions in people with Alzheimer's disease.

D3.2 Symptoms of stress

D3.2.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-9

Table D-9 Overview of PICO criteria of included studies: Symptoms of stress

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Kurebayashi 2020 (26)	RCT	Symptoms of stress	Shiatsu (plus rest)	No intervention (control)^ OR Anma plus Reiki	None	Stress QoL
Lucini 2009 (27)	NRSI	Symptoms of stress	Shiatsu	Educational advice ^ OR Breathing relaxation training	None	Stress Fatigue
Shiatsu vs 'other' intervention**						
No additional studies found						

Abbreviations: RCT, randomised control trial; NRSI, non-randomised study of interventions; QoL, quality of life

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

^ Study included three groups. The inactive control is considered in the evidence synthesis.

D3.2.2 Risk of bias per item

The risk of bias for each item in the included RCTs for stress is described below and shown graphically in Figure D-5.

Randomised controlled trials

Bias arising from the randomisation process

Kurebayashi 2020 was judged to have some concerns in this domain due to the lack of information provided regarding allocation concealment and minimal reporting of baseline characteristics.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

Kurebayashi 2020 was judged to be at low risk of bias for this domain; any discontinuations from intended interventions were judged to be unrelated to the trial context.

Bias due to missing outcome data

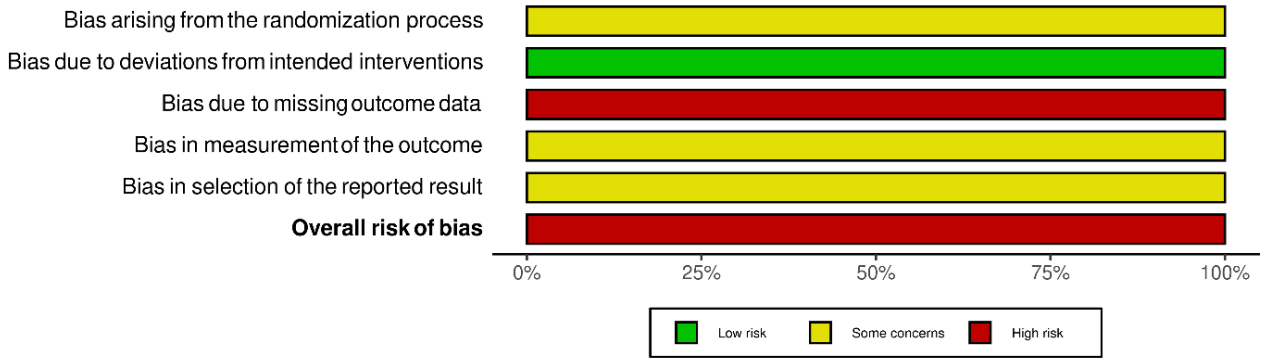
Kurebayashi 2020 was judged to be at high risk of bias for this domain, due to data missing from more than 15% of randomised participants and a lack of information regarding the missing outcome data.

Bias in measurement of the outcome

There were some concerns regarding the measurement of outcomes in Kurebayashi 2020. Due to the nature of the intervention, the participants and outcome assessors were not blinded, with the primary or key outcomes being subjective measures, which could be influenced by knowledge of the intervention received.

Bias in selection of the reported result
Kurebayashi 2020 reported all eligible specified results and, in the absence of an available protocol were judged to be at some concerns for this domain.

Figure D-5 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included RCT – Symptoms of stress



Nonrandomised studies of interventions

The risk of bias for each item in the included studies for stress (NRSI) is described below and shown graphically in Figure D-6.

Bias due to confounding
Lucini 2009 was judged to have some concerns of bias for this domain, with appropriate measures implemented to measure and control for confounders and multivariate factor analysis considered reasonable.

Bias of selection of participants into the study
Lucini 2009 was assessed at low risk of bias in this domain. Participants were followed from the start of the intervention making it unlikely that there was misclassification of outcome status. Participant outcome observations occurred at comparable time points.

Bias in classification of interventions
There was no serious risk of bias for this domain, as interventions were well defined prior to enrolment and collected at the time of intervention.

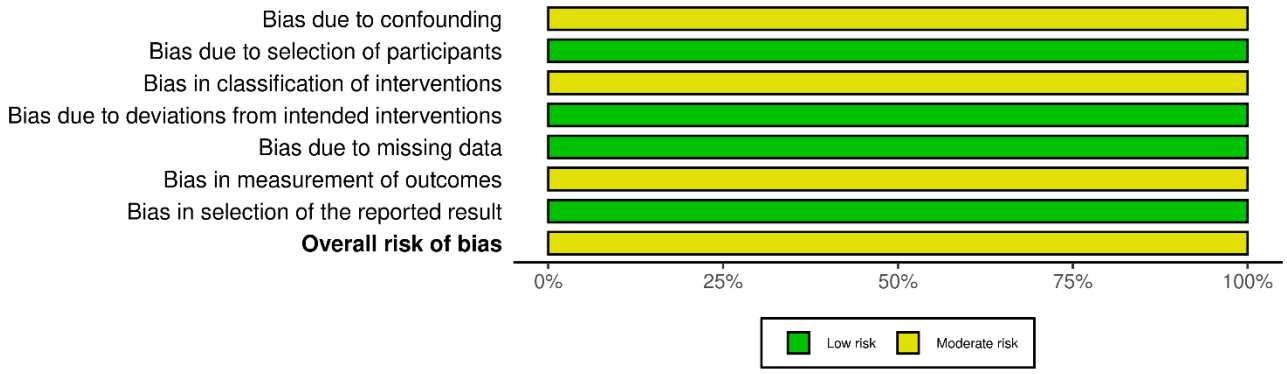
Bias due to deviations from intended interventions
Lucini 2009 was judged to be at low risk of bias in this domain. The authors do not report any deviations from the intended intervention, with the number of participants in each treatment arm remaining unchanged from preliminary assessment to end of treatment (3 months). No co-interventions were included in the study.

Bias due to missing data
Lucini 2009 was assessed at low risk of bias in this domain, as outcome data was available for all participants throughout the trial.

Bias in measurement of outcomes
There were concerns of bias for this domain, related to the likelihood of subjective outcomes being influenced by knowledge of the intervention received. Objective outcomes (such as heart rate, blood pressure) were at low risk of bias.

Bias in selection of the reported result
Lucini 2009 was assessed to be at low risk of bias in this domain, as outcomes were measured appropriately and analysts implemented several different analytical methods to evaluate the effect of the intervention, which was pre-specified in the methodology and the data was available in the results.

Figure D-6 Risk of bias summary: review authors' judgements about each risk of bias item presented as percentages across all included NRSI – Symptoms of stress



D3.2.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in people with symptoms of stress are listed in Table D-10.

Table D-10 Outcomes considered by the NTWC to be critical or important for decision-making: Symptoms of stress

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Kurebayashi 2020	Lucini 2009
Quality of life	SF-12	Critical	No	✓	--
Stress symptoms	Vasconcellos Stress Symptoms List	Critical	Yes	✓	--
Psychosocial wellbeing	Spielberger State Anxiety Inventory	Critical	No	X	--
Fatigue	Visual analogue scale	Critical	Yes	--	✓
Functional status	No measures reported in eligible studies	Important	No	--	--
Cognitive function	No measures reported in eligible studies	Important	No	--	--
Physical health	No measures reported in eligible studies	Important	No	--	--

Abbreviations: SF-12, 12-Item Short Form Survey

✓ A study result is available for inclusion in the synthesis

X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators

-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results

? No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

Comparison 1 (vs sham)

There were no studies identified comparing shiatsu with sham in people with symptoms of stress.

Comparison 2 (vs control)

One RCT (Kurebayashi 2020) and one NRSI (Lucini 2009) comparing shiatsu with no intervention or usual care in people with symptoms of stress were eligible for this comparison and contributed data to three of seven important or critical outcomes.

Quality of life

One trial (122 participants) reported quality of life measured with the SF-12 at the end of treatment (1 month) (Kurebayashi 2020). The SF-12 is a shortened version of the SF-36 that assesses quality of life across eight domains. Scores were summarised into two composite scores (physical and mental health) reported on a range from 0 to 100, with a population mean of 50 and standard deviation of 10. Higher scores represent improved quality of life. The MCID in people with stress is not established but is estimated to be between 2 to 4 points for the general population (i.e. ~0.5 of the SD) (28).

The results showed an effect in favour of shiatsu compared with the control group for both the physical (MD –5.90; 95% CI –9.44, –2.36; p = 0.001) and mental component scores (MD –7.30; 95% CI –12.04, –2.56; p = 0.003) *(GRADE: Low)*.

Stress Symptoms

One trial (122 participants) measured stress using the Vasconcellos Stress Symptoms List at the end of treatment (1 month) (Kurebayashi 2020). The inventory is composed of 59 psychophysiological and psychosocial stress symptoms for which participants rank the presence and frequency of each symptom on a scale of 0 to 3, giving a total of 177 points. Scores from 12 to 28 points suggest low stress; from 29 to 60 points, medium stress; from 61 to 120 points, high stress; and above 120 points, very high stress (29). Lower scores indicate the absence or reduced frequency of symptoms (26). No MCID for the Vasconcellos Stress Symptoms list has been established.

The results showed an effect in favour of shiatsu compared with the control group (MD –15.50; 95% CI –24.46, –6.54; p = 0.0007) *(GRADE: Low)*.

Fatigue

One trial (70 participants) measured fatigue using a visual analogue scale (VAS) at the end of treatment (3 months) (Lucini 2009). The VAS was a subjective assessment of tiredness perception, reported by participants and measured on a Likert-scale scale from 0 (no perception) to 10 (strong perception). Higher values indicate worse fatigue. No MCID has been established for VAS fatigue in people with stress, with the MCID reported to be between –0.82 to –1.12 for improvement and 1.13 to 1.26 for worsening fatigue on a 0-10 VAS fatigue scale for people with rheumatoid arthritis (30).

The results showed an effect in favour of shiatsu compared with control group (MD –2.41; 95% CI –3.94, –0.88; p = 0.002) *(GRADE: Very Low)*.

Comparison 3 (vs other)

There were no studies identified comparing shiatsu with ‘other’ interventions in people with stress.

D4 Sleep-wake disorders

D4.1 Insomnia (or sleep problems)

D4.1.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-11.

Table D-11 Overview of PICO criteria of included studies: Insomnia (or sleep problems)

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Yue 2016 (31)	Quasi-RCT	Sleep problems (PSQI ≥5)	Acupoint massage alone OR Acupoint massage plus Tai Chi^^	Tai Chi	None	Sleep quality Quality of life
Shiatsu vs 'other' intervention**						
Kao 2017 (32)	RCT	Insomnia (chronic)	Acupoint massage	Placebo^ OR Lavender OR Blended essential oil	None	Sleep quality Quality of life Emotional wellbeing

Abbreviations: RCT, randomised control trial; QoL, Quality of life

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

^ The placebo group included a night time diffuser (using distilled water [without oil]) so was considered to be active.

^^ Group considered in the evidence synthesis as acupressure massage delivered as an adjunct to Tai Chi.

D4.1.2 Risk of bias per item

The risk of bias for each item in the included studies for people with insomnia (or sleep problems) is described below and shown graphically in Figure D-7.

Bias arising from the randomisation process

Some concerns raised in both studies. Yue 2016 randomised participants using a random numbers table but did not provide any information on allocation concealment. Kao 2017 did not provide any information on the how participants were randomised or the allocation concealment. In both studies, reported baseline characteristics or baseline outcomes measures appeared matched between treatment groups.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

Kao 2017 was judged to be at low risk of bias for this domain; any discontinuations from intended interventions were judged to be unrelated to the trial context. Concerns were raised with Yue 2016 due to a lack of information regarding any deviations from intended interventions.

