Project

Pilates for preventing and treating health conditions: an evidence evaluation

Prepared for

National Health and Medical Research Council

NHMRC | Natural Therapies Working Committee
Canberra ACT 2601

CONFIDENTIAL

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Dates

This evidence evaluation report and accompanying technical reports received approval from the National Health and Medical Research Council (NHMRC) Natural Therapies Working Committee (NTWC) on 11 August 2022. The protocol for the evidence evaluation received approval from the NTWC on 25 May 2020 (PROSPERO: CRD42020191918).

History

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

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

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

Funding

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Acknowledgments

Thanks to the members of the Department's NTREAP and the NHMRC's NTWC for their advice and comments throughout the creation of this document.

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

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

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

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List of abbreviations

ACL	Anterior cruciate ligament
ADT	Androgen deprivation therapy
BMD	Bone mineral density
BP	Blood pressure
BRISA	Regional Base of Health Technology Assessment Reports of the Americas
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
COMET	Core Outcome Measures in Effectiveness Trials
CRP	C-reactive protein
CVD	Cardiovascular disease
EDDS	Expanded Disability Status Scale
EMAS	European Menopause and Andropause Society
ESR	Erythrocyte sedimentation rate
GRADE	Grading of Recommendations Assessment, Development and Evaluation
IBD	Inflammatory bowel disease
ITT	Intention-to-treat
LBP	Low back pain
MCID	Minimal Clinically Important Difference
MID	Minimal Important Difference
MD	Mean Difference
MQ	Memory quotient
MS	Multiple sclerosis
NHMRC	National Health and Medical Research Council
NPS	Numerical Pain Scale
NRSI	Nonrandomised study of an intervention
NSAIDs	Nonsteroidal anti-inflammatory drugs
NTREAP	Natural Therapies Review Expert Advisory Panel
NTWC	Natural Therapies Working Committee
OR	Odds ratios
PAHO	Pan American Health Organization
PD	Parkinson's disease

PDDS	Patient Determined Disease Steps
PICO	Population, Intervention, Comparator, Outcome
PP	Per-protocol
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSQI	Pittsburgh Sleep Quality Index
PSSE	Physiotherapeutic scoliosis-specific exercises
QoL	Quality of life
RCT	Randomised controlled trial
RoB	Risk of bias
RR	Risk ratios
SMD	Standardised mean difference
SR	Systematic review
SD	Standard deviation
TENS	Transcutaneous electrical nerve stimulation
TIDIER	Template for Intervention Description and Replication

Plain language summary

What was the aim of this review?

The aim of this review was to identify eligible studies and assess whether they demonstrate that Pilates is effective in preventing and/or treating certain injuries, diseases, medical conditions or pre-clinical conditions relevant to the Australian population. Pilates is an exercise system focused on strengthening muscles, whilst improving posture and flexibility. Some key principles underpinning Pilates include centring, concentration, control, flow and focused coordinated breathing. This review is targeted for the Australian Government Department of Health and Aged Care to assist in their Natural Therapies Review, which is designed to determine whether certain natural therapies, including Pilates, have enough evidence of effectiveness to be considered re-eligible for private health insurance rebates. This review is not designed to be a complete review of all studies published for Pilates, nor is it intended to inform decisions about whether an individual or practitioner should use Pilates.

Key messages

For the populations (or conditions) assessed, Pilates appears to provide people who practise it with some benefit for some of the included conditions and outcomes, when compared with people who do not practise Pilates. However, in general the evidence assessed in this review provides low certainty and more studies are needed to confirm the findings. The results of this review are consistent with other systematic reviews of Pilates.

What was studied in this review?

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

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

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

- very low certainty – meaning the true effect is probably markedly different from the estimated effect
- low certainty – meaning the true effect might be markedly different from the estimated effect
- moderate certainty – meaning that the true effect is probably close to the estimated effect
- high certainty – meaning the authors have a lot of confidence that the true effect is similar to the estimated effect

What studies did we identify in this review?

Using a planned approach, 1630 studies from 11 databases were collected and examined, including 128 studies submitted by the public via the Department's public call for evidence.

Out of 1630 studies identified, 105 studies covering 26 prioritised conditions, were assessed in the evidence evaluation and are included in the results. Pilates exercises reported in eligible studies were consistent with how Pilates is practised in Australia. Many studies included women only. Most studies evaluated group Pilates classes that were 45 to 60 minutes long, with outcomes evaluated at the beginning and at the end of treatment. Sessions gradually increased in intensity over the course of treatment, which varied from one to five sessions per week, lasting between four and 26 weeks. The treatment provider was often not specified, but when reported, tended to be experienced Pilates instructors or physical therapists trained in the Pilates method. No studies continued for more than 6-months. A further 51 studies were not in English and 116 studies had been registered but were not completed at the time the search was conducted for this review. Results had been collected for 22 of these ongoing studies for conditions prioritised in this review. However, results were not accessible at the time of the search.

What were the main results of the review?

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

The evidence provides moderate certainty that Pilates is effective in:

- improving incontinence-related quality of life in men (after radical prostatectomy) (from two studies, 126 participants)
- reducing disability (12 studies, 937 participants) and improving overall quality of life (one study, 295 participants) in people with chronic low pain back.

The evidence provides low certainty that Pilates is effective in:

- reducing pain in people with low back pain (12 studies, 1062 participants)
- improving physical wellbeing in people with post viral arthropathies (one study, 42 participants)
- reducing neck-related disability (two studies, 101 participants) and improves some measures of quality of life for people with chronic neck pain (one study, 64 participants)
- improving sleep quality (one study, 72 participants), vasomotor (one study, 74 participants) and physical symptoms (one study, 74 participants) in women with symptoms of menopause
- improving quality of life in people with osteoporosis (one study, 40 participants), knee stability in people rehabilitating after knee injury (one study, 50 participants) and physical functioning in people at risk of age-related decline (two studies, 60 participants)
- improving activities of daily living in women with type 2 diabetes (one study, 24 participants)
- improving mental wellbeing in people with multiple sclerosis (one study, 30 participants) and anxiety in people at risk of mental health conditions (one study, 62 participants).

The evidence provides moderate certainty that Pilates has little (to no) effect on:

- functional capacity for people with low back pain (two studies, 381 participants).

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

- physical (one study, 45 participants) and mental wellbeing (one study, 45 participants), body mass index (one study, 45 participants) and fatigue (one study, 45 participants) for women with type 2 diabetes
- physical wellbeing (one study, 30 participants) and functional mobility (3 studies, 80 participants) in people with multiple sclerosis
- functional mobility in stroke recovery (one study, 20 participants)
- global perceived effect (one study, 55 participants), physical functioning (one study, 55 participants), quality of life (one study, 55 participants) and spinal mobility (one study, 55 participants) in people with spondyloarthropathies
- non-narcotic analgesic use (one study, 60, participants) in people with low back pain
- static balance in people with osteoporosis (one study, 40 participants)
- general health perception in people at risk of age-related mental decline (one study, 64 participants).

The effect of Pilates for women undergoing breast cancer treatment, people with hypertensive heart disease, people with chronic widespread pain, or people with shoulder pain is unknown, as no studies were found with outcomes selected as critical or important.

Implications for health policy and research

This review assesses the evidence for certain conditions and groups of people to inform the Australian Government about health policy decisions for private health insurance rebates. The review does not cover all the reasons that people practise Pilates, or the reasons practitioners prescribe Pilates and is not intended to inform individual choices about practising Pilates.

The results of this review indicate that Pilates may be useful for some conditions and outcomes and not useful for others. However, these conclusions are based on a small number of studies with limited numbers of participants, with results across studies often imprecise and inconsistent and outcomes that are relevant to patients were often not reported. A number of studies focussed on the effect of Pilates in people who received treatment for 12 weeks or less, so it is difficult to conclude the possible benefits of Pilates in people who continue to practise Pilates for more than 12 weeks. It is unknown whether the effects of Pilates continue once people stop practising Pilates. This review listed, but did not assess Pilates versus other interventions, so no comment can be made on whether Pilates is better or worse than other exercises or other interventions.

Future research could be improved by undertaking more studies of Pilates versus control (or inactive comparator); including more participants; improving registering and reporting of the methods used in studies; and including outcomes that are considered critical or important for decision-making.

How up to date is this review?

Searches were conducted from the earliest date included in the databases until 21 June 2020. Studies published after this date are not included in this review.

Executive summary

Background

Pilates is practised for general wellbeing and is also used by people with a broad range of clinical and preclinical conditions, including problems associated with chronic pain and ageing, as well as conditions related to neuromuscular dysfunction (such as multiple sclerosis and balance disorders). Pilates is believed to encourage improvement in core stability, strength, flexibility, posture, muscle control, proprioception and body awareness, and facilitate a return to functional activities. Pilates classes typically range from 60 to 90 minutes in length and programs are tailored to the individual, class or group size and setting (e.g., gymnasium, private studio, or physiotherapy clinic). Typically, Pilates is practised in a designated room, with Pilates exercises performed on a mat, using auxiliary apparatus (such as balls or bands) or specially designed equipment (such as a Reformer or Wunda Chair) that provide adjustable spring resistance. An integral aspect is the supervised and tailored use of small apparatus or equipment that aids or provides resistance during the completion of various movements or exercises. Classes or exercise sessions can be adapted to provide gentle, moderate, or high intensity strength, flexibility and stability training, or tailored to provide individual targeted workouts.

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

Objectives

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

Search methods

Literature searches were conducted in EMBASE, MEDLINE, EMCARE, PsycInfo, AMED, CINAHL, SPORTDiscus, CENTRAL, PEDro, PUBMED and PAHO VHL to identify relevant studies published from database inception to 21 June 2020. Reference lists of key relevant articles were checked to identify any additional studies not identified through searches of the primary databases. The public was also invited by the Department to submit references for published research evidence. There were no limits on language of publication or date of publication in the search.