Bias due to missing outcome data

Kao 2017 was judged to be at low risk of bias for this domain as outcome data appeared to be available for all (or nearly all) participants. Yue 2016 was judged to be at high risk of bias for this domain due to a lack of information regarding missing outcome data.

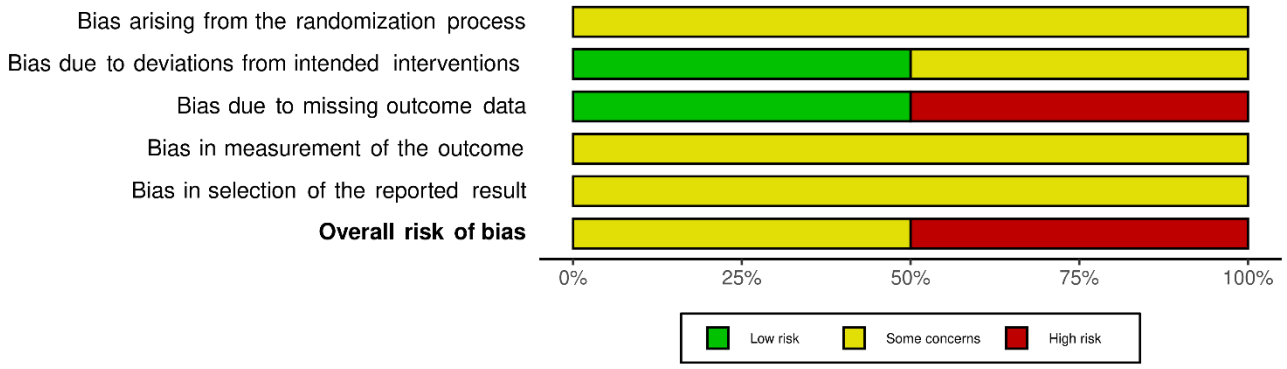
Bias in measurement of the outcome

Both studies (Kao 2017, Yue 2016) were assessed to have some concerns regarding the measurement of outcomes. Neither of the included studies blinded the participant or outcome assessors and many of the key outcomes were subjective, results of which could be influenced by knowledge of the intervention.

Bias in selection of the reported result

Both studies (Kao 2017, Yue 2016) reported all eligible specified results and, in the absence of an available protocol were judged to be at some concerns for this domain.

Figure D-7 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included RCTs – Insomnia



D4.1.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in people with insomnia (or sleep problems) are listed in Table D-12.

Table D-12 Outcomes considered by the NTWC to be critical or important for decision-making: insomnia (or sleep problems)

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Kao 2017	Yue 2016
Sleep quality	PSQI, SPIEGEL sleep quality scale	Critical	Yes	✓	✓
Fatigue	No measures reported in eligible studies	Critical	No	--	--
Quality of life	Life quality assessment questionnaire (GQ-OLI-74)	Critical	Yes	✓	✓
Cognitive function	MMSE	Critical	No	--	--
Global clinical improvement	Reduction of SPIEGEL score	Important	No	--	--
Psychosocial wellbeing	Exon emotional stability scale (30-items)	Important	Yes	--	✓
Cardiorespiratory health	No measures reported in eligible studies	Important	No	--	--

Abbreviations: MMSE, Mini Mental State Examination; PSQI, Pittsburgh Sleep Quality Index; SF-36, 36 item short form survey

✓ A study result is available for inclusion in the synthesis

X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators

-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results

? No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

Comparison 1 (vs sham)
No studies found.

Comparison 2 (vs control)
One RCT (Yue 2016) comparing shiatsu with no intervention (delivered as an adjunct to Tai Chi) in people with insomnia was eligible for this comparison and contributed data relevant to three of the seven critical or important outcomes.

Sleep quality
One RCT (62 participants) reported sleep quality measured with the SPIEGEL sleep scale at the end of treatment (12 weeks) (Yue 2016). The SPIEGEL sleep quality scale is a subjective assessment of sleep quality, reported by participants and measured across six dimensions including time to go to bed each night, total sleep time each night, times for waking up, sleep depth, confirmations about their dress, feel after waking up. Scores range from 0 (no insomnia symptoms) to 30 (obvious insomnia symptoms), with higher values indicate worse insomnia. An MCID for the SPIEGEL sleep scale has not been established.

The results suggest an effect in favour of shiatsu compared with no intervention (when delivered as an adjunct to Tai Chi) (MD –4.12; 95% CI –5.30, –2.94; $p < 0.00001$). *(GRADE: Very low)*

Quality of Life
One trial (60 participants) reported quality of life measured with the life quality assessment questionnaire (GQ-OLI-74) at the end of treatment (12 weeks) (Yue 2016). The assessment includes four aspects: body, psychology, society and material, as well as an overall life quality factor. Body, psychology and society each have five dimensions and material function includes four dimensions (total 20 factors). Higher values indicate better quality of life. No additional details (i.e. score range, MCID) on this measure were found.

The results suggest an effect in favour of shiatsu compared with the control group (when delivered as an adjunct to Tai Chi) (MD –3.76; 95% CI –6.10, –1.42; $p = 0.002$). *(GRADE: Very low)*

Psychosocial wellbeing
One trial (60 participants) reported anxiety measured with the Exon Emotional stability scale at the end-of-treatment (12 weeks) (Yue 2016). The 30 item emotional scale measures emotional wellbeing and is summarised on a scale of 0 (no anxiety) to 30 (severe). A score of 15 or less indicates no anxiety and a score greater than 15 indicates the presence of increased symptoms of anxiety.

The results suggest an effect in favour of shiatsu compared with the control group (when delivered as an adjunct to Tai Chi) (MD –2.70; 95% CI –4.27, –1.13; $p = 0.0007$). *(GRADE: Very low)*

Comparison 3 (vs other)
Two studies (Kao 2017 and Yue 2016) comparing shiatsu with 'other' interventions in people with insomnia (or sleep problems) were eligible for this comparison and contributed data to three critical or important outcomes.

Available data are presented in Appendix F2.1 Supplementary outcome data.

D5 Diseases of the nervous system

D5.1 Headache disorders

D5.1.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-13.

Table D-13 Overview of PICO criteria of included studies: headache disorders

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Villani 2017 (33)	Quasi RCT	Headache disorder, primary (refractory)	Shiatsu OR Shiatsu plus amitriptyline^	amitriptyline	None	Clinical efficacy Frequency Pain
Shiatsu vs 'other' intervention**						
No studies found						

Abbreviations: RCT, randomised control trial

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

^ Group considered in the evidence synthesis as shiatsu delivered as an adjunct to amitriptyline

D5.1.2 Risk of bias per item

The risk of bias for each item in the included studies for headache disorders is described below and shown graphically in Figure D-8.

Bias arising from the randomisation process

Villani 2017 was judged to have some concerns for this domain as details relating to method of randomisation and allocation concealment were not provided. Baseline differences between intervention groups, however, did not suggest a problem with the randomisation process.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

Villani 2017 was judged to be at low risk of bias as no deviations from the trial protocol were reported.

Bias due to missing outcome data

Concerns were raised with Villani 2017 due to a lack of information regarding missing outcome data.

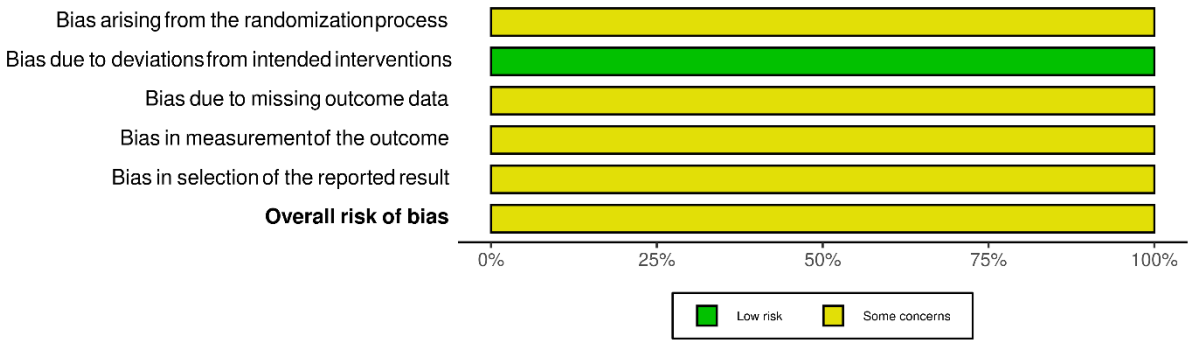
Bias in measurement of the outcome

Villani 2017 did not blind the participants. However, the neurologists were blinded to the participants treatment allocation. The primary outcome measure of headache reduction and many of the secondary outcomes are subjective and require the participant to record information using a daily diary. The use of the daily diary is subject to recall bias causing some concerns in the measurement of the outcome.

Bias in selection of the reported result

Villani 2017 was judged to have some concerns of bias due to a lack of information.

Figure D-8 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included RCTs – Headache disorders



D5.1.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in people living with headache disorders are listed in Table D-14.

Table D-14 Outcomes considered by the NTWC to be critical or important for decision-making: headache disorders

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Villiani 2017
Symptom severity	No measures reported in eligible studies	Critical	No	--
Frequency	Number of days with headache per month	Critical	Yes	✓
Pain	Visual Analogue Scale	Critical	Yes	✓
Clinical efficacy	50% reduction in days with a headache per month	Critical	Yes	✓
Functional impairment (ADL)	No measures reported in eligible studies	Critical	No	--
HRQoL	Headache QoL	Critical	No	--
Psychosocial wellbeing	Visual Analogue Scale	Critical	No	--

Abbreviations: ADL, activities of daily living; HRQoL, health-related quality of life
✓ A study result is available for inclusion in the synthesis
X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators
-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results
? No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

Comparison 1 (vs sham)

There were no studies identified comparing shiatsu with sham in people with headache disorders.

Comparison 2 (vs control)

One quasi-RCT (Villiani 2017) comparing shiatsu with no intervention (delivered as an adjunct to amitriptyline) in people with headache disorders was eligible for this comparison and contributed data relevant to three of the seven critical or important outcomes.

Headache Frequency

One trial (27 participants) reported headache frequency measured by the average number of days with headache per month over the treatment period (12 weeks) (Villiani 2017). The measure is a subjective assessment of headaches, reported by participants and measured each day using diary.

The result suggested no important difference between treatment groups for the average number of days with headache per month (MD 0.50; 95% CI –4.33, 5.33; *p* = 0.84) (*GRADE: Very Low*).

Pain

One trial (27 participants) reported pain intensity measured with a visual analogue scale (VAS) at the end of treatment (12 weeks) (Villiani 2017). The VAS is a subjective assessment of pain, reported by participants and measured on a continuous scale (cm) from 0 (no pain) to 10 (worst imaginable pain). Higher values indicate worse pain. An MCID for the pain VAS is reported to be 2.7 cm (25–29) in people with headache (34) but can vary from 0.8 to 4.0 cm across different patient groups (35).

The results showed no important difference between treatment groups comparing shiatsu (plus amitriptyline) with control (amitriptyline alone) (MD –0.20; 95% CI –1.48, 1.08; *p* = 0.76) (*GRADE: Very Low*).

Clinical efficacy

One trial (27 participants) reported clinical efficacy measured by the proportion of participants who experienced a more than 50% reduction in the average number of days with headache per month (over the three-month treatment period) compared with the pre-treatment period (Villiani 2017). The measure is a subjective assessment of headaches, reported by participants and measured each day using diary.

The result suggested no important difference between treatment groups, with 55% of participants who received shiatsu (plus amitriptyline) experiencing improvement in the average number of days with headache per month compared with 62% of participants in the control group (amitriptyline alone) (RR 0.89; 95% CI 0.44, 1.77; *p* = 0.73) (*GRADE: Very Low*).

Comparison 3 (vs other)

One study (Villiani 2017) comparing shiatsu with 'other' interventions in people with headache disorders was eligible for this comparison and contributed data relevant to three of the seven critical or important outcomes.