Selection criteria

Randomised controlled trials and non-randomised studies that examined Pilates exercises compared to control (or another intervention, where applicable) were eligible, including quasi-randomised studies, cluster-randomised and crossover trials. Any exercise activity named as Pilates that was delivered by an instructor to an individual or group of individuals, or Pilates that was self-practised was eligible for inclusion. There were no limits on intensity, duration of practise or mode of delivery. Studies that examined Pilates

delivered as an adjunct to another therapy (both groups received the other therapy) were eligible for inclusion.

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

The search was not restricted by comparators, however the main comparator of interest for this review was Pilates versus control (including no intervention, waitlist, or usual care, if considered inactive), the secondary comparator of interest included Pilates versus other comparator (including usual care or control, if considered active). The search did not use outcomes to screen studies for eligibility. Studies were not excluded based on country of origin, however studies published in a language other than English were not translated and were not included in the synthesis but were listed in an inventory for completeness.

Data collection and analysis

After initial searching and screening, and to determine what data to extract from studies, a blinded outcome prioritisation process was developed for NTWC to complete. As part of the process NTWC was asked to specify up to seven 'critical' or 'important' outcomes for inclusion in the analysis and synthesis of the review. Where a study did not report a prioritised outcome for that population or condition, this was noted as an evidence gap in the review. The NTWC were guided by GRADE methodology, scoring outcome domains on a scale of 0 (of limited importance for decision making) to 9 (critical for decision making). Harms and cost effectiveness measures were out of scope.

In addition, to ensure the review was most relevant to the Australian population, NTWC conducted a blinded population (or condition) prioritisation process. In determining the priority conditions for inclusion in the analysis and synthesis of the review, NTWC were guided by relevant patient or practitioner reported Australian survey data (where available) and expert advice from the Department's NTREAP.

Data collection was performed by two researchers, the first researcher collected data using data extraction forms and the second researcher checked the forms for completeness and accuracy. Critical appraisal of the eligible studies was conducted using the most appropriate risk of bias assessment tool recommended by the Cochrane Collaboration (according to study type).

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

Main results

A total of 138 studies were identified as eligible for inclusion in this review. Of these, 105 studies covering 26 conditions were considered in the evidence evaluation and are included in the results. For the synthesis 66 studies covering 22 prioritised conditions compared Pilates exercises with inactive control (no intervention, wait list or usual care). Results for studies of prioritised conditions with active comparators are

presented in Appendix F2, but not in the synthesis, as the wide range of comparators and outcomes did not allow for synthesis as planned in the protocol.

At the time of the search, an additional 83 studies were awaiting classification and an additional 116 studies were recorded as ongoing (registered but not published at the time of the search). Of the studies awaiting classification, 51 were not published in English and 27 were conference abstracts with the remaining five studies not able to be retrieved and therefore not assessed. Of the ongoing studies, at the time of search 10 studies were not yet recruiting participants, 28 studies were recruiting participants, 38 studies had recruited participants but not collected data, 30 studies were complete but had not reported any results at the time of the search, three had brief results not sufficient to be included in the review and the status of six studies was unknown. Results for approximately 22 of the ongoing studies, that were complete but not yet available for full text review, may have been eligible for inclusion for conditions prioritised in this review, and may have reported on some of the outcomes considered critical or important by NTWC.

Approximately one-third of the studies included in the synthesis (21 studies) were conducted in people with chronic low back pain, with the remaining synthesis comprised of one to two studies for other prioritised conditions. Summary of findings tables were restricted to outcomes rated as critical and important by NTWC, study results for outcomes not considered critical or important were not included in the synthesis. The results for four prioritised conditions, including women with breast cancer undergoing treatment, people with hypertension, people with chronic widespread pain, or people with shoulder pain could not be determined, as no studies were found with outcomes that were considered critical or important for this review.

All included studies examined Pilates exercises delivered in a manner that was applicable to the Australian context based on the description. Women were the main participants for many of the studies. Most studies evaluated group Pilates classes that were 45 to 60 minutes in duration, with outcomes evaluated at the beginning and at the end of treatment. Sessions gradually increased in intensity over the course of treatment, which varied from between one and five sessions per week, lasting for anywhere between four and 26 weeks after randomisation (or enrolment). No studies provided any longer-term data (more than 6-months). The treatment provider was often not specified, but when reported, tended to be experienced instructors or physical therapists trained in the Pilates method.

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

This review identified 15 conditions for which there was evidence about the effect of Pilates on an outcome considered critical or important by NTWC. The evidence provides:

- moderate certainty that Pilates is effective in:
    - improving incontinence-related quality of life in men after radical prostatectomy (from two studies, 126 participants)
    - providing a moderate reduction in disability (12 studies, 937 participants) and slightly improving overall quality of life (one study, 295 participants) in people with chronic low pain back.

- low certainty that Pilates provides:

  - a large decrease in pain in people with chronic low back pain (12 studies, 1062 participants)
  - a large improvement in sleep quality in women with symptoms of menopause (one study, 72 participants)
  - a large improvement in knee stability in people rehabilitating after knee injury (one study, 50 participants)
  - a large improvement in physical functioning in people at risk of age-related decline (two studies, 60 participants)
  - a moderate improvement in physical wellbeing in people with postviral arthropathies (one study, 42 participants)
  - a moderate reduction in neck-related disability in people with chronic neck pain (two studies, 101 participants)
  - a moderate improvement in some (but not all) measures of quality of life for people with neck pain (one study, 64 participants)
  - a moderate improvement in vasomotor symptoms (one study, 74 participants) and physical symptoms (one study, 74 participants) in women with symptoms of menopause
  - a moderate improvement in trait anxiety in people at risk of mental health conditions (one study, 62 participants)
  - a moderate improvement in mental wellbeing in sedentary adults at risk of metabolic disorders or weight problems (one study, 99 participants)
  - a slight improvement in activities of daily living in women with type 2 diabetes (one study, 24 participants)
  - a slight improvement in quality of life in people with osteoporosis (one study, 40 participants)
  - a slight improvement in mental wellbeing in people with multiple sclerosis (one study, 30 participants)
  - a slight improvement in state anxiety in people at risk of mental health conditions (one study, 62 participants)
  - a slight improvement in physical wellbeing (except pain) in sedentary adults at risk of metabolic disorders or weight problems (one study, 99 participants)

- moderate certainty that Pilates provides little to no benefit in:
  - improving the functional capacity of people with low back pain (from two studies, 382 participants)

- low certainty that Pilates provides little (to no) benefit in:
  - mental wellbeing (one study, 45 participants) and fatigue (one study, 45 participants) in women with type 2 diabetes
  - physical wellbeing (one study, 30 participants) and functional mobility (three studies, 80 participants) in people with multiple sclerosis
  - functional mobility (one study, 20 participants) in stroke recovery
  - global perceived effect (one study, 55 participants), physical functioning (one study, 55 participants), quality of life (one study, 55 participants) and spinal mobility (one study, 55 participants) in people with spondyloarthropathies
  - static balance in people with osteoporosis (one study, 40 participants)
  - non-narcotic analgesic use (one study, 60, participants) in people with low back pain
  - general health perception in people at risk of age-related mental decline (one study, 64 participants).

The evidence provides very low certainty of the effect of Pilates versus inactive control (no intervention, wait list or usual care) for 51 out of the 196 critical or important outcomes prioritised for analysis in this review. For these outcomes, the estimate of effect did not reach statistical significance, nor was a clinically important difference observed (this may relate to study design, size, or duration of the study).

There were no outcomes reported across studies for 122 out of 196 critical or important outcomes prioritised in this review, and therefore the effect of Pilates on these outcomes is unknown.

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

Limitations

This review is limited to analysis of conditions prioritised by NTWC, who were guided by relevant patient and/or practitioner reported Australian survey data (where available) and expert advice from NTREAP during the prioritisation process, therefore this report may not cover all the reasons people practise Pilates.

The outcomes assessed in this review were limited to those deemed critical or important by NTWC for each priority condition. This meant that most conditions were limited to evidence that assessed one to three of the critical or important outcomes, with four conditions having no available evidence for critical or important outcomes.

A third of the evidence included in the synthesis assessed chronic low back pain, with most other conditions limited to one or two small studies, with participants ranging from five to 296 participants.

Given the limited number of studies spread across a diverse range of prioritised conditions, it is challenging to conclude the effectiveness of Pilates for the conditions prioritised. An additional limitation of this review is that a number of studies were ongoing, unpublished, or not translated at the time of the search. The effectiveness of Pilates compared with other forms of exercise or active comparators was not conducted, due to the wide variety of active comparators, outcomes, and conditions across these studies. It is unknown whether the results of these studies would impact the overall conclusions of this review.

Conclusions

The evidence provides moderate to low certainty that practising Pilates is more effective than not practising Pilates for some of the prioritised conditions and outcomes assessed in this review. However, the evidence also provides moderate to very low certainty that Pilates has little (to no) benefit for some of the prioritised conditions and outcomes assessed in this review. There are some conditions and outcomes assessed in this review where the effect of Pilates is unknown.

The results of this review are generally consistent with systematic reviews of Pilates published up until June 2021, which conclude that there is an absence of high certainty evidence that practising Pilates is more effective than not practising Pilates. More research is needed to reach a definitive conclusion on the effectiveness of Pilates for preventing and treating health conditions.

1 Background

In 2015, a review of Pilates conducted for the Australian Government found no reliable evidence demonstrating its efficacy in treating any clinical condition (6, 7). The 2015 review was underpinned by an overview of systematic reviews (SRs) that focused solely on Pilates and were published in the English language between 2008 and June 2014. Randomised controlled trials (RCTs) that were reported within included SRs and assessed Pilates delivered to treat any clinical condition were eligible, with outcomes selected according to predefined criteria. In this 2020 update, the evidence review builds upon the 2015 review but is not limited by publication date and a broader range of study types were eligible for inclusion (inclusive of quasi-randomised studies and nonrandomised studies of interventions [NRSIs]). This review also includes studies that assess Pilates delivered for primary prevention. Similar to the 2015 review, eligible comparisons are Pilates versus inactive control and Pilates versus other intervention. Studies not published in the English language were not translated, and databases in languages other than English were not searched.

1.1 Description of the condition

Pilates was initially developed as a mind-body exercise for the fit population, and was primarily taught to gymnasts, dancers and boxers (8). However, since the late 1980s the use of Pilates has expanded considerably, and it is now used by the general population for wellbeing as well as being used by people with a broad range of clinical and preclinical conditions. These include conditions related to neuromuscular dysfunction (such as multiple sclerosis and balance disorders) and problems associated with chronic pain and ageing. The traditional Pilates method has also been modified for use in preventing or managing acute, subacute or chronic musculoskeletal dysfunction (such as low back pain) as well as injury management for post-acute rehabilitation (such as total hip or knee arthroscopy) (8).

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

Pilates can be practised in a range of settings (see Section 1.2 Description of the intervention) and as such this review was not limited by setting.

1.2 Description of the intervention

The traditional Pilates method was developed by Joseph Hubertus Pilates during the 1920s as a comprehensive body conditioning method directed towards development of both the body and the mind (9). The early form of Pilates' method focused on building strength, similar to boxing training, and was targeted primarily at dancers (9). From the late 1930s Joseph Pilates taught group exercise classes to specific populations and semi-private studio sessions using Pilates-specific equipment, as well as individually prescribed programs for those who had a range of problems or conditions (9).

Since the 1980s Pilates exercises have expanded beyond the dancing community, with second and third generation Pilates instructors (including Romana Kryzanowski, Eve Gentry, Philip Friedman and Gail Eisen) reinterpreting and modifying the traditional Pilates method over time. The Pilates method and exercises have been further refined over time to reflect contemporary knowledge of anatomy, physiology and human movement (9).

The Pilates system of body conditioning is founded on stabilising the core musculature (including the abdominal, gluteal and paraspinal muscles), while performing a controlled range of motions (10, 11). Exercises are performed according to six key principles: centring (tightening and strengthening the body's

core ‘trunk’ muscles); concentration (with sensory awareness); control (ensuring postural integrity and functional alignment); precision (the accurate application of the exercise technique); flow (ensuring a smooth transition between movements and exercises); and focused coordinated breathing (9, 12).

Contemporary Pilates involves a range of more than 500 exercises, which may be performed on a mat using auxiliary apparatus or specially designed equipment. Pilates professional teaching skills are specific to the method and include the use of cueing by demonstration or verbal direction for correct anatomical function, as well as using imagery, metaphor and non-invasive hands-on assistance for the correct performance of each exercise to facilitate improved motor control.

The intervention may be divided into two main categories: mat and apparatus exercises (12), with the large apparatus exercises involving the use of specialised Pilates equipment that provides adjustable spring resistance (e.g. Reformer, Trapeze Table or Cadillac, Wunda chair and Barrels). However, comprehensive Pilates may incorporate the use of both mat as well as small and large apparatus exercise within a single session, or a Pilates session may only use mat and selected apparatus. An integral aspect is the supervised and tailored use of small apparatus or the various large Pilates equipment, which assists or provides resistance during the completion of various movements or exercises.

Pilates can be practised at any time, with or without specialised equipment, and in any location where there is sufficient space. Most commonly Pilates is practised in a designated Pilates studio using specialised equipment with an accredited Pilates professional providing supervised exercise and teaching mindful movement. It can be practised by anyone, regardless of age or level of fitness, and is usually taught and practised in small groups or individual sessions. Classes or exercise sessions can be adapted to provide gentle, moderate or high intensity strength, flexibility and stability training, tailored to provide individual problem or condition-specific Pilates exercises and variations, or it can be modified to provide a more challenging traditional Pilates workout. After being taught the Pilates principles and completing a series of supervised tailored exercise sessions individuals may also practise Pilates at home, following a prescribed homework exercise program.

Contemporary Pilates classes typically range from 60 to 90 minutes in length and vary in the expertise of the instructor, the extent to which a program is tailored to the individual (e.g., general fitness or individual programs), size (groups or private sessions) and setting (gymnasium, private studio or in allied health practices such as physiotherapy clinics).

In Australia there are two main industry bodies that support Pilates practitioners in their professional practice, the Australian Pilates Method Association and the Pilates Alliance Australasia. While the training of Pilates professionals varies, accredited member instructors typically hold a Diploma, or industry equivalent. The professional bodies also aim to regulate the quality and scope of Pilates practices, through provision of codes of conduct, codes of ethics and provision of continuing education.

1.3 How the intervention might work

Numerous physical benefits of Pilates have been suggested and are thought to arise in part due to the regular practice of exercise, which can enhance cardiopulmonary fitness. Pilates is also reported to improve muscular endurance and flexibility (13). By focusing on core muscle activity, the local, single-joint muscles and multi-joint muscles provide stability and produce motion (14). This integrated core muscle activity is thought to result in proximal stability for distal mobility which assists functional motor control. The Pilates instructor’s attention to anatomically accurate supervision and informed cueing is also thought to be effective in strengthening small underactive muscles and improving neuromuscular control (15).

Pilates is not a disease modifier, instead its practise is intended to treat general signs and symptoms associated with a condition or to manage side effects of treatment. Pilates exercises have been reported to reduce pain and disability and improve posture and enhance quality of life. This is proposed to occur through improvement in core stability, strength, flexibility, posture, muscle control, proprioception and body awareness (6).

The use of Pilates-specific equipment is said to not only improve strength, but also provide eccentric training at end range of movement and provide variable resistance training which is believed to produce the greatest comprehensive strength adaptations (16). It is suggested that the increase in coordinated muscle activity taught in Pilates contributes to improved static and dynamic balance, (15) particularly in older adults (17).

Pilates is believed to encourage movement, improve motor control and facilitate a return to functional activities, which is why it is increasingly incorporated into physical therapy rehabilitation programs. In people with low back pain, the practise of Pilates is intended to improve deep muscle stability and control of the spine while reducing the activity of superficial muscles, as well as to improve posture and body awareness, so as to ease pain and disability (11). The integration of mind and body balanced with breath control using modified Pilates is also thought to improve quality of life in people with certain conditions (18, 19) and has been suggested to be more effective than other physical therapies on upper extremity pain and function (20).

1.4 Why it is important to do this review

In Australia, natural therapies, including Pilates, are most often used in conjunction with conventional medicine and other strategies for maintaining good health and wellness. Pilates is also a popular form of exercise in Australia, with a 2013-14 survey estimating that more than 197 000 Australians participate in Pilates annually (21). To enable consumers, health care providers and policy makers to make informed decisions about care, the Australian Government will use this review to assist in deciding whether to reinclude Pilates as eligible for private health insurance rebates.

The 2015 Australian Government review identified 10 SRs containing evidence from 18 unique RCTs involving 11 to 422 participants across five clinical conditions. The authors proposed that, compared with control, there is (a) very low certainty evidence to suggest that Pilates may have some beneficial health effects in a number of conditions for a limited number of outcomes including the elderly (strength, balance and falls), people who are overweight and obese, survivors of breast cancer, and women with stress urinary incontinence; and (b) low to very low certainty evidence that Pilates may have an effect on selected outcomes in people with low back pain.

Compared to other comparators, the 2015 Australian Government review suggested that there is very low certainty evidence that Pilates may have beneficial effects relative to other comparators on selected outcomes in people with low back pain.

Overall, the health effects of Pilates were uncertain (6). This was primarily due to the methodological limitations of the primary studies, which included small sample sizes, short follow-up periods and inconsistent outcome reporting. Incomplete reporting of effect estimates within included SRs was also noted as problematic.

2 Objectives

To conduct a systematic review of RCTs and NRSIs to evaluate the effectiveness of Pilates in individuals with a described injury, disease, medical condition or preclinical condition, including disease prevention in at-risk individuals.

The intent is to evaluate the evidence representative of the populations (or conditions) commonly seen by the natural therapist in Australia, the intervention(s) commonly used by the therapist, and outcomes that align with the reasons why patients use the therapy and/or practitioners prescribe the therapy.

Table 1 lists the conditions identified and considered in this review and specifies whether studies were identified that assessed Pilates versus the main comparator of interest, inactive control.

Prioritised populations (no hierarchy) are listed below:

- Breast cancer (survivors, on treatment)
- Prostate cancer (after radical prostatectomy)
- Diabetes (Type 2)
- Multiple sclerosis
- Myelopathy (HTLV-1 associated)
- Parkinson's Disease
- Stroke recovery
- Hypertension
- Osteoarthritis (knee)
- Postviral Arthropathies,
- Ankylosing spondylopathies
- Spinal deformities (forward head, hyperkyphosis, hyperlordosis, scoliosis)
- Osteoporosis
- Chronic widespread pain (fibromyalgia)
- Low back pain (chronic, nonspecific)
- Neck pain (chronic)
- Shoulder pain (chronic, nonmechanical)
- Menopausal symptom or complaint
- Postpartum recovery
- Rehabilitation of the knee (after ACL injury, after arthroplasty)
- Employment conditions (elevated anxiety, stress)
- Prevention of metabolic diseases (at-risk due to sedentary behaviour)
- Prevention of age-related physical or cognitive decline
- Falls prevention (at-risk due to balance impairment, history of falls)

3 Methods

Methods reported in this systematic review are based on those described in the *Cochrane Handbook for Systematic Reviews of Interventions* (22) and relevant sections in the *JBI Manual for Evidence Synthesis* (23, 24). Covidence (www.covidence.org), a web-based platform for producing SRs, was used for screening citations and recording decisions made. Covidence is compatible with EndNote and Microsoft Excel, which were used for managing citations and data extraction, respectively. Where appropriate, RevMan 5.4 (25) was used for the main analyses and GRADEpro GDT software (www.gradepro.org) was used to record decisions and derive an overall assessment of the certainty of evidence for each outcome guided by GRADE methodology (5).

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

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

The final approved review protocol was registered on the international prospective register of SRs (PROSPERO: CRD42020191918).

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

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

4 Results

4.1 Description of studies

4.1.1 Flow of studies

The literature was searched on 21 June 2020 to identify relevant studies published from database inception to the literature search date. The results of the search and application of the study selection criteria are provided in Appendix A1 – A5 and Appendix C1 and C2.

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

The search retrieved 208 citations corresponding to 129 studies that were eligible for inclusion. An additional nine studies (not retrieved in the search) were identified and included from the Department's public call for evidence (see Included studies), the remaining studies provided from the Department's call were already identified in the search and screened for eligibility. A further 83 studies are awaiting classification and 116 studies are recorded as ongoing.