Available data are presented in Appendix F2.1 Supplementary outcome data.

D5.2 Rehabilitation after stroke

D5.2.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-15.

Table D-15 Overview of PICO criteria of included studies: rehabilitation after stroke

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Tian 2020 (36)	RCT	Stroke recovery (with deglutition disorder)	Acupoint massage alone OR Acupoint massage plus electrical stimulation ^	Electrical stimulation	Routine medical care (drug treatment and rehabilitation for swallowing)	Disability Swallowing muscle function Clinical efficacy
Shiatsu vs 'other' intervention**						
No studies found						

Abbreviations: RCT, randomised control trial; QoL, Quality of life

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

^ Group considered in the evidence synthesis as acupoint massage delivered as an adjunct to electrical stimulation

D5.2.2 Risk of bias per item

The risk of bias for each item in the included studies for recovery after stroke is described below and shown graphically in Figure D-9.

Bias arising from the randomisation process

Tian 2020 did not provide information on the randomisation procedure or allocation concealment therefore was judged to have some concerns for this domain. Baseline characteristics across treatment groups did not suggest a problem with the randomisation process.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

Tian 2020 was judged to be at low risk of bias as no deviations from the trial protocol were reported.

Bias due to missing outcome data

Tian 2020 was judged to be at low risk of bias for this domain as outcome data appeared to be available for all participants.

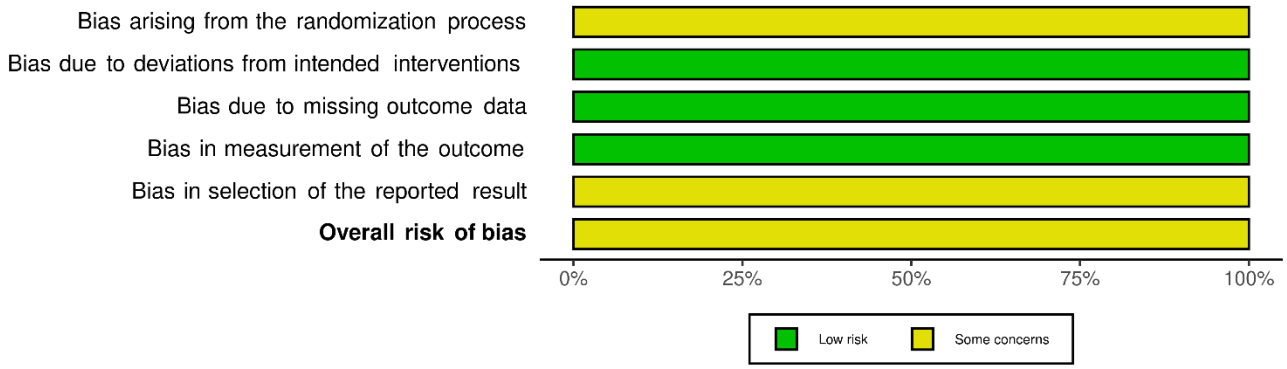
Bias in measurement of the outcome

Tian 2020 was judged to be at low risk of bias regarding the measurement of outcomes. The studies did not blind the participants and it is unclear if the outcome assessors were blinded. However, measure of food intake and swallowing muscle function were not likely to be substantially biased because of knowledge of treatment received.

Bias in selection of the reported result

In the absence of information, Tian 2020 was judged to have some concerns of bias for this domain.

Figure D-9 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included RCTs – Stroke recovery



D5.2.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in people recovering after a stroke are listed in Table D-16.

Table D-16 Outcomes considered by the NTWC to be critical or important for decision-making: recovery after stroke

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Tian 2020
Activities of daily living	No eligible measures reported	Critical	No	--
Disability	Fujishima Ichiro Food intake levels scale	Critical	Yes	✓
Quality of life	SF-36 or similar	Critical	No	--
Motor function	No eligible measures reported	Critical	No	--
Cardiorespiratory health	Heart rate, blood pressure	Critical	No	?
Pain	Visual Analogue scale	Critical	No	?

Abbreviations: BP, blood pressure; HR, heart rate

✓ A study result is available for inclusion in the synthesis

X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators

-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results

? No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

Comparison 1 (vs sham)

There were no studies identified comparing shiatsu with sham in people recovering after stroke.

Comparison 2 (vs 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 six critical or important outcomes.

Disability

One trial (60 participants) reported disability associated with dysphagia measured with the Fujishima Ichiro Food intake levels scale at the end of treatment (4 weeks) (Tian 2020). The FILS is a subjective assessment of swallowing function and is scored on a continuous scale from 1 to 10. A score between 1 to 3 points suggested severe deglutition disorder (unable to eat orally); between 4 to 6 points suggested moderate disorder (can eat orally, but supplementary nutrition was needed); between 7 to 9 points suggested mild disorder (enough nutrition could be taken orally); and a score of 10 points suggested normal swallowing function (37). An MCID for the FILS has not been established.

The results showed an effect favouring shiatsu compared with the control group (MD –1.36; 95% CI –1.80, –0.92; $p < 0.00001$) (*GRADE: Low*).

Comparison 3 (vs other)

One RCT (Tian 2020) comparing shiatsu with an 'other' intervention (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 six critical or important outcomes.

Available data are presented in Appendix F2.1 Supplementary outcome data.

D6 Diseases of the circulatory system

D6.1 Hypertensive heart disease

D6.1.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-17

Table D-17 Overview of PICO criteria of included studies: Hypertensive heart disease

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Lei 2015 (38)	Quasi-RCT	Hypertension, primary (adults older than 60 years)	Acupoint massage	No intervention	Health education	Sleep quality Neurocognitive function
Shiatsu vs 'other' intervention**						
No studies found						

Abbreviations: RCT, randomised control trial; QoL, Quality of life

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

Abbreviations: RCT, randomised control trial

D6.1.2 Risk of bias per item

The risk of bias for each item in the included studies for hypertensive heart disease is described below and shown graphically in Figure D-10.

Bias arising from the randomisation process

One study (Lei 2015) was judged to have some concerns of bias due to a lack of information. The authors do not clearly describe the method of randomisation or report on allocation concealment, but baseline characteristics are matched between groups.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

Lei 2015 was judged to be at low risk of bias for this domain as no deviations from the trial protocol were reported. Due to the nature of the intervention, participants in both groups were aware of their allocated interventions.

Bias due to missing outcome data

Lei 2015 was judged to be at low risk of bias for this domain as outcome data appeared to be available for all (or nearly all) participants.

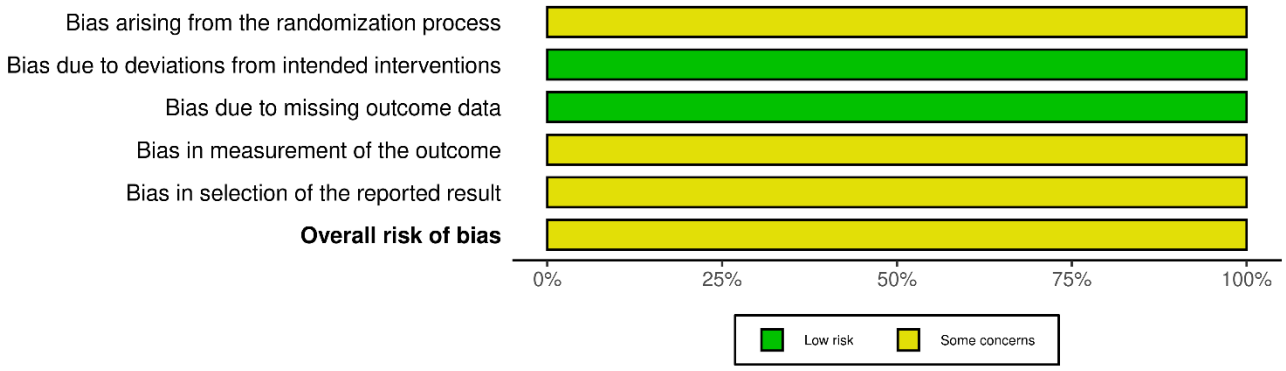
Bias in measurement of the outcome

Concerns of bias were raised in one study (Lei 2015) due to the outcome measures being subjective. It is not stated if the outcome assessors were blinded to the intervention received, therefore it is possible that the outcomes being assessed could be influenced by assessor and participant knowledge of the intervention.

Bias in selection of the reported result

Concern of bias were raised in one study (Lei 2015) due to a lack of information or clear description about a pre-specified analysis plan.

Figure D-10 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included RCTs – Hypertensive heart disease



D6.1.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in people with hypertensive heart disease are listed in Table D-18.

Table D-18 Outcomes considered by the NTWC to be critical or important for decision-making: hypertensive heart disease

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Lei 2015
Cardiovascular health	Blood pressure	Critical	No	?
Cognitive function	MMSE	Important	Yes	✓

Abbreviations: MMSE, Mini-Mental State Examination
✓ A study result is available for inclusion in the synthesis
X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators
-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results
? No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

Comparison 1 (vs sham)

There were no studies found comparing shiatsu with sham in people with hypertensive heart disease.

Comparison 2 (vs control)

One quasi-RCT (Lei 2015) comparing shiatsu to control (no intervention) in participants with primary hypertension was eligible for this comparison and contributed data relevant to one of two critical or important outcomes.

Mini-Mental State Examination

One trial (68 participants) reported cognitive function measured with the MMSE at the end of treatment (4 weeks) (Lei 2015).

The MMSE is a widely used screening test for cognitive impairment in the elderly population and is designed to measure orientation, short and long-term memory, registration, recall, constructional ability, language and the ability to understand and follow commands (22). The MMSE is conducted by healthcare professionals with the result summarised on a scale from 0 (worse) to 30 (best). A MMSE score below 25 suggests cognitive impairment (24). An MCID for MMSE has not been established in primary hypertension, with a difference of 1 to 2 points is indicative of a change in cognitive function in people with Alzheimer's disease (22).

The results showed an effect in favour of shiatsu compared with the control group (MD –2.11; 95% CI –3.20, –1.02, *p* = 0.0001) (SMD 0.91) (*GRADE: Low*)

Comparison 3 (vs other)

There were no studies found comparing shiatsu with 'other' active interventions in people with hypertensive heart disease.

D7 Diseases of the digestive system

D7.1 Constipation

D7.1.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-19.

Table D-19 Overview of PICO criteria of included studies: Chronic constipation

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Chen 2021 (39)	Quasi-RCT	Functional constipation (chronic)	Acupoint massage therapy	Control (no intervention)	None	Symptom severity Quality of life
Ho 2020 (40)	Quasi-RCT	Functional constipation	Acupoint pressure therapy & abdominal massage	Control (no intervention) OR Abdominal massage ^	Standard care (laxatives)	Symptom severity
shiatsu vs 'other' intervention**						

Abbreviations: RCT, randomised control trial

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

^ Eligible comparisons are (i) Acupoint pressure + abdominal massage vs abdominal massage (the effect of acupoint pressure alone) AND (ii) Acupoint pressure + abdominal massage vs Control (no intervention) (effect of acupoint pressure + abdominal massage).

D7.1.2 Risk of bias

The risk of bias for each item in the included studies for constipation is described below and shown graphically in Figure D-11.

Bias arising from the randomisation process

One study (Chen 2021) did not provide information about the randomisation process raising some concerns, but there was no significant difference in baseline characteristics between intervention groups. One study (Ho 2020) was judged to be high risk of bias for this domain, as there was reason to suspect that participants had knowledge of the forthcoming intervention (participants were alternately assigned to the intervention group by the principle investigator) and there was an imbalance in more than one baseline characteristic between intervention groups.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

Both studies (Chen 2021, Ho 2020) were judged to be at low risk of bias for this domain, as no deviations from the trial protocol were reported. Due to the nature of the intervention, participants in both studies were aware of their allocated interventions.

Bias due to missing outcome data

Both studies (Chen 2021, Ho 2020) were judged to be at low risk of bias for this domain. Outcome data was available for all (or nearly all) participants in Chen 2021 and missing data was appropriately corrected for in Ho 2020.

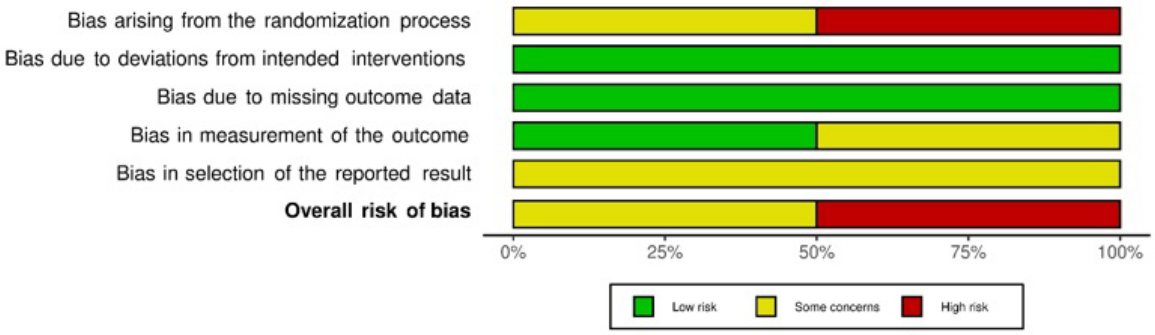
Bias in measurement of the outcome

One study (Ho 2020) was judged to be at low risk of bias for this domain. One study (Chen 2021) had some concern of bias raised for subjective outcome measures, that could have been influenced by knowledge of the intervention received. The study did not state if outcome assessors were blinded.

Bias in selection of the reported result

All included studies were judged to have some concerns of bias due to a lack of information relating to the study protocol or statistical analysis plan.

Figure D-11 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included RCTs – Functional constipation



D7.1.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in people with functional constipation are listed in Table D-20

Table D-20 Outcomes considered by the NTWC to be critical or important for decision-making: Functional constipation

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Chen 2021	Ho 2020
Symptom severity	The Bowel Function Index or NANDA-I total score	Critical	No	X	X
Health related QoL	Patient Assessment of Constipation - QoL	Critical	Yes	✓	?
Clinical efficacy	No measures reported in included studies	Important	No	--	--

Abbreviations: NANDA, North American Nursing Diagnosis Association; QoL, quality of life

✓ A study result is available for inclusion in the synthesis

X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators

-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results

? No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

Comparison 1 (vs sham)

There were no studies identified comparing shiatsu with sham in people with functional constipation.

Comparison 2 (vs control)

Two studies (Chen 2021, Ho 2020) comparing shiatsu with no intervention in people with constipation were eligible for this comparison and contributed data to one outcome.

Symptom severity

One trial (90 participants) measured symptom severity with the Nursing Diagnosis of Constipation Index (NANDA-I) over the course of treatment (10 days). The NANDA-I contains 28 items completed by participants relating to ease of defecation, frequency and consistency, firmness of faeces, feeling of incomplete bowel evacuation and other signs and symptoms of constipation. Items are rated on a 3-point Likert scale ranging from 0 (no problems) to 2 (severe problems) (total 56 points). A higher score indicates more severe symptoms or adverse effects of constipation.

The authors do not report any usable data, with the study authors investigating the association of eight potential covariates with outcomes (age, bowel movements less than twice per week, bedridden, activity dependent, oral intake methods, chronic disease, fluid intake and fruit intake).

Quality of life

One trial (101 participants) reported quality of life measured by the Patient Assessment of Constipation – Quality of Life (PAC - QoL) questionnaire at the end of treatment (3 months) (Chen 2021). The 28 item self-reported tool that is designed to measure the impact constipation has had on your daily life over the previous 2 weeks. There are 4 subscales (physical discomfort, psychosocial discomfort, worries and concerns, and satisfaction), each measured with a 5-point Likert scale (41). Authors report a total PAC-QoL score, on a scale of 0 (best) to 112 (worst). A reduction of more than 1 in PAC-QoL score has been reported as the MCID in people with chronic non-cancer pain and opioid induced constipation (42).

The results showed an effect in favour of shiatsu compared with the control group (MD –10.98; 95% CI –17.12, –4.84; p = 0.0005). *(GRADE: Low)*

Comparison 3 (vs other)

There were no studies identified comparing shiatsu with 'other' active interventions in people with constipation.

D8 Musculoskeletal system

D8.1 Chronic musculoskeletal pain

D8.1.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-21.

Table D-21 Overview of PICO criteria of included studies: chronic musculoskeletal pain

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Koboyashi 2019 (43)	RCT	Low back pain	Shiatsu	Control (No intervention)	None	Disability Pain Quality of life
Shiatsu vs 'other' intervention**						
Donoyama 2010 (44)	Quasi RCT	Neck and shoulder stiffness (chronic)	Shiatsu	Attention control (rest on massage table)	None	Symptom severity Psychosocial wellbeing Stress
Faull 2005 (45)	RCT	Fibromyalgia	Watsu	Aix	None	Disability Pain Quality of life
Yuan 2013 (46-48)	Cluster RCT	Fibromyalgia	Shiatsu	Education and stretching	Usual care (pharmacotherapy)	Pain Psychosocial wellbeing Fatigue Disability

Abbreviations: RCT, randomised control trial

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

D8.1.2 Risk of bias

The risk of bias for each item in the included studies for chronic musculoskeletal pain is described below and shown graphically in Figure D-12.

Bias arising from the randomisation process

Faull 2005 was assessed to have high risk of bias for this domain due to lack of information provided regarding the randomisation and allocation concealment processes. Baseline demographics was also not provided for each of the intervention groups. There is some difference noted in the baseline SF-36 subscales with scores lower in the intervention group, suggesting a potential bias towards the intervention group.

Concerns of bias were raised for three studies due to missing information. Koboyashi 2019 randomised participants using a computer-generated randomisation list, but did not provide any information on allocation concealment Donoyama 2010 did not provide any information on the method of randomisation or allocation concealment. Yaun 2013 randomised into the intervention or control group based on the rehabilitation clinic they attended, but no further information on the cluster-design was provided. In all three studies, reported baseline characteristics appeared matched between treatment groups.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])
All four studies (Faull 2005, Yaun 2013, Koboyashi 2019, Donoyama 2010) were judged to have low risk of bias for this domain; any discontinuations from intended interventions were judged to be unrelated to the trial context.

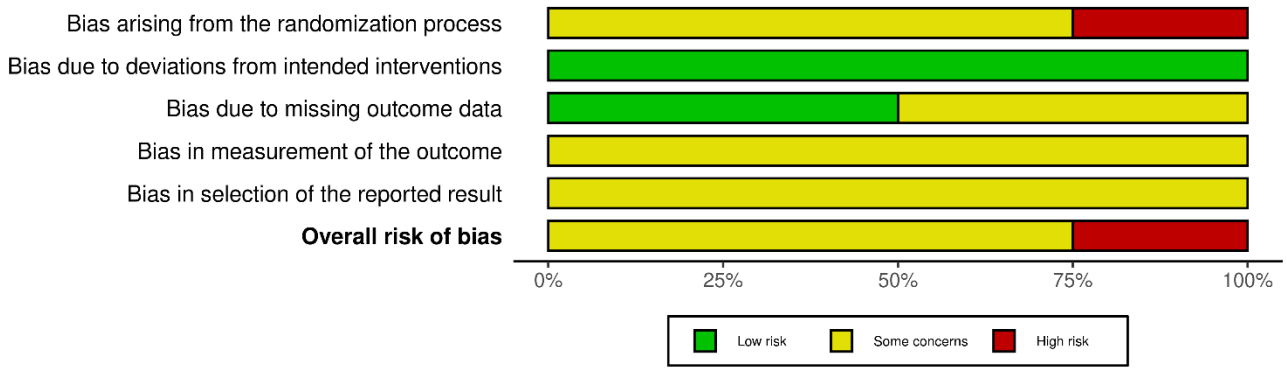
Bias due to missing outcome data
The analysis in Koboyashi 2019 addressed missing data and is likely to have removed any risk of bias. A per protocol analysis was also carried out to assess if the result was biased and was judged to be at low risk of bias.

Three studies (Faull 2005, Yaun 2013, Donoyama 2010) had some concerns raised as missingness of the data differed across intervention groups and there was little detail to make further assessments.

Bias in measurement of the outcome
All four studies (Faull 2005, Yaun 2013, Koboyashi 2019, Donoyama 2010) had concerns raised regarding the measurement of outcomes as, due to the nature of interventions, they could not blind the participants. As many of the key outcomes were subjective, the results could be influenced by knowledge of the intervention received.

Bias in selection of the reported result
All four studies (Faull 2005, Yaun 2013, Koboyashi 2019, Donoyama 2010) reported all eligible specified results and, in the absence of an available protocol or analysis plan, were judged to be at some concerns for this domain.

Figure D-12 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included RCTs – chronic musculoskeletal pain



D8.1.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in people with chronic musculoskeletal pain are listed in Table D-22.

Table D-22 Outcomes considered by the NTWC to be critical or important for decision-making: chronic musculoskeletal pain

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Faull 2005	Yuan 2013	Koboyashi 2019	Donoyama 2010
Pain	VAS or McGill Pain Questionnaire	Critical	Yes	--	--	✓	✓
Functional capacity	SF-36 physical components	Critical	No	--	--	--	--
Disability	ODI or neck pain disability score or fibromyalgia impact questionnaire	Critical	Yes	--	--	✓	--
Quality of life	EQ-5D	Critical	Yes	--	--	✓	--
Stress	No measures reported in eligible studies	Critical	No	--	--	--	--
Fatigue	Fatigue severity scale	Critical	No	--	--	--	--
Psychosocial wellbeing	STAI (20 items) or SF-36 mental components	Critical	No	--	--	--	✓

Abbreviations: EQ-5D, European Quality of Life Five Dimension; ODI, Oswestry disability index; SF-36, 36-item Short Form Survey; STAI, state-trait anxiety index; VAS, Visual Analogue Scale

✓ A study result is available for inclusion in the synthesis

X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators

-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results

? No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

Comparison 1 (vs sham)

No studies found.

Comparison 2 (vs control)

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

Pain

One trial (59 participants) reported pain measured with the short-form McGill Pain Questionnaire (MPQ-SF) at the end of treatment (four weeks) (Koboyashi 2019). The MPQ-SF is a self-reported, multidimensional measure of pain that examines the sensory and affective dimensions of subjective pain. It consists of 15 descriptors of pain (11 sensory, 4 affective), of which people choose those that best describe their experience of pain. Descriptors are rated on a Likert scale ranging from zero (no pain) to 3 (severe pain), the sum of which is used to derive a total score (maximum 45). The MCID for the MPQ-SF has not been established in people with low back pain.

The study authors reported mean change from baseline scores, with no difference between shiatsu and the control group observed (MD –0.30; 95% CI –1.96, 1.36; p = 0.72) *(GRADE: Low)*.

Disability

One trial (59 participants) reported disability measured with the Oswestry Disability Index (ODI) at end of treatment (four weeks) (Koboyashi 2019). The ODI is used to quantify disability related to lower back pain. The questionnaire is comprised of 10 questions that assess the ability of people with low back pain to manage everyday life. Answers are scored on a Likert scale of 0 (no disability) to 5 (great deal of disability) scale. The final score ranges from 0–100, with a score of 0–20 indicating minimal disability, 21–40 indicates moderate disability, 41–60 indicates severe disability, 61–80 indicates crippled (back pain impinges on all aspects of life), and 81–100 indicating complete disability (bed-bound). In people with chronic low back pain the minimal important change is calculated to be 12.88 (sensitivity 88%, specificity 85%) (49).