4.1.2 Excluded studies

There were 341 citations screened at full text that were excluded for not meeting the reviews eligibility criteria. Of these, 117 were in a population out of scope (e.g. healthy population not at risk), 111 had a study design out of scope (e.g. systematic review), 51 had an intervention out of scope (e.g. unable to assess Pilates independent of other interventions), 34 had a comparator out of scope (e.g. studies comparing different forms of Pilates) and 28 had a publication type out of scope (e.g. grey literature). As per Cochrane guidelines, details of citations which are likely to be considered eligible but are not, are presented in Appendix C1. Note that some studies may have been out of scope for more than one reason, but only one reason is listed for each.

4.1.3 Studies awaiting classification

Completed studies identified as potentially eligible for inclusion that could not be retrieved, translated or provided insufficient or inadequate data, are listed in the *Characteristics of studies awaiting classification* tables (see Appendix C4). This includes 27 conference proceedings with incomplete information about the study (Appendix C4.1), 51 studies published in languages other than English (Appendix C4.2) that are possibly eligible for inclusion (pending translation into English), and five citations that were not able to be retrieved (Appendix C4.3).

Among the 83 studies awaiting classification, 49 were conducted in a priority population[a] with 29 of these comparing Pilates with an inactive control (no intervention, wait list or usual activities)[b]. The studies appeared to be comparable to those included in the evidence synthesis in terms of sample size, study duration, outcomes measured. Among those published in a language other than English, many were from similar (non-English) countries (i.e. Turkey, Iran, Brazil, China) to those identified and included in the review.

[a] 28 studies were in a language other than English.

[b] 19 studies were in a language other than English.

An additional three studies were unable to be translated or interpreted at the title/abstract stage (see Appendix C4.4).

4.1.4 Ongoing studies

Ongoing studies that did not have published results at the time of the search are listed in the *Characteristics of ongoing studies* table (see Appendix C5). There were 10 studies 'not yet recruiting', 28 studies currently 'recruiting', and one study 'active but not recruiting'. A further 37 studies had completed recruitment, but the study data were not yet available, 31 studies had completed data synthesis, but results were not yet published, and three studies had brief results available on the trial registry (but had not been through peer review). The status of six studies is unknown.

Among the 116 ongoing studies, 69 were conducted in a priority population with 35 of these comparing Pilates with an inactive control (no intervention, wait list or usual activities); The ongoing studies appeared to be comparable to those included in the evidence synthesis in terms of sample size, study duration, outcomes measured. Many ongoing studies were found on Clinical trial registries of countries corresponding those identified and included in the review (i.e. Turkey, Iran, Brazil, China).

4.1.5 Included studies

There were 138 studies (70 RCTs, 53 quasi RCTs and 15 NRSIs) identified as eligible for inclusion in the review. After prioritisation of the populations (or conditions) considered most relevant to the practise of Pilates in Australia (see Appendix A6.1), 105 studies (57 RCTs, 40 quasi RCTs, and 8 NRSIs) were considered in the evidence evaluation.

For the main comparison of Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) 66 studies were considered for synthesis. Those that included NTWC prioritised critical and important outcome domains and measures, were included in the final analysis. The prioritised outcome domains are highlighted in a blue box in Appendix F1. Pilates versus other active comparators are included in qualitative descriptions in the report, and results are listed in Appendix F2.

There were 33 studies that met the eligibility criteria for the review but were conducted in populations (or conditions) not prioritised for analysis or synthesis by NTWC. The studies are listed in an inventory titled *Citation details of studies from non-priority populations* (Appendix C3, Table C.3) with a narrative description of studies provided in Appendix C6.

An overview of the studies identified and included in this review is provided in Table 1 *List of conditions and population groups identified and considered in this review* (below). Appendix D provides detailed descriptions of the included studies, including 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.

Figure 1 Literature screening results: Pilates

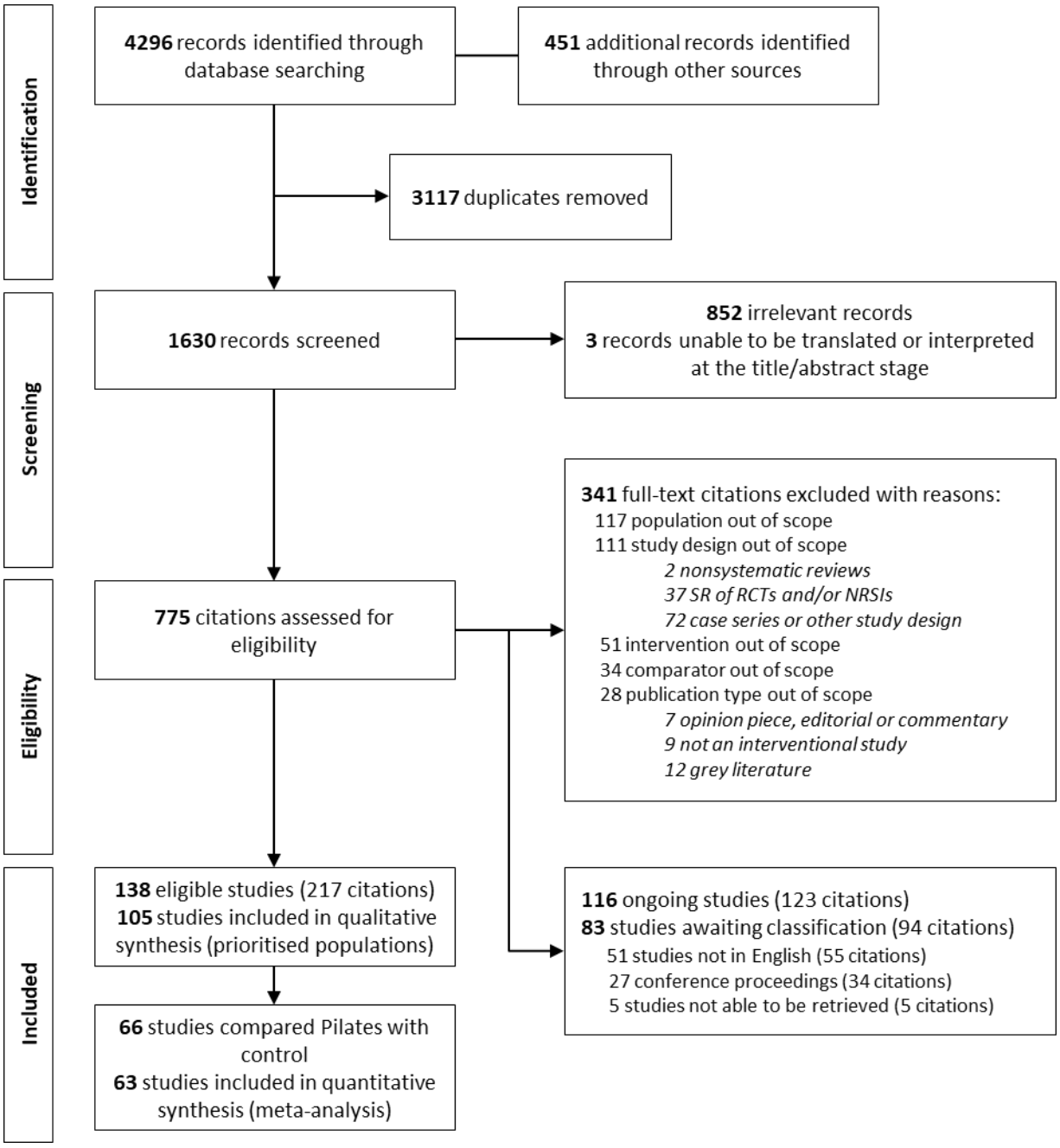


Table 1 List of conditions and population groups identified and considered in this review

ICD-11[a]	POPULATION	# NRSIs	# RCTs OR quasi RCTs	Included as a priority population	Included in main comparison
02 Neoplasms					
	Breast cancer (survivors)		6	Yes	Yes
	Breast cancer (on treatment)		1	Yes	No
	Prostate cancer (after radical prostatectomy)		2	Yes	Yes
	Thyroid cancer (with shoulder dysfunction)		1	No	--
05 Endocrine, nutritional and metabolic diseases					
	Diabetes (Type 1)		1	No	--
	Diabetes (Type 2)		3	Yes	Yes
	Obesity	2	7	No	--
06 Mental and behavioural disorders					
	Mild cognitive impairment		1	No	--
	Neurodevelopmental (ADHD, learning disorders)		2	No	--
	Schizophrenia		1	No	--
08 Diseases of the nervous system					
	Multiple sclerosis	2	11	Yes	Yes
	Myelopathy (HTLV-1 associated)		1	Yes	Yes
	Parkinson's Disease		3	Yes	Yes
	Stroke recovery	1	4	Yes	Yes
10 Diseases of the ear or mastoid process					
	Congenital hearing impairment		2	No	--
11 Diseases of the circulatory system					
	Cardiac Arrhythmia	1		No	--
	Heart failure		1	No	--
	Hypertension	1		Yes	No
15 Diseases of the musculoskeletal system or connective tissue					
	Arthropathies, Juvenile Idiopathic Arthritis		1	No	--
	Arthropathies, Osteoarthritis (knee)		1	Yes	Yes
	Arthropathies, Postviral		1	Yes	Yes
	Lateral epicondylitis or epicondylosis		1	No	--
	Osteoporosis		3	Yes	Yes
	Spinal deformities (forward head, hyperkyphosis, hyperlordosis, scoliosis)		6	Yes	Yes
	Spondylopathies, ankylosing		1	Yes	Yes
16 Diseases of the genitourinary system					
	Chronic kidney disease		4	No	--
	Menopausal symptom or complaint		3	Yes	Yes
	Urinary incontinence (stress, urge, mixed)	2	2	No	--
18 Pregnancy, childbirth or the puerperium					
	Perinatal	2	2	No	--
	Postpartum		1		Yes
21 Symptoms, signs or clinical findings, not elsewhere classified					
	Chronic widespread pain (fibromyalgia)		3	Yes	No

ICD-11[a]	POPULATION	# NRSIs	# RCTs OR quasi RCTs	Included as a priority population	Included in main comparison
	Low back pain (chronic, nonspecific)	3	30	Yes	Yes
	Neck pain (chronic)		3	Yes	Yes
	Shoulder pain (chronic, nonmechanical)		1	Yes	No
22 Injury, poisoning or certain other consequences of external causes					
	Rehabilitation after ACL injury, nonsurgical		1	Yes	Yes
23 External causes of morbidity or mortality					
	Rehabilitation after surgery, knee arthroplasty		1	Yes	Yes
24 Factors influencing health status or contact with health services					
	Employment conditions, emergency dept students (elevated anxiety)		1	Yes	Yes
	Sedentary behaviour (metabolic control)		2	Yes	Yes
	Age-related physical or cognitive decline	1	5	Yes	Yes
	Older adults with history of falls or balance impairment		3	Yes	Yes
Grand Total (Number of studies)		**15**	**123**	**105**	**66**

Abbreviations: ACL, anterior cruciate ligament; ADHD, Attention deficit/hyperactivity disorder; HTLV, Human T-cell leukaemia virus type 1; ICU, intensive care unit; yrs, years.

a. International Statistical Classification of Diseases and Related Health Problems 11th Revision (ICD-11)-WHO Version (2021)

4.2 Breast cancer

4.2.1 Description of the condition

Breast cancer is the most common type of cancer for females, with an estimated 1 in 7 females being diagnosed before the age of 85 (26). In 2020, approximately 19 807 females and 167 males will be diagnosed with breast cancer, with about 2997 females and 33 males expected to die from the disease (27). Breast cancer is caused by abnormal growth of cells in the lobules, ducts and connective tissue (27). There are five stages of breast cancer, from stage 0 to IV (27). Stage 0 refers to preinvasive breast cancer. Treatment often involves breast surgery or radiotherapy to prevent invasive breast cancer developing. Stage I to Stage IIB (early) refers to early breast cancer. Stage IIB (advanced) to IV, refers to locally advanced breast cancer or metastatic breast cancer. Locally advanced or metastatic breast cancer usually involves a combination of treatments, including chemotherapy, breast surgery, radiotherapy or targeted and hormonal therapies (27).

There are many risk factors associated with breast cancer (such as age, genetic mutations, family history of breast or ovarian cancer) that are not modifiable (28). However, there are lifestyle factors that are associated with a decreased risk of breast cancer including physical activity and a diet with high vegetable intake, calcium and dairy consumption (28). Local and international guidelines (29-31) encourage physical therapy before, during and after treatment as exercise is believed to provide functional and psychological benefits, improve quality of life and reducing the risk of recurrence. Cancer Australia guidelines (31) advise people with cancer to undertake regular aerobic and resistance exercise (strength training) that is tailored to the person's fitness, health and abilities.

4.2.2 Description of studies

Fourteen citations (32-45) corresponding to five RCTs (Alpozgen 2017, Eyigor 2010, Gajbhiye 2013, Odynets 2018, Odynets 2019) and two quasi RCTs (Martin 2013, Sener 2017) were identified in the literature. There were nine ongoing studies, and one study awaiting classification (Azamian 2015) (46) that was published in a language other than English. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D1.1.1.

Five studies were carried out in single centre settings in either Turkey (Eyigor 2010, Sener 2017), India (Gajbhiye 2013), United States (Martin 2013), or Ukraine (Odynets 2019). One study (Alpozgen 2017) was carried out in a multicentre setting in Turkey and another study (Odynets 2018) did not report the setting of the trial but was carried out in Ukraine. Sample sizes ranged from 26 to 124 participants (total 422), with all studies enrolling breast cancer survivors. Two studies (Odynets 2018, Odynets 2019) included survivors with Stage I or II disease, six studies excluded people with Stage IV disease and one study (Eyigor 2010) did not specify the Stage of disease at inclusion. One study (Sener 2017) included female breast cancer survivors who developed lymphedema after undergoing treatment. Two studies (Alpozgen 2017, Gajibhive 2013) included female breast cancer survivors with upper extremity limitations secondary to breast cancer treatment. In all trials, participants were female and middle-aged (mean age ranged between 44 and 59 years). One study (Gajbhiye 2013) did not report the mean age of included participants but only people between 25 and 65 years were enrolled. In the studies reporting body mass index (BMI) (Alpozgen 2017, Odynets 2018, Odynets 2019, Sener 2017), participants had a mean BMI ranging between 24 and 30 kg/m^2.

Two studies (Eyigor 2010, Martin 2013) compared a modified form of Pilates with no intervention in breast cancer survivors. The remaining five studies compared Pilates with another intervention. Two studies (Gajibhive 2013 and Alpozgen 2017) compared modified Pilates with an exercise program consisting of stretching and breathing exercises. Alpozgen 2017 also included a third control group with a home exercise program. Odynets 2018 and Odynets 2019 compared modified Pilates with a water physical rehabilitation

program. Odynets 2019 also included a third control group with a yoga program. Sener 2017 compared Pilates with lumbopelvic stability exercises. In all studies the Pilates sessions were typically 40 to 60 minutes in duration, but the treatment programs ranged in intensity from daily for three weeks (Gajibhive 2013) to three times a week for 8 weeks (Alpozgen 2017, Eyigor 2010, Martin 2013, Sener 2017), 12 weeks (Odynets 2018) or 8 weeks (Odynets 2019).

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see 4.2.4.1) (and Appendix F2).

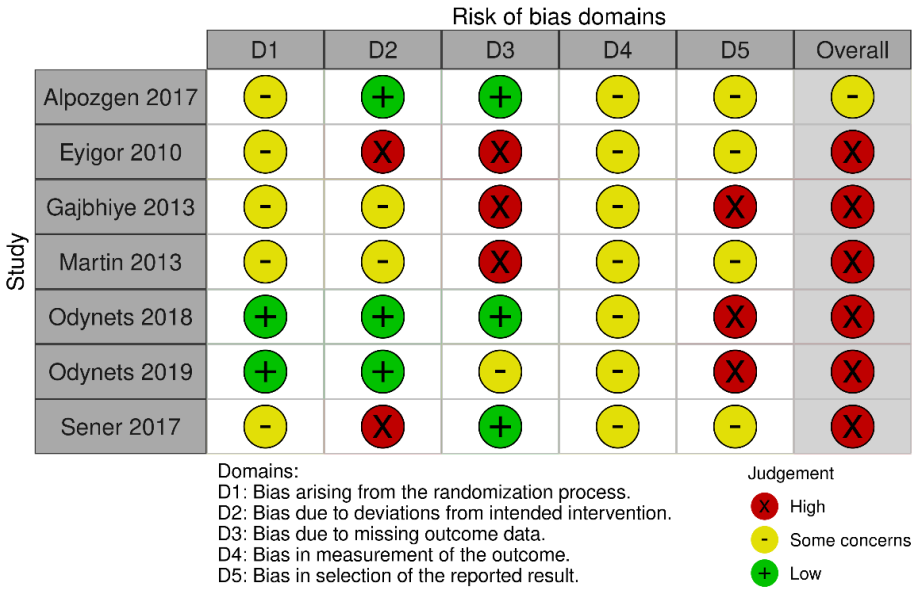
Results of the five studies that examined Pilates versus an active comparator are presented in Appendix F2.

4.2.3 Risk of bias - per item

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

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

Figure 2 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Breast cancer



4.2.4 Main comparison (vs control)

Two RCTs were eligible for this comparison. One RCT (Eyigor 2010) contributed data for three outcomes. The other identified RCT (Martin 2013) was a feasibility study that did not measure or assess any outcomes considered critical or important to this review. There was one study published in a language other than English that compared Pilates with no intervention in breast cancer survivors (total 27 participants) that could have contributed data, but it did not measure or assess any outcomes considered to be critical important for this review (see Appendix C6). There were no ongoing studies eligible for this comparison.

4.2.4.1 Summary of findings and evidence statements

Breast cancer (survivors)

Pilates compared to Control (no intervention) for breast cancer (survivors)

Patient or population: Breast cancer (survivors)
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with Control	Risk with Pilates				
QoL assessed with: EORTC-QLQ30 - global score (higher is best) Scale from: 0 to 100 follow-up: 8 weeks	The mean quality of life, global score was **63.78** points	MD **13.24 points higher** (27.83 higher to 1.35 lower)	-	42 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on quality of life in breast cancer survivors. **
Functional status, upper extremity - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on upper extremity functional status in breast cancer survivors is unknown.
Pain - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on pain in breast cancer survivors is unknown.
Fatigue assessed with: Brief fatigue inventory (higher is worse) Scale from: 0 to 10 follow-up: 8 weeks	The mean fatigue score was **6.55** points	MD **0.97 points lower** (3.82 lower to 1.88 higher)	-	42 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,e,f	The evidence is very uncertain about the effect of Pilates in breast cancer survivors.***
Function assessed with: EORTC QLQ-C30 – Functional score (higher is best) Scale from: 0 to 100 follow-up: 8 weeks	The mean functional score was **78** points	MD **5.26 points higher** (17.04 higher to 6.52 lower)	-	42 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,e,g	The evidence is very uncertain about the effect of Pilates on functional status in breast cancer survivors. ****
Lymphedema - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on lymphedema in breast cancer survivors is unknown.
Physical activity - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on physical activity in breast cancer survivors is unknown.

Pilates compared to Control (no intervention) for breast cancer (survivors)

Patient or population: Breast cancer (survivors)
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist or usual care)

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

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

** In people with breast cancer the MCID for global health status is 22.4 points.

*** In people with breast cancer a score between 4–7 suggests moderate fatigue.

**** In people with breast cancer the MCID for functional health is between 17 and 19.6.

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

CI: Confidence interval; **MD:** Mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. One study (100% weight) at high risk of bias for the outcome. Certainty of evidence downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The available evidence is applicable to breast cancer survivors. Certainty of evidence not downgraded.
d. Small study (fewer than 50 participants). Wide confidence intervals (lower bound falls below the MCID). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.
f. Small study (fewer than 50 participants). Wide confidence intervals (upper and lower bounds overlap with cut-offs for mild, moderate and severe fatigue). Certainty of evidence downgraded.
g. Small study (fewer than 50 participants). Wide confidence intervals (upper bound falls above the MCID). Certainty of evidence downgraded.