The study authors reported mean change from baseline scores, with no difference between shiatsu and the control group observed (MD –1.20; 95% CI –3.52, 1.12; p = 0.31) *(GRADE: Low).*

Quality of life

One trial (59 participants) reported disability measured with the EQ-5D at end of treatment (four weeks) (Koboyashi 2019). The EQ-5D is used to quantify health related quality of life. The questionnaire is comprised of five questions across multiple dimensions including mobility, self-care, usual care activities, pain/discomfort, and anxiety/depression. Answers are scored on a Likert scale from 1 (full health) to 5 (worst health) scale,

The study authors reported mean change from baseline scores, with no difference between shiatsu and the control group observed (MD –0.06; 95% CI –0.11, –0.00; p = 0.04) *(GRADE: Low).*

Comparison 3 (vs other)

One trial (Donoyama 2010) comparing shiatsu with placebo in people with chronic neck and shoulder pain was eligible for this comparison and contributed data relevant to one of the seven outcomes.

Three studies (Donoyamam 2010, Faull 2013, Yuan 2013) comparing shiatsu with 'other' interventions in people with chronic musculoskeletal pain (fibromyalgia, neck/shoulder) were eligible for this comparison and contributed data relevant to two of the critical outcomes.

Available data are presented in Appendix F2.1 Supplementary outcome data.

D9 Diseases of the genitourinary system

D9.1 Primary dysmenorrhoea

D9.1.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-23.

Table D-23 Overview of PICO criteria of included studies: Primary dysmenorrhoea

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Soliman 2017 (50)	Quasi RCT	Primary dysmenorrhoea (age 20-22 years)	Shiatsu	Educational advice	None	Pain
Shiatsu vs 'other' intervention**						
No studies found						

Abbreviations: RCT, randomised control trial

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

D9.1.2 Risk of bias per item

The risk of bias for each item in the included RCT for primary dysmenorrhoea is described below and shown graphically in Figure D-13.

Bias arising from the randomisation process

Concerns of bias were raised for Soliman 2017 due to missing information. The study randomised participants according to the study year group they were enrolled (alternate allocation according to even-odd years). No further information on the randomisation process was provided but reported baseline demographics did not appear to differ between the intervention and control group.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

Soliman 2017 failed to provide any information relating to the number of participants allocated to the intervention groups, or if there were any deviations or dropouts that occurred during the study.

Bias due to missing outcome data

Soliman 2017 failed to provide any information relating to the amount of missing data.

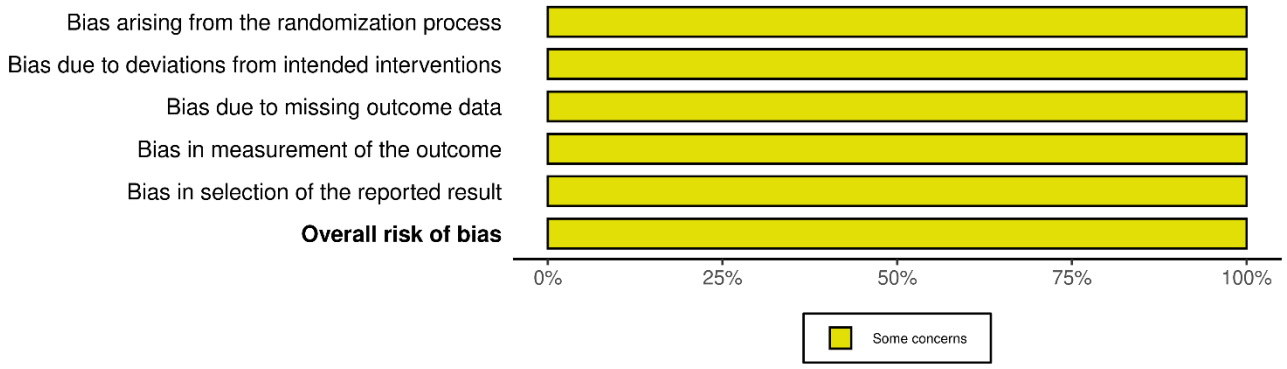
Bias in measurement of the outcome

Concerns were raised regarding the measurement of outcomes as, due to the nature of interventions, they could not blind the participants. As many of the key outcomes were subjective, the results could be influenced by knowledge of the intervention received.

Bias in selection of the reported result

Soliman 2017 reported all eligible specified results and, in the absence of an available protocol or analysis plan, were judged to be at some concerns for this domain.

Figure D-13 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included RCTs – Primary dysmenorrhoea



D9.1.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in women with dysmenorrhoea is listed in Table D-24.

Table D-24 Outcomes considered by the NTWC to be critical or important for decision-making: Primary dysmenorrhoea

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Soliman 2017
Symptom severity	Menstrual Symptom Severity List or similar	Critical	Yes	✓
Health-related QoL	SF-36 or similar	Critical	No	--
Pain	Visual Analogue Scale	Critical	Yes	✓
Anxiety	No measures reported in eligible studies	Critical	No	--
Emotional function	No measures reported in eligible studies	Critical	No	--
Depression	No measures reported in eligible studies	Important	No	--
Sleep quality	No measures reported in eligible studies	Important	No	--

Abbreviations: QoL, quality of life

✓ A study result is available for inclusion in the synthesis

X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators

-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results

? No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

Comparison 1 (vs sham)

There were no studies found comparing shiatsu with sham in women with dysmenorrhoea.

Comparison 2 (vs control)

One quasi-RCT (Soliman 2017) comparing shiatsu to control (usual care) in women with primary dysmenorrhoea was eligible for this comparison and contributed data relevant to two of the seven critical or important outcomes.

Symptom severity

One trial (82 participants) measured and reported symptom severity at the end of treatment (immediately after the intervention) (Soliman 2017).

Specific details on the measure used and how it is to be interpreted were lacking, but it is assumed to be based on the 15-item symptom severity scale, where participants recall their level of discomfort in the previous cycle. Symptoms are rated from 0 (no symptom) to 5 (worst possible) (51, 52). The authors reported individual scores relating to the following 12 symptoms: tension/anxiety, bowel disturbances, constipation, abdominal distention, backache, breast tenderness, leg pain, nausea/vomiting, anorexia, fatigue, and vertigo. A summary score was also provided, but it is not clear how this was determined (or the minimum/maximum range).

The results suggest an effect that favours self-care shiatsu compared with no intervention (MD –9.75; 95% CI –12.57, –6.93; $p < 0.00001$). In the absence of information about the scale, the effect size was standardised to allow interpretation of the effect (SMD –1.61; 95% CI –2.12, –1.11; $p < 0.00001$). *(GRADE: Low)*

Pain

One trial (82 participants) reported pain related to primary dysmenorrhoea measured with a visual analogue scale (VAS) immediately after the intervention (at the first and second menstrual cycle)[1] (Soliman 2017). The VAS is a subjective assessment of pain, reported by participants and measured on a continuous scale (cm) from 0 (no pain) to 10 (worst imaginable pain). Higher values indicate worse pain. The MCID for pain not been established in females with primary dysmenorrhoea, with the MCID reported to be 10 mm (or 1 on a 10–point scale) in females with endometriosis (53).

The results suggest an effect that favour of shiatsu compared with the control group (MD –0.70; 95% CI –1.04, –0.36; $p < 0.0001$), but the effect does not reach the MCID. *(GRADE: Low)*

Comparison 3 (vs other)

There were no studies found comparing shiatsu with 'other' active interventions in women with dysmenorrhoea.

[1] To avoid bias due to repeated measures at multiple timepoints, only the second menstrual cycle results are presented here.

D10 Pregnancy, childbirth or the puerperium

D10.1 Pregnancy and childbirth

D10.1.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-25.

Table D-25 Overview of PICO criteria of included studies: Pregnancy and childbirth

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Schitter 2015 (54)	NRSI	Pregnant women (more than 34 weeks gestations	Watsu	No intervention	--	Perceived stress Quality of life Pregnancy-related pain
Teimoori 2014 (55)	RCT	Pregnant women (42 weeks gestation)	Shiatsu	No intervention	--	Birth experience
Shiatsu vs 'other' intervention**						
No studies found						

Abbreviations: NRSI, non-randomised studies of interventions; RCT, randomised control trial

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

D10.1.2 Risk of bias per item

The risk of bias for each item in the included studies for pregnancy and prenatal is described below and shown graphically in Figure D-14.

Randomised controlled trials

Bias arising from the randomisation process

One RCT (Teimoori 2014) was judged to be at low concerns of bias for this domain, as an appropriate randomisation process was used and baseline characteristics balanced.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

One RCT (Teimoori 2014) was judged to be at some concerns of bias for this domain, as there is no information provided regarding if participants were lost to follow up or deviated from intended intervention. Of 600 women referred, 288 participants were included in the analysis.

Bias due to missing outcome data

One RCT (Teimoori 2014) was judged to be at low risk of bias for this domain, as data appeared to be available for all enrolled participants.

Bias in measurement of the outcome

One RCT (Teimoori 2014) was judged to be at low risk of bias for this domain, as the study used validated methods for outcomes measures and outcomes are unable to influenced by knowledge of intervention received (labour induction).

Bias in selection of the reported result
One study (Teimoori 2014) reported all eligible specified results and, in the absence of an available protocol or analysis plan, were judged to be at some concerns for this domain.

Non-randomised studies of interventions

Bias due to confounding
One study (Schitter 2015) was assessed at serious concerns for this domain. Although we do not expect serious residual confounding there is no evidence that pre-intervention variables that have the potential for confounding of the effect of the intervention, have been appropriately controlled for, this includes breech presentation and whether the women are first-time mothers.

Bias of selection of participants into the study
One study (Schitter 2015) was assessed at low risk of bias in this domain. Participants were followed from the start of the intervention making it unlikely that there was misclassification of outcome status. It is assumed all eligible participants were invited to participate.

Bias in classification of interventions
One study (Schitter 2015) was assessed at low risk of bias in this domain. Intervention status was well defined and was determined after enrolment into the study.

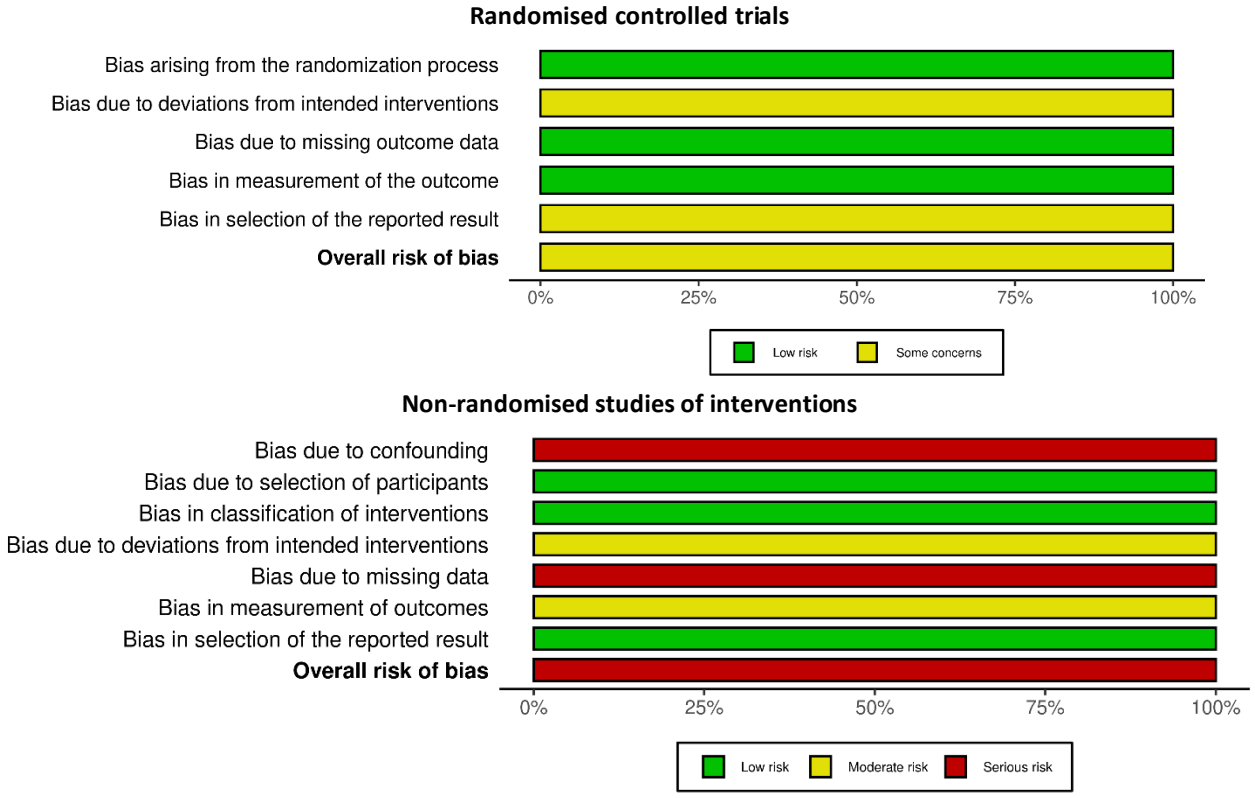
Bias due to deviations from intended interventions
One study (Schitter 2015) was assessed at moderate risk of bias in this domain. Participants were allocated to the control group if they refused the intervention group, with any deviations from intended intervention reflecting usual practice.