Breast cancer (on treatment)

There were no studies found for outcomes selected *a priori* as critical or important, thus the effect of Pilates compared with control on these outcomes in people undergoing treatment for breast cancer is unknown.

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

- quality of life
- pain
- fatigue
- functional status, upper extremity
- physical function

- anxiety
- emotional wellbeing

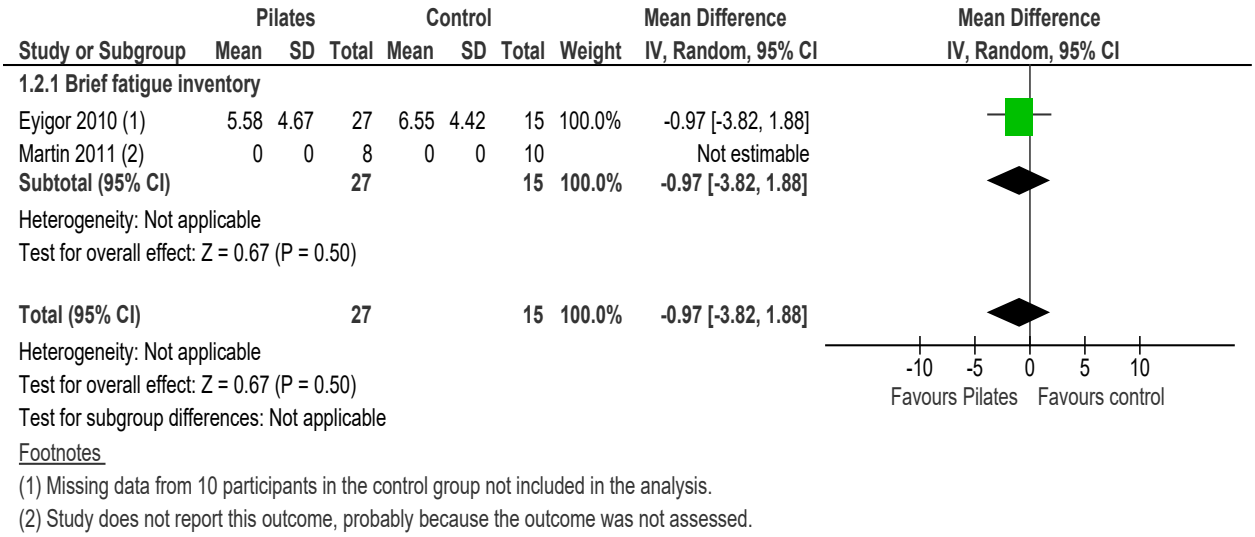
4.2.4.2 Forest plots

Outcome results related to global health status (QoL) for breast cancer survivors are presented in Figure 3.

Outcome results related to fatigue for breast cancer survivors are presented are Figure 4.

Outcome results related to functioning in breast cancer survivors are presented in Figure 5.

Figure 3 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): breast cancer – quality of life, global

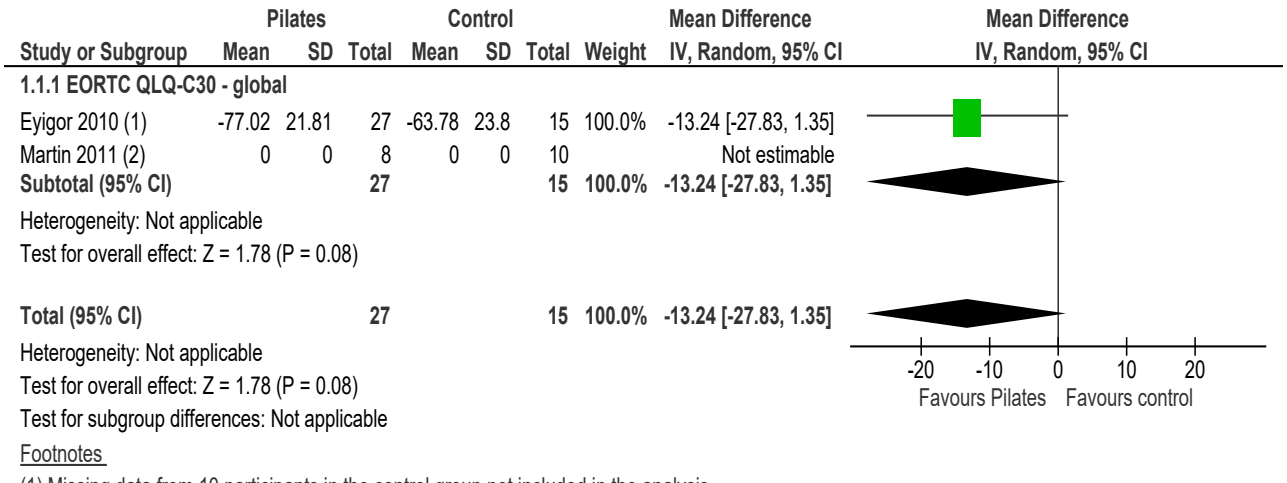


Footnotes

(1) Missing data from 10 participants in the control group not included in the analysis.

(2) Study does not report this outcome, probably because the outcome was not assessed.

Figure 4 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): breast cancer – fatigue

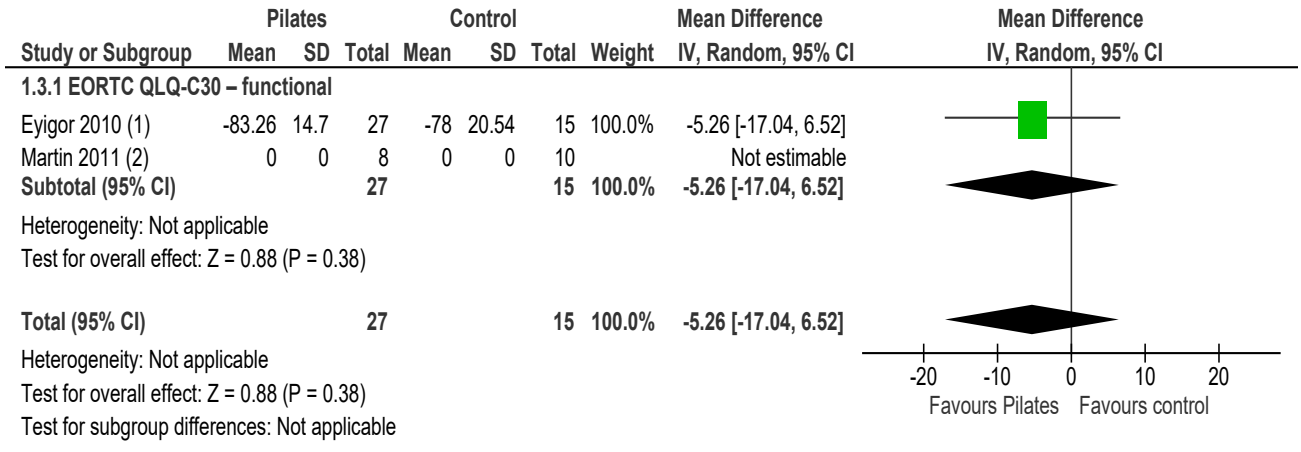


Footnotes

(1) Missing data from 10 participants in the control group not included in the analysis.

(2) Study does not report this outcome, probably because the outcome was not assessed.

Figure 5 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): breast cancer – functioning



Footnotes

(1) Missing data from 10 participants in the control group not included in the analysis.

(2) Study does not report this outcome, probably because the outcome was not assessed.

4.3 Prostate cancer

4.3.1 Description of the condition

Prostate cancer is the most frequently diagnosed cancer among Australian males. In 2019, it was estimated that 19 508 men would be diagnosed with the disease (47). The prostate is a small, walnut-size gland of the male reproductive system, which produces the fluid that combines with sperm to form semen (48, 49). Prostate cancer is caused by the development and uncontrolled multiplication of abnormal cells in the prostate gland (48, 49). It is often slow growing and remains within the prostate (localised or early-stage disease). Some prostate cancers grow quickly, spreading to nearby body parts such as the bladder or rectum, nearby lymph nodes or distant sites such as the bones, liver or lungs (50, 51). In the early stages, prostate cancer rarely causes symptoms. People with advanced disease may experience symptoms such as unexplained weight loss; frequent or urgent need to urinate; difficulty or discomfort while urinating; blood in the urine or semen; or pain in the lower back, upper thighs or hips (48, 49).

Prostate cancer is the second most common cause of death in Australian men, behind lung cancer. The AIHW reported that prostate cancer would be responsible for an estimated 3306 deaths in 2019 (26). The overall five-year relative survival rate (i.e. the probability of being alive 5 years after diagnosis compared to the general population) for men with prostate cancer was 95.2% between 2011 and 2015 (26). For people with stage I–III disease, the five-year relative survival rate was close to 100%, while for people with stage IV disease it was significantly lower, at 36% (26).

Available treatment options include androgen deprivation therapy (ADT), surgery, radiation therapy and chemotherapy (52-54). Local and international guidelines recommend aerobic and resistant exercises to maintain bone health, improve quality of life and reduce fatigue as well as other symptoms associated with ADT (52, 53). Physical therapy is also encouraged to combat mental, physical and functional effects such as urinary incontinence experienced by people with prostate cancer (52, 53).

4.3.2 Description of studies

Three citations (55-57) corresponding to two RCTs (Gomes 2018, Pedriali 2014) were identified in the literature. There were no ongoing studies and one study awaiting classification (Guan 2019) (58) that was published in a language other than English. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D1.2.1.

Both Gomes 2018 and Pedriali 2014 were carried out in single centre settings in Brazil with the sample size ranging from 90 to 110 participants (total 200). Both studies included people with post-prostatectomy urinary incontinence (after prostate cancer). Participants in the included trials were over 50 years (mean age ranged between 62-67 years) and were male (100%).

Gomes 2018 and Pedriali 2014 compared a modified form of Pilates with no intervention in one group and pelvic floor muscle exercises combined with anal electrical stimulation in another comparator group. The Pilates sessions were 45 minutes in duration, once a week for 10 weeks. Participants also received written guidelines to perform daily Pilates exercise at home in one study (Gomes 2018) and three exercises as well as two of the Pilates sessions at home each day (Pedriali 2014).

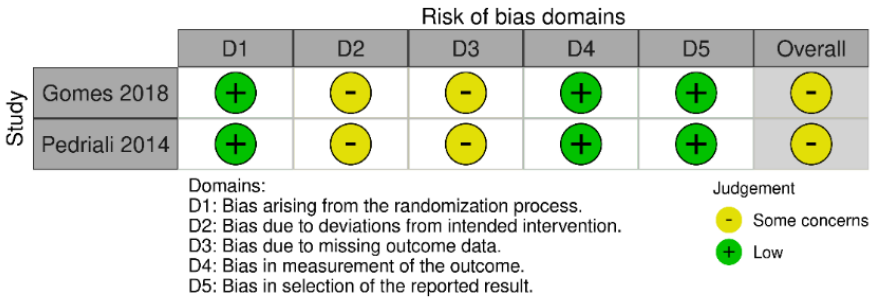
Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see 4.3.4.1) (and Appendix F2). Results for Pilates versus an active comparator are presented in Appendix F2.

4.3.3 Risk of bias – per item

The risk of bias for each item in the included RCTs is summarised in Figure 6. Details are provided in Appendix D1.2.2.

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

Figure 6 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Prostate cancer



4.3.4 Main comparison (vs control)

Two RCTs (Gomes 2018, Pedriali 2014) were eligible for this comparison and contributed data to two outcomes. There were no studies awaiting classification or ongoing that compared Pilates with no intervention in men with post-prostatectomy urinary that could have contributed data to these outcomes (see Appendix C6).

4.3.4.1 Summary of findings

Pilates compared to Control (no intervention, waitlist or usual care) for prostate cancer

Patient or population: Prostate cancer (with post-prostatectomy urinary incontinence)
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with Control	Risk with Pilates				
QoL, global – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on overall quality of life in men with post-prostatectomy urinary incontinence is unknown.
Function – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on function in men with post-prostatectomy urinary incontinence is unknown.
Fatigue – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on fatigue in men with post-prostatectomy urinary incontinence is unknown.

Pilates compared to Control (no intervention, waitlist or usual care) for prostate cancer

Patient or population: Prostate cancer (with post-prostatectomy urinary incontinence)
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with Control	Risk with Pilates				
Pain – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on pain in men with post-prostatectomy urinary incontinence is unknown.
QoL, incontinence-related assessed with: ICIQ-short (higher is worse) Scale from: 0 to 21 follow-up: 10 weeks	The mean incontinence-related QoL ranged from **8.09 to 8.2** points	MD **3.66 points lower** (5.26 lower to 2.06 lower)	-	126 (2 RCTs)	⊕⊕⊕◯ MODERATE a,b,c,d,e	Pilates probably improves incontinence-related quality of life in men with post-prostatectomy urinary incontinence. **
Urinary incontinence assessed with: 24-hr pad test (pad weight) (higher is worse) follow-up: 10 weeks	The 24-hr pad weight ranged from **72.88 to 80.25 grams**	SMD **0.45 SD higher^** (0.28 lower to 1.18 higher)	-	126 (2 RCTs)	⊕◯◯◯ VERY LOW a,d,e,f,g	The evidence is very uncertain about the effect of Pilates on urinary incontinence in men with post-prostatectomy urinary incontinence.
Urinary frequency/urgency/irritation – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on urinary frequency, urgency or irritation in men with post-prostatectomy urinary incontinence is unknown.
Psychological wellbeing – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on psychological wellbeing in men with post-prostatectomy urinary incontinence is unknown.
Sexual function / symptoms – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on sexual function in men with post-prostatectomy urinary incontinence is unknown.

Pilates compared to Control (no intervention, waitlist or usual care) for prostate cancer

Patient or population: Prostate cancer (with post-prostatectomy urinary incontinence)
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist or usual care)

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

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
** The MCID in men with post-prostatectomy urinary incontinence is unknown. A moderate effect assumed based on a 17% change from total score.#

In the absence of an MCID, effect estimates were considered on three levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).
^ As a rule of thumb, an SMD of 0.2 is considered a small difference, 0.5 is medium, and 0.8 is large difference (59).

CI: Confidence interval; **ICIQ:** International Consultation on Incontinence Questionnaire; **MD:** Mean difference; **SMD:** Standardised mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. Concerns of study bias not likely to seriously alter the confidence in results. Certainty of evidence not downgraded.
b. No serious inconsistency. Certainty of evidence not downgraded.
c. No serious imprecision. Certainty of evidence not downgraded.
d. No serious indirectness. The available evidence is generalisable to men with mild post-prostatectomy urinary incontinence. Certainty of evidence not downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.
f. Significant heterogeneity (I^2 statistic greater than 70%) and effect estimate are importantly different across studies. Certainty of evidence downgraded.
g. Wide confidence intervals (upper and lower bounds overlap with a small or large difference). Certainty of evidence downgraded.

4.3.4.2 Forest plots

Outcome results related to urinary incontinence-related quality of life in participants with post-prostatectomy urinary incontinence are presented in Figure 7.

Outcome results related to urinary incontinence in participants with post-prostatectomy urinary incontinence are presented in Figure 8.

Figure 7 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Prostate cancer – quality of Life, disease specific

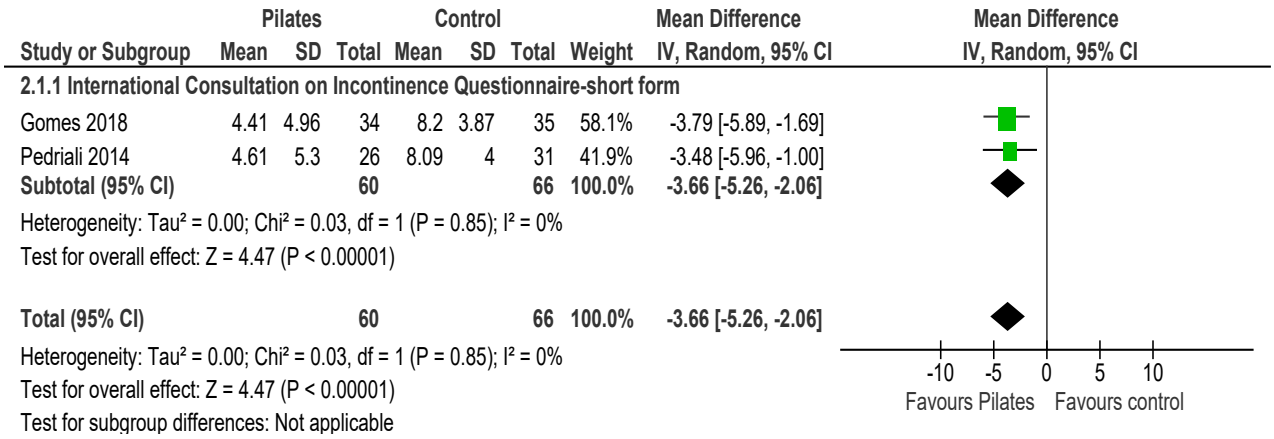
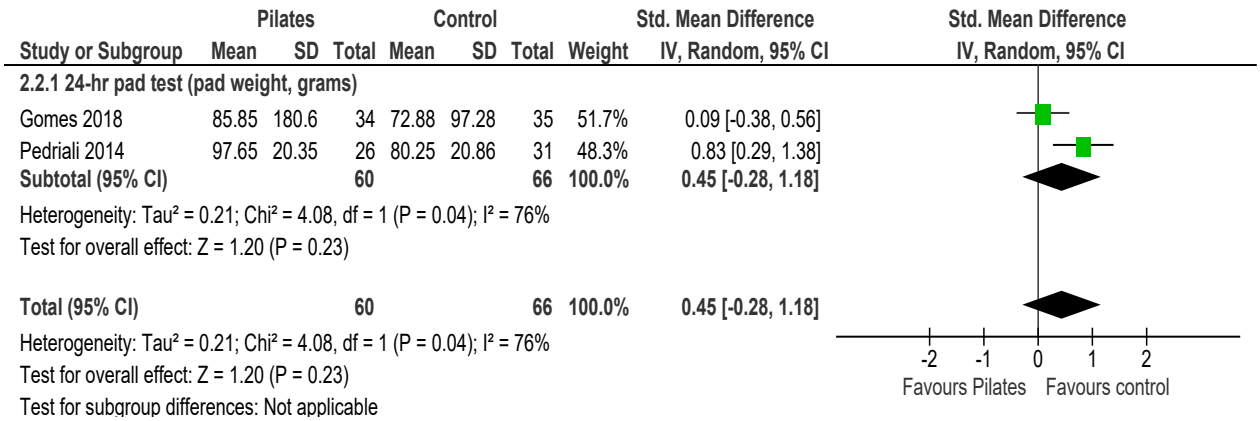


Figure 8 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Prostate cancer – urinary incontinence



4.4 Diabetes mellitus

4.4.1 Description of the condition

Diabetes mellitus is a group of metabolic diseases characterised by elevated levels of blood glucose or hyperglycaemia resulting from defects in insulin secretion, insulin action, or both (60). The chronic hyperglycaemia of diabetes is associated with long-term damage, dysfunction and failure of various organs, especially the eyes, kidneys, nerves, heart, and blood vessels (60). There are three types: Type 1, Type 2 and gestational.