Bias due to missing data
One study (Schitter 2015) was assessed at serious risk of bias in this domain, due to a 38% drop out rate in the intervention group, which is likely to overstate the effect of the intervention. The method of analysis used to account for this missing data (last value carried forward) was considered appropriate.

Bias in measurement of outcomes
One study (Schitter 2015) was assessed at moderate risk of bias in this domain, as outcomes were subjective and could have been influenced by knowledge of the intervention received.

Bias in selection of the reported result
One study (Schitter 2015) was assessed at low risk of bias in this domain, as outcomes measures were measured appropriately.

Figure D-14 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies – Pregnancy and childbirth



D10.1.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in pregnant women are listed in Table D-26.

Table D-26 Outcomes considered by the NTWC to be critical or important for decision-making: Pregnancy, prenatal

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Schitter 2015	Teimoori 2014
Birth experience	Duration of labour	Critical	No	--	✓
Quality of life	SF 36	Critical	Yes	✓	--
Pregnancy-related pain	Visual analogue scale	Critical	No	X	--
Perceived stress	Visual analogue scale	Critical	Yes	✓	--
Functional capacity	Activities of daily living or similar	Critical	No	--	--
Maternal morbidity	None reported	Important	No	--	--
Foetal health	Ultrasound	Important	No	X	--

Abbreviations: QoL, quality of life; SF-36, 36-item short-form

✓ A study result is available for inclusion in the synthesis

X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators

-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results

? No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

Comparison 1 (vs sham)

There were no studies found comparing shiatsu with sham in pregnant women.

Comparison 2 (vs control)

One RCT (Teimoori 2014) and one NRSI (Schitter 2015) comparing shiatsu to control (no intervention) in pregnant women were eligible for this comparison and contributed data relevant to the three of the seven critical or important outcomes.

Birth experience

One RCT (288 participants) reported the mean duration of labour after the application of shiatsu to induce labour among post-term mothers (Teimoori 2014). Measurement details were lacking and are assumed to be measured from onset of dilation of the cervix (stage one) through birth (stage two) and until the delivery of the placenta (stage three). Available data were limited to absolute numbers (no standard deviation, confidence interval etc. reported), with the authors noting the mean duration of labour stages being 15.4 hours in the shiatsu group and 13.2 hours in the control group, which were not significantly different ($p > 0.05$). *(GRADE: Low)*

Quality of life

One trial (17 participants) reported quality of life measured with the SF-36 Health Survey Questionnaire at followup (four days after the end of treatment (four days)) (Schitter 2015). The SF-36 is a well-established tool used to indicate the health status of a particular population that uses 36 questions to assess eight health concepts relating to physical functioning, bodily pain, role limitations to due physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue and general health perceptions (56). Scores for each domain are converted and pooled using a scoring system, for a total of score indicating a range of 0 (best) to 100 (worse) quality of life (57). Scores were summarised into two composite scores (physical and mental health) which should be interpreted in comparison to the overall scores (57). A non-disease specific MCID for the physical (2 points) and mental components (3 points) of the SF-36 questionnaire has been previously established (58).

The results showed no difference between the shiatsu and control groups for mean changes in SF-36 physical components score (MD –1.80; 95% CI –7.99, 4.39; $p = 0.57$) or the SF-36 mental components score (MD 0.20; 95% CI –3.41, 3.81; $p = 0.91$). *(GRADE: Very Low)*

Perceived stress

One trial (17 participants) measured perceived stress with a visual analogue scale (VAS) at followup (four days after the end of treatment (four days) (Schitter 2015). The VAS is a widely used tool in clinical practice to empirically assess perceived stress, measured on a 100 mm scale with 0 mm indicating no stress and 100 mm indicating maximal perception of stress (54, 59). The MCID for a perceived stress VAS has not been established.

The results suggest an effect in favour of shiatsu compared with the control group (MD –3.00; 95% CI –5.64, –0.36; $p = 0.03$). *(GRADE: Very Low)*

Comparison 3 (vs other)

There were no studies found comparing shiatsu with ‘other’ active interventions in pregnant women.

D10.2 Postpartum care

D10.2.1 List of studies

An overview of the PICO criteria of included studies is provided Table D-27

Table D-27 Overview of PICO criteria of included studies: postpartum care

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Sheng 2021 (60)	RCT	Mothers of infants in NICU (less than 34 weeks gestation)	Breast massage and acupoint stimulation	No intervention	Education and support	Breast feeding
Shiatsu vs 'other' intervention**						
No studies found						

Abbreviations: RCT, randomised control trial; NICU, neonatal intensive care unit

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

D10.2.2 Risk of bias per item

The risk of bias for each item in the included studies for preterm infant mothers is described below and shown graphically in Figure D-15.

Bias arising from the randomisation process

One study (Sheng 2021) was judged to be at low concerns of bias for this domain, as an appropriate randomisation process was used, and baseline characteristics balanced.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

One study (Sheng 2021) was judged to be at low concerns of bias for this domain, as no deviations arose from the trial context, despite participants being aware of their assigned intervention.

Bias due to missing outcome data

One study (Sheng 2021) was judged to be at low risk of bias for this domain, as data was available for all, or nearly all, participants.

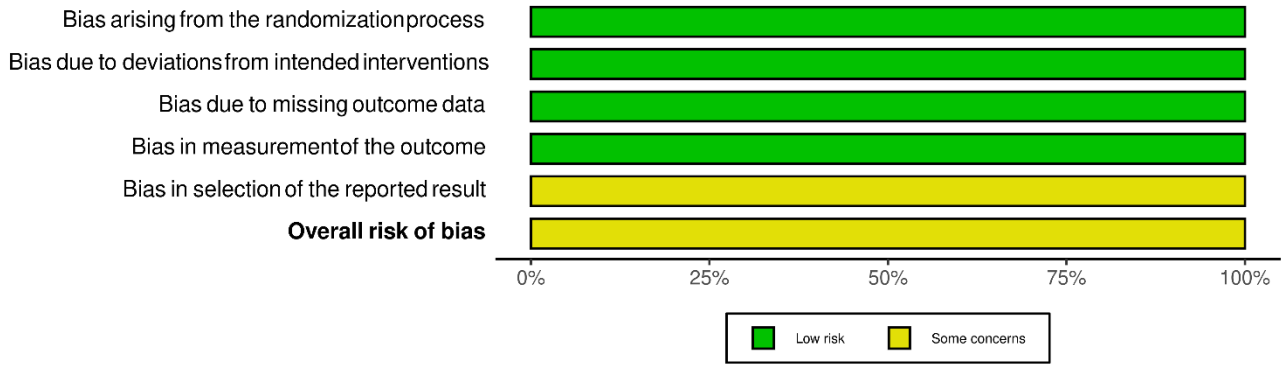
Bias in measurement of the outcome

One study (Sheng 2021) was judged to be at low risk of bias for this domain, as the study used validated methods for outcomes measures and assessment of outcomes and outcome results are unable to influenced by knowledge of intervention received, as milk expression is objective.

Bias in selection of the reported result

One study (Sheng 2021) was judged to be at some concerns of bias for this domain, as no pre-specified analysis plan was available.

Figure D-15 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included RCTs – postpartum care



D10.2.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in postpartum care are listed in Table D-28.

Table D-28 Outcomes considered by the NTWC to be critical or important for decision-making: postpartum care

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Sheng 2021
Birth experience	Duration of labour	Critical	No	--
Pelvic floor muscle function	No eligible measures reported	Critical	No	--
Pelvic pain and dysfunction	Visual analogue scale or similar	Critical	No	--
Quality of life	SF-36 or similar	Critical	No	--

Abbreviations: QoL, quality of life

✓ A study result is available for inclusion in the synthesis

X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators

-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results

? No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

Comparison 1 (vs sham)

There were no studies found comparing shiatsu with sham in postpartum care .

Comparison 2 (vs control)

One RCT (Sheng 2021) comparing shiatsu to control (no intervention) in mothers with infants in the NICU was eligible for this comparison but did not contribute any data relevant to the seven critical or important outcomes.

Comparison 3 (vs other)

There were no studies found comparing shiatsu with 'other' active interventions in postpartum care.

D11 Injury, poisoning or certain other consequences of external causes

D11.1 Burn injuries

D11.1.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-29

Table D-29 Overview of PICO criteria of included studies: Burn injuries

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Ardabili 2014 (61)	Quasi RCT	Burn injury (inpatient, 10-45% TBSA)	Shiatsu (hands and legs) OR Shiatsu (hands only) OR Shiatsu (legs only)	Control (no intervention)	Analgesia^	Pain Emotional wellbeing
Shiatsu vs 'other' intervention**						
No studies found						

Abbreviations: RCT, randomised control trial; TBSA, total body surface area

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

^ not clear if used as a co-intervention or administered when requested.

D11.1.2 Risk of bias per item

The risk of bias for each item in the included studies for burns is described below and shown graphically in Figure D-16.

Bias arising from the randomisation process

One study (Ardabili 2014) was judged to have some concerns in this domain due to the lack of information provided. The authors do not report a randomisation method, allocation concealment or baseline characteristics.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

One study (Ardabili 2014) had some concerns raised as missingness of the data differ slightly across intervention groups.

Bias due to missing outcome data

One study (Ardabili 2014) was judged to be at high risk of bias for this domain due to a lack of information regarding missing outcome data.

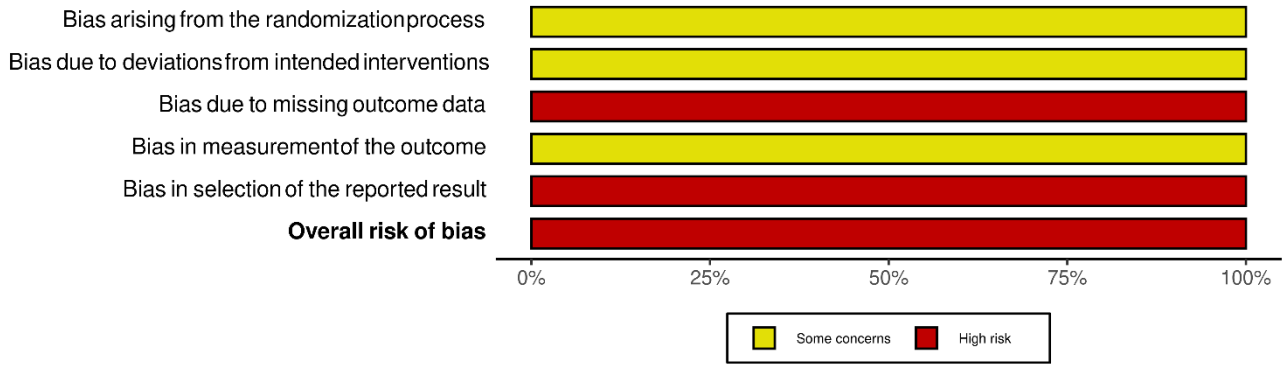
Bias in measurement of the outcome

One study (Ardabili 2014) was assessed to have some concerns regarding the measurement of outcomes. They study did not blind the participant or outcome assessors and many of the key outcomes were subjective, results of which could be influenced by knowledge of the intervention.

Bias in selection of the reported result

One study (Ardabili 2014) was judged to be at high risk of bias because of incomplete reporting, suggesting selective reporting of results.

Figure D-16 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included RCTs – Burn injuries



D11.1.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in people with burn injuries are listed in Table D-30.

Table D-30 Outcomes considered by the NTWC to be critical or important for decision-making: Burn injuries

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Ardabili 2014
Pain	Visual analogue scale	Critical	Yes	✓
Health-related QoL	No measures reported in eligible studies	Critical	No	?
Functional capacity	No measures reported in eligible studies	Critical	No	--
Sleep quality	No measures reported in eligible studies	Critical	No	--
Burden of care	No measures reported in eligible studies	Critical	No	--
Scar issues	No measures reported in eligible studies	Critical	No	?

Abbreviations: QoL, Quality of life

✓ A study result is available for inclusion in the synthesis

X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators

-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results

? No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

Comparison 1 (vs sham)

There were no studies found comparing shiatsu with sham in people burn injuries.

Comparison 2 (vs control)

One quasi-RCT (Ardabili 2014) comparing shiatsu with no intervention in people with burn injuries was eligible for this comparison and contributed data relevant to one of the six critical or important outcomes.

Pain

One trial (120 participants) reported pain intensity measured with a visual analogue scale (VAS) at the end of treatment (one 20 minute session prior to wound dressing change) (Ardabili 2014). The VAS is a subjective assessment of pain, reported by participants and measured on a continuous scale (mm) from 0 (no pain) to 100 (worst imaginable pain). Higher values indicate worse pain. The MCID has not been established in people with burns, with the median absolute MCID reported to be 20 points (IQR 15–30) in people with chronic pain (62).

The authors provide box and whisker plots, but data were minimal, with the number of participant enrolled in each group not reported (assumed 30 per group). After shiatsu massage (foot and hand, hand only, or leg only), the change in pain intensity score were lower than that of the control group but baseline scores were skewed (the pain intensity score in the control group were higher than the shiatsu massage groups). *(GRADE: Very Low)*

The outcome (pain) was judged to be at high risk of bias, but a sensitivity analysis was not performed as there was only one study contributing data.

Comparison 3 (vs other)

There were no studies found comparing shiatsu with 'other' active intervention in people with burn injuries.

D12 Factors influencing health status or contact with health services

D12.1 Recovery after minimally invasive surgery.

D12.1.1 List of studies

An overview of the PICO criteria of included studies is provided in Table D-31.

Table D-31 Overview of PICO criteria of included studies: Recovery after minimally invasive surgery

STUDY ID	STUDY DESIGN	POPULATION	INTERVENTION	COMPARATOR	CO-INTERVENTION	OUTCOME DOMAINS
Shiatsu vs sham *						
No studies found						
Shiatsu vs control (no intervention, waitlist, usual care)*						
Ruan 2021 (63)	Quasi RCT	Recovery after gynaecologic surgery (laparoscopic)	Acupoint massage	Control (no intervention)	Standard nursing care	Bowel recovery
Sui 2019 (64)	RCT	Spontaneous pneumothorax after VATS	Acupoint stimulation	Control (no intervention)	None reported	Pulmonary function Clinical recovery
Xia 2014 (65)	RCT	Recovery after ureteroscopy (holmium laser lithotripsy, ureteral calculus)	Acupoint massage	Control (no intervention)	Standard nursing care	Pain
Zhenqing 2019 (66)	RCT	Recovery after cholecystectomy (laparoscopic)	Acupoint massage with acupoint application (wrist bands)	Control (no intervention)	Standard nursing care	Pulmonary function Post operative complications
Shiatsu vs 'other' intervention**						
No studies found						

Abbreviations: RCT, randomised control trial; VATS, video-assisted thoracoscopic surgery

* Studies that compared shiatsu with sham or an inactive control were eligible for inclusion in the evidence synthesis and are included in the Summary of findings tables if they reported outcomes considered critical or important to this review.

** Studies that compared shiatsu with an active intervention are included in the supplementary outcome tables (Appendix F2.1) if they reported data for outcomes considered critical or important to this review.

D12.1.2 Risk of bias per item

The risk of bias for each item in the included studies for recovery after minimally invasive surgery is described below and shown graphically in Figure D-17.

Bias arising from the randomisation process

Three studies (Sui 2019, Zhenqing 2019 and Xia 2014) were judged to be at low risk of bias for this domain. One study (Ruan 2021) had concerns raised, as there was no information provided about the randomisation process.

Bias due to deviations from intended interventions (effect of assignment to intervention [ITT])

Two studies (Ruan 2021, Sui 2019) were judged to be at low risk of bias for this domain, as there were no deviations or dropouts or they were considered consistent with what would occur outside the trial context. Two studies (Xia 2014, Zhenqing 2019) had some concerns raised as there was a lack of information about trial deviations.

Bias due to missing outcome data

All four studies (Ruan 2021, Sui 2019, Zhenqing 2019, Xia 2014) were judged to be at low risk of bias for this domain, as outcome data appeared to be available for all (or nearly all) participants.

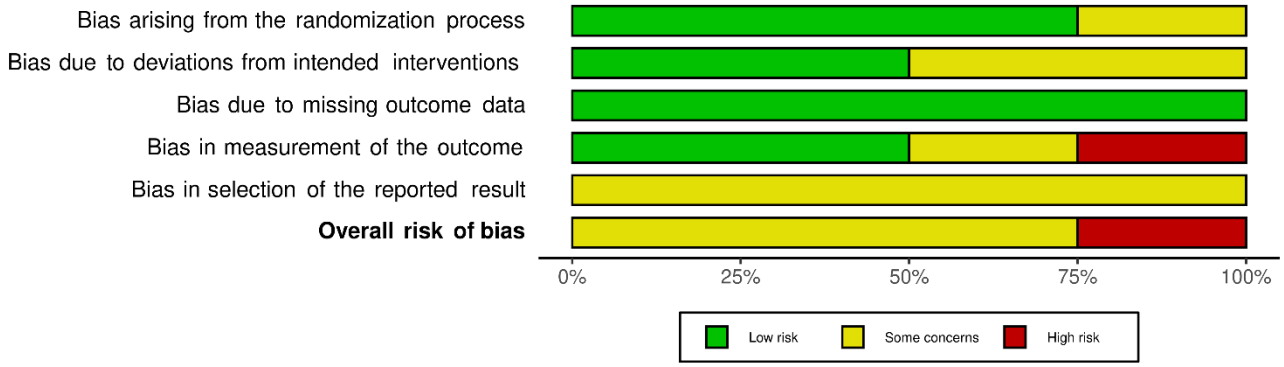
Bias in measurement of the outcome

Two studies (Ruan 2021, Sui 2019) were judged to be at low risk of bias for this domain, as the primary outcomes were objective, so it is unlikely that assessment of the outcome was influenced by knowledge of the intervention received. There were some concerns of bias related to knowledge of the intervention received in one study (Zhenqing 2019) and one study (Xia 2014) was judged to be at high concerns of bias for this domain, due to participants reporting on their own subjective outcome.

Bias in selection of the reported result

In the absence of a prespecified analysis plan or published protocol, all four studies (Ruan 2021, Sui 2019, Zhenqing 2019, Xia 2014) were judged to have some concern of bias for this domain.

Figure D-17 Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included RCTs – Recovery after minimally invasive surgery



D12.1.3 Effect of intervention

Outcomes considered by the NTWC to be critical or important for decision-making in external causes are listed in Table D-32.

Table D-32 Outcomes considered by the NTWC to be critical or important for decision-making: external causes – recovery after minimally invasive surgery

Outcome domain	Measured with	consensus rating	Data available for comparison 1 or 2?	Ruan 2021	Sui 2019	Xia 2014	Zhenqing 2019
Clinical recovery	No measures reported in eligible studies	Critical	No	--	--	--	--
Postoperative nausea and vomiting	Incidence of nausea and vomiting	Critical	Yes	--	--	--	✓
Postoperative Pain	Visual analogue scale	Critical	Yes	--		✓	✓
Bowel recovery	Time between first and last defecation	Critical	Yes	✓			
Pulmonary function	Oxygen saturation	Critical	Yes	--	✓		✓

Abbreviations:
✓ A study result is available for inclusion in the synthesis

X No study result is available for inclusion, (probably) because the P value, magnitude or direction of the results generated were considered unfavourable by the study investigators
-- No study result is available for inclusion, (probably) because the outcome was not assessed, or for a reason unrelated to the P value, magnitude or direction of the results
? No study result is available for inclusion, and it is unclear if the outcome was assessed in the study

Comparison 1 (vs sham)

There were no studies found comparing shiatsu with sham in people recovering after minimally invasive surgery.

Comparison 2 (vs 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 four outcomes.

Postoperative nausea and vomiting

One trial (98 participants) reported the total number of postoperative nausea and vomiting episodes over the 6-day study period (Zhenqing 2019). The episodes were recorded according to routine nursing records.

The results suggest the number of nausea and vomiting episodes is reduced in the shiatsu group compared with the control group (RR 0.46; 95% CI 0.25, 0.83; p = 0.01) *(GRADE: Moderate)*.

Postoperative Pain

Two trials (190 participants) reported post-operative pain either measured with a VAS at 6, 12, 24 hours after the operation (Xia 2014) or as a frequency over the 6-day post-operative period (Zhenqing 2019). The VAS is a subjective assessment of pain, reported by participants and measured on a continuous scale (mm) from 0 (no pain) to 100 (worst imaginable pain). Higher values indicate worse pain. Xia 2014 dichotomised the pain results, with 0 representing no pain, 1 to 3 for mild pain, 4 to 6 for moderate pain, and more than 6 for severe pain.

The combined results suggest an effect that favours shiatsu compared with the control group for pain after surgery (RR 0.32; 95% CI 0.18, 0.56; p = 0.0001) *(GRADE: Moderate)*.

In a sensitivity analysis to remove the study judged to be at high risk of bias (Xia 2014) there was no important change in the results (RR 0.30; 95% CI 0.14, 0.64; p = 0.002).

Bowel recovery

One trial (160 participants) reported bowel recovery by measuring the time elapsed before first defaecation after treatment (6 hours post-operative) (Ruan 2021). Constipation is one of the most frequent adverse reactions following minimally invasive surgery, where post-operative bowel management is vital (67). The authors specified that recovery was considered complete if defection returned within 12 hours, significant recovery if defection returned within 12 to 24 hours; an improvement if defection returned within 34 to 36 hours; and no improvement of if there was an absence of defection beyond 36 hours.

The results showed an effect in favour of shiatsu compared with the control group (MD –11.95; 95% CI –14.33 – 9.57; p = 0.00001). *(GRADE: Moderate)*.

Pulmonary function

Two trials (total 496 participants) reported pulmonary function measured by oxygen saturation (SpO2) either at the end of surgery (Zhenqing 2019) or at 30 days post-surgery (Sui 2019). SpO2 is commonly measured via a pulse oximeter, or an arterial blood has test, to assess the level of oxygen the haemoglobin in the blood in carrying (68). Results are demonstrated as a percentage or mmHg, with normal levels being greater than 95% (95 mmHg) for a person with no lung disease and less than 95 % (95 mmHg) indicating hypoxia – that can be caused from either a ventilation or perfusion problem (69). The commonly accepted MCID for SpO2 is 4 percentage points, obtained from research in people with cystic fibrosis (70).

The results showed no important difference between treatment groups at the end of surgery (MD –2.20; 95% CI –2.54, –1.86; $p < 0.00001$) or 30 days after surgery (MD –0.55; 95% CI –0.19, –1.29; $p = 0.15$). *(GRADE: Moderate)*.

Comparison 3 (vs other)

There were no studies identified comparing shiatsu with 'other' in people with extern causes.

Appendix E Risk of bias forms

This appendix documents the risk of bias judgements and quality appraisal made on studies that met the prespecified inclusion criteria for a systematic review on the effect of shiatsu for preventing and treating any health condition.

E1 Systematic review of shiatsu

This appendix documents the risk of bias judgements made on studies that met the prespecified inclusion criteria for a systematic review on the effect of shiatsu.

The risk of bias of included studies was assessed using the most appropriate risk of bias assessment tool (see www.riskofbias.info) according to the type of study as follows:

- RCTs: Revised Cochrane Risk of Bias tool v2.0 (71, 72).
- NRSIs: ROBINS-I: a tool for assessing risk of bias in nonrandomised studies of interventions (73).

Where possible, the assessment was based on the primary outcome for that study (or that for which the study was powered). In some circumstance, two assessments were made to account for risk of bias associated with different (e.g. subjective and objective) outcome measures.

Studies are organised by ICD-11 category. Within the ICD-11 category, the studies are ordered alphabetically. For each study there is the signalling question associated with each risk of bias domain, the judgement answered as yes, partial yes, no, partial no, no information or not applicable and a comment that briefly explains the reasoning that underpins the judgement.

(See separate spreadsheet)

E2 Supplementary overview of acupressure

This appendix documents the judgments on systematic review quality, made on systematic reviews that met the prespecified inclusion criteria for the supplementary overview on the effect of acupressure on populations where evidence was found for the systematic review of shiatsu.

The methodological quality of included systematic reviews was assessed using the AMSTAR-2 quality assessment checklist (74), noting that the AMSTAR-2 leads to a judgement of methodological quality (or limitations) of a SR, not a judgement about risk of bias of the body of evidence included within the SR.

Studies are organised by ICD-11 category. Within the ICD-11 category, the reviews are ordered by publication year (earliest first). For each systematic review the second column shows the signalling question associated with each AMSTAR-2 item (column one), with the judgement for each systematic review answered as either yes [y], no [n], or partial yes [py]. For AMSTAR-2 items that must be answered as YES or NO, the review should satisfy all questions (unless indicated as optional). For AMSTAR-2 items that have a PARTIAL YES option, the review must satisfy the first few questions (up to the point where lower-case partial yes [or no] is indicated), with questions after this point being required to meet a full YES. Where the item question is greyed out, the question is not needed to be considered.

The overall conclusion for each AMSTAR-2 item is capitalised and highlighted in GREEN (YES), YELLOW (PARTIAL YES) or RED (NO).

(See separate spreadsheet)

Appendix F Characteristics of included studies

This appendix documents the data extracted from studies that met the prespecified inclusion criteria for a systematic review on the effect of shiatsu for preventing and treating any health condition. All extracted data is presented, including that which was not synthesised in the main report.

F1 Study details

F1.1 Systematic review of shiatsu

Appendix F1.1 (see attachment) lists the characteristics of each included study in order of ICD-11 category. Studies within the ICD-11 category are then ordered by the condition and listed alphabetically.

For each study, the data extraction has included (but was not limited to) the following characteristics: study ID, study reference, study design, source of funds, declaration of interest of the study authors, year conducted, setting and location, participant inclusion criteria, intervention and comparator characteristics (including number of treatment sessions, program duration, co-interventions), outcomes (including measurement method and timing), and method of analysis.

Outcome domains and measures considered critical or important for inclusion in the review are highlighted with a blue box. Conversely, outcome domains and measures that were of limited importance are not highlighted.

F1.2 Supplementary overview of acupressure

Appendix F1.2 (see attachment) lists the characteristics of each included systematic review in order of ICD-11 category. Studies within the ICD-11 category are then ordered by the publish year, with the earlier reviews listed first.

For each study, the data extraction has included (but was not limited to) the following characteristics: review ID, review title, review objective, source of funds, declaration of interest of the review authors, review method of analysis, inclusion and exclusion criteria of the review (population, intervention, and comparator characteristics), databases searched, outcomes included in the review, and risk of bias assessments of the included primary studies (if available). Characteristics of the eligible studies included in the review were listed, with the study ID, study design, and population, intervention, and comparator characteristics noted.

Outcomes considered critical or important for inclusion in the overview are highlighted with a blue box. Conversely, outcome domains and measures that were of limited importance are not highlighted.

F2 Supplementary outcome data

F2.1 Systematic review of shiatsu

Appendix F2 (see attachment F2.1) lists the data extracted for critical or important outcomes identified in each included study (for priority populations) in order of ICD-11 category. Studies within the ICD-11 category are then ordered by the prioritised condition. Within each sheet, studies are listed by comparison (Shiatsu vs sham, Shiatsu vs control or Shiatsu vs 'other') with the study results per outcome reported (critical or important outcome measures) that includes (but is not limited to) the following: outcome domain, timing, outcome measure, measure details, number of included participants, point estimates, p-value, direction of effect.

Data extracted is that reported by the study authors at the end of treatment (where possible) with footnotes included if further explanation was required (e.g., authors do not provide end-of treatment results therefore the mean change from baseline data are reported). The final column lists the risk of bias assessment for that outcome as made by the review authors (see Appendix E1 – RCTs or Appendix E2 – NRSIs).

Appendix G Differences between protocol & review

G1 Methods not implemented

There were some methods that were not implemented in the review relating to the following sections:

Studies identified in the literature search

It was intended that, if a study did not contain the required PICO information for a decision to be made regarding its eligibility, the information would be sought from the study's authors through an open-ended request. Given time and resource constraints, we did not contact authors for additional information regarding eligibility criteria.

Requests for data

Eligible primary studies not published in English, ongoing trials and studies published as conference abstracts with incomplete results were identified for inclusion and listed as either 'Ongoing' or within the 'Studies Awaiting Classification'. It was intended that study authors would be contacted through an open-ended request for further information, and, if available, the study would be included in the evidence appraisal. Given time and resource constraints, we did not contact study authors for additional information regarding missing data.

Risk of reporting bias across studies

To assess potential bias due to 'non-reporting', it was intended that funnel plots (of effect estimates against their standard errors) would be generated in RevMan 5.4 (if there were more than ten RCTs included for a PICO); with visual inspection of the funnel plot being used to look for evidence of asymmetry (suggesting small-study effects or missing results). Other possible reasons for funnel plot asymmetry were to be considered at this time (e.g. poor methodological quality, true heterogeneity, chance) (75). There were less than ten RCTs included for most PICOs, therefore funnel plot asymmetry was not able to be assessed. In the absence of funnel plots, non-reporting bias was suspected when the evidence was limited to a small number of small trials reporting favourable results; supplemented through inspection of outcomes reported in the 'Ongoing Studies' and 'Studies Awaiting Classification' (if available) (see Appendix B3.3).

Quantitative synthesis

The NTWC could request that data comparing shiatsu with 'other' (active) intervention be synthesised (prior to provision of the first draft evaluation report), where:

i. at least two studies compare the effect of Shiatsu with the same active comparator, and the comparator is sufficiently homogenous across studies to support synthesis, and
ii. at least two of these studies are at low or moderate risk of bias, and
iii. the comparator represents an accepted, evidence-based 'gold standard' of care for the population in question.

No such cases were identified or requested.

Subgroup analyses and investigations of heterogeneity

We did not plan to undertake any subgroup analyses of subsets of participants within or across studies, unless there was substantial inconsistency between effect estimates. Any subgroup analysis was intended to explore possible sources of heterogeneity relating to delivery of the intervention. Studies were to be grouped according to intervention characteristics (i.e. intensity, duration, mode of delivery) and a standard test for heterogeneity across the subgroups was to be reported. At least 10 studies are needed for subgroup analysis and most conditions did not meet this.

G2 Changes from protocol

Full text screening

It was intended that full text articles would be screened by a single evidence reviewer, with any uncertainty regarding inclusion to be escalated and considered through discussion with the lead reviewer (MJ). The lead reviewer was to then randomly reinspect approximately 20% of articles marked as excluded to ensure adherence to the *a priori* exclusion criteria, with any differences resolved by discussion. After title abstract screening, a pragmatic decision was made to have two reviewers screen independently, ensuring all articles were screened in duplicate for enhanced transparency and accuracy (89.2% agreement, Cohen's Kappa = 0.642).

Assessment of nonrandomised studies

It was intended that, for any included NRSI, any potential confounders or cointerventions would be identified and agreed through discussion with the NTWC prior to assessment of the risk of bias. Given the small number of NRSIs identified for inclusion, these studies were judged by the evidence review team alone.

We also specified that the evidence from RCTs and NRSIs would be evaluated separately in the summary of findings table, but there was only two NRSI included in the evidence synthesis. A pragmatic decision was made to report these studies alongside the RCTs, as it was considered to not seriously alter the results or evidence statements made.

Data extraction process for the overview of acupressure

It was intended that outcome results reported by systematic review authors would be extracted into a different form after agreement was reached with the NTWC regarding critical and important outcomes to be considered in the evidence synthesis. However, many of the included reviews did not adequately report results or reported combined results that were irrelevant to this review (e.g. studies were in auricular acupressure or acupuncture). Given time and resource constraints, data within the systematic review were directly extracted into RevMan 5.4 for applicable primary studies and outcomes. Where data from a selected systematic review was augmented with data obtained from another systematic review, this was documented using footnotes within the computer program.

A return to primary studies for the overview of acupressure

We planned to retrieve primary studies found with a systematic review if the results data were missing, incomplete or problematic. Given time and resource constraints, we did not return to the primary studies for any additional information.

Appendix H How comments from Methodological review were addressed

Methodological review (or peer review) was conducted to appraise the methodological quality and assess the appropriateness of reporting for this systematic review (including appendices).

For reporting, the methodological review assessed the systematic review against the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis) Checklist (2020) and where applicable, the MECIR (Methodological Expectations of Cochrane Intervention Reviews) manual.

The ROBIS (Risk of Bias in Systematic Reviews) tool was used to assess the methodological quality of the systematic review, to ensure it was designed and conducted in accordance with:

- NHMRC's Developing your Guideline module in NHMRC's Guidelines for Guidelines Handbook
- Cochrane Handbook for Systematic Reviews of Interventions (updated 2022)
- GRADE guidance and GRADE working group criteria for determining whether the GRADE approach was used (GRADE handbook).

The ROBIS assessment included specification and application of criteria for considering studies for the review and synthesis, search methods, data extraction and analysis, assessment of risk of bias of studies, assessment of the certainty of evidence using GRADE, and the interpretation and summary of findings.

The systematic review (including appendices) has been updated to reflect the amendments suggested by methodological review and NHMRC's Natural Therapies Working Committee, where appropriate. In summary, updates included additional information and/ or clarification of the Plain Language Summary, Executive Summary, Results sections and Appendices, including:

- Clarification of terminology between the main systematic review of shiatsu and the Supplementary overview of acupressure.
- Additional information provided in the discussion on the number of studies in languages other than English, and whether they might have affected conclusions.
- Clarification of what was meant by sham comparators provided in the Appendix, and the term sham used throughout instead of placebo as this better reflected the comparator.
- Clarification or addition of footnotes for the Summary of Findings tables where appropriate.

A detailed record of responses to all comments indicating changes that were made was provided to NHMRC together with the amended Report and Appendices documents.

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