Type 1 diabetes, also known as juvenile diabetes constitutes about 5-10% of all diabetes cases (61) and is caused by the autoimmune destruction of insulin-producing beta cells in the islets of Langerhans leading to little to no production of insulin (62, 63). The exact cause of Type 1 diabetes is unknown but risk factors include genetic predisposition and environmental triggers such as exposure to certain viruses (64, 65). Type 2 diabetes is the most common, making up 85-90% of all diabetes cases and usually occurs in adults over the age of 45 (66). It is characterised by insulin resistance and/or the gradual loss to produce enough insulin in the pancreas and is associated with modifiable lifestyle risk factors such as diet and exercise (66). Gestational diabetes is defined as an intolerance to glucose that is first diagnosed or has its onset during pregnancy. It is estimated to affect almost 5% of pregnancies in Australia and between 3% and 9% worldwide (67). Although some women will continue to have elevated glucose levels, gestational diabetes usually disappears after giving birth (68), but a history of gestational diabetes is associated with an increased risk of progression to type 2 diabetes later in life (69).

Based on self-reported data from the Australian Bureau of Statistics (ABS) 2017–18 National Health Survey, an estimated 1.2 million Australians (4.9% of the total population) had diabetes in 2017–18 (70). This is likely to be an underestimate of the true prevalence given it does not include people with undiagnosed diabetes (70). Prevalence of diabetes in 2017-18 was higher in males (5.0%) than females (3.8%) and increases with age (70). It is also approximately twice as high among people living in the lowest socioeconomic areas (6.7% and 5.8% for males and females, respectively) compared with the highest socioeconomic areas (4.1% and 2.2% for males and females, respectively) (70). In 2015–16, an estimated 2.3% ($2.7 billion) of total disease expenditure in the Australian health system was attributed to diabetes (70).

The effects of exercise on metabolic control in people with diabetes are conflicting. Some studies show a limited effect of exercise on HbA1c levels (71, 72). However, other studies showed positive correlation between physical activity and better metabolic control (73, 74).

4.4.2 Description of studies

Two citations (75, 76), corresponding to one RCT (Yucel 2016) and one quasi RCT (Melo 2020), were identified in the literature search. There were two ongoing studies and one study awaiting classification (Hassani 2018) (77) that was published in a language other than English. One additional study (Torabian 2013) (78) was identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D2.1.1.

All three studies (Melo 2020, Torabian 2013, Yucel 2016) were conducted in women with Type 2 diabetes, with the sample size ranging from 22 to 70 participants (total 123). Studies were carried out in single centres in Brazil (Melo 2020), Iran (Torabian 2013) and Turkey (Yucel 2016). The mean age of participants in the study by Melo 2020 was 65.5 years in the Pilates group and 67.5 years and control group. Participants in Torabian 2013 were aged between 30 and 70 years, with most participants aged 41 or over (74.2% in the Pilates group and 77.1% in the control group). The mean age of participants in the study by Yucel 2016 was 58.5 years in the Pilates group and 53.5 years in the control group. Participants in Yucel 2016, on average,

had shorter duration of Type 2 diabetes (mean duration of 2.0 years in the Pilates group and 4.0 years in the control group) compared to Melo 2020 (mean duration of 9.9 years in the Pilates group and 6.7 years in the control group) and Torabian 2013 (where 74.2% and 68.5% of participants in the Pilates and Control group, respectively, had Type 2 diabetes for six or more years). On average, participants in the study by Yucel 2016 had a higher baseline BMI compared to Melo 2020, however, they had better longer-term glycaemic control (i.e., lower HbA1c).

All three studies investigated Pilates delivered as an adjunct to standard medical care that included prescribed medical and dietary treatments. Participants allocated to control groups engaged in their usual activities. In one study (Torabian 2013), Pilates was implemented as a modified program over 8 weeks, with two 60-minute sessions per week. Two studies (Melo 2020, Yucel 2018) investigated the effectiveness of a 12-weeks Pilates training program. In Melo 2020, each Pilates session was led by a certified instructor at moderate intensity, three times a week at 60 minutes per session. In Yucel 2019, the mat-based Pilates program was offered three times a week and was led by a trained physiotherapist. Sessions lasted 45 minutes, increasing to 70 minutes by the end of the study.

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see 4.4.4.1) (and Appendix F2).

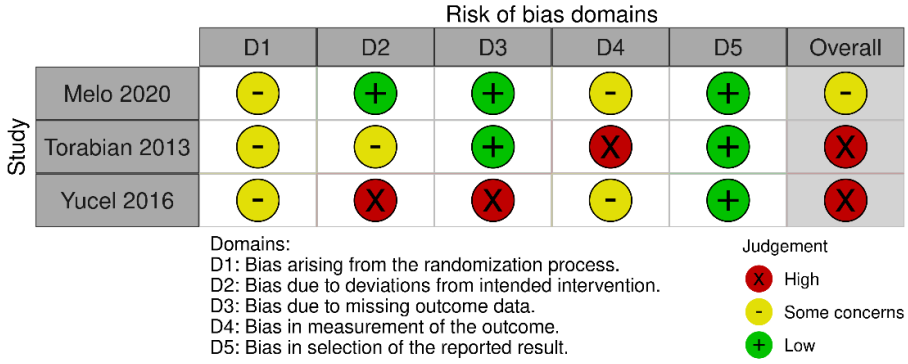
There were no studies identified comparing Pilates with an active intervention in people with type 2 diabetes.

4.4.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 9. Details are provided in Appendix D.2.1.2.

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

Figure 9 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Diabetes mellitus (type 2)



4.4.4 Main comparison (vs control)

Three RCTs (Melo 2020, Torabian 2013, Yucel 2016) were eligible for this comparison and contributed data to five of seven outcomes. There was one additional study published in a language other than English (awaiting classification) that compared Pilates with no intervention in people with type 2 diabetes that could have contributed data to these outcomes but there was no information to make a judgment regarding the extent of missing data (see Appendix C6).

4.4.4.1 Summary of findings

Pilates compared to Control (no intervention, waitlist, usual care) for diabetes, type 2

Patient or population: Diabetes, type 2
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with Control	Risk with Pilates				
Quality of life - mental assessed with: SF-36 (higher is best) Scale from: 0 to 100 follow-up: 12 weeks	The mean quality of life - mental summary score was **35** points	MD **0.00 points** (0.59 lower to 0.59 higher)	-	45 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	The evidence suggests that Pilates results in little to no difference in mental wellbeing in women with type 2 diabetes.**
Quality of life - physical assessed with: SF-36 (higher is best) Scale from: 1 to 100 follow-up: 12 weeks	The mean quality of life - physical summary score was **41** points	MD **0.00 points** (2.34 lower to 2.34 higher)	-	45 (1 RCT)	⊕◯◯◯ VERY LOW [a,b,c,e.f]	The evidence is very uncertain about the effect of Pilates on physical wellbeing in women with type 2 diabetes.**
Activities of daily living assessed with: GLADM test battery (higher is worse) follow-up: 12 weeks	The mean activities of daily living score was **35.3** points	MD **8.1 points lower** (11.55 lower to 4.65 lower)	-	24 (1 RCT)	⊕⊕◯◯ LOW [b,c,e,g]	The evidence suggests Pilates results in a slight improvement in activities of daily living in women with type 2 diabetes.***
Cardiovascular disease risk - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on cardiovascular disease risk in people with type 2 diabetes is unknown.
Physical function - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on physical function in people with type 2 diabetes is unknown.
Body composition assessed with: Body mass index (kg/m^2) (higher is worse) follow-up: 12 weeks	The mean BMI was **30.36** kg/m^2	MD **1.67 kg/m^2 higher** (2.81 lower to 6.15 higher)	-	45 (1 RCT)	⊕◯◯◯ VERY LOW [a,b,c,e,f]	The evidence is very uncertain about the effect of Pilates results on body composition in women with type 2 diabetes.****
Fatigue assessed with: visual analogue scale (higher is worse) Scale from: 1 to 10 follow-up: 12 weeks	The mean fatigue was **4.0** points	MD **0.00 points** (0.94 lower to 0.94 higher)	-	45 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	The evidence suggests that Pilates results in little to no difference in fatigue in women with type 2 diabetes.*****
Depression assessed with: HADS or GHQ-28 (higher is worse) follow-up: range 8 weeks to 12 weeks	-	SMD **0.96 SD lower^** (2.84 lower to 0.92 higher)	-	115 (2 RCTs)	⊕◯◯◯ VERY LOW [c,e,h,l,j]	The evidence is very uncertain about the effect of Pilates on depression in people with type 2 diabetes.

Pilates compared to Control (no intervention, waitlist, usual care) for diabetes, type 2

Patient or population: Diabetes, type 2
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual care)

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

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
** The MCID in people with type 2 diabetes unknown. A change score >1 is likely important. #
*** A score cut-off < 22.28 suggests very good autonomy and > 33.01 suggests insufficient autonomy.
**** A cut-off score of below 30 means participants are overweight; a score between 30 to 39.9 means participants are obese.
***** The MCID for the fatigue VAS-10 ranges between 0.8 to 1.1 (for improvement) (79).

Effect estimates were considered on three levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).
^As a rule of thumb, an SMD of 0.2 is considered a small difference, 0.5 is medium, and 0.8 is large difference (59).

CI: Confidence interval; **MD:** Mean difference; **SF-36**: 36-item short-form; **SMD:** Standardised mean difference; **GLADM:** Group of Latin American development to maturity; **HADS:** Hamilton anxiety and depression scale

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. One RCT (100% weight) at high risk of bias for the outcome. Certainty of evidence downgraded.
b. Single study. Heterogeneity not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is directly generalisable to the Australian population with some caveats. The available evidence is in women with type 2 diabetes which may not be generalisable to the men with type 2 diabetes. Certainty of evidence is not downgraded.
d. No. Certainty of evidence not downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.
f. Serious imprecision. Small study (fewer than 50 participants). Wide confidence intervals (upper and lower bounds overlap with an important difference). Certainty of evidence downgraded.
g. Small study (fewer than 30 participants). Certainty of evidence downgraded.
h. Two RCTs (~50% weight each) at high risk of bias for the outcome. Certainty of evidence downgraded.
i. Significant heterogeneity (I^2 = 95%). Evidence is inconsistent with minimal overlap in confidence intervals. Certainty of evidence downgraded.
j. Serious imprecision. Wide confidence intervals (upper and lower bounds overlap with an important (or no) difference). Certainty of evidence downgraded.

4.4.4.2 Forest plots

Outcome results related to quality of life in people with type 2 diabetes are presented in Figure 10.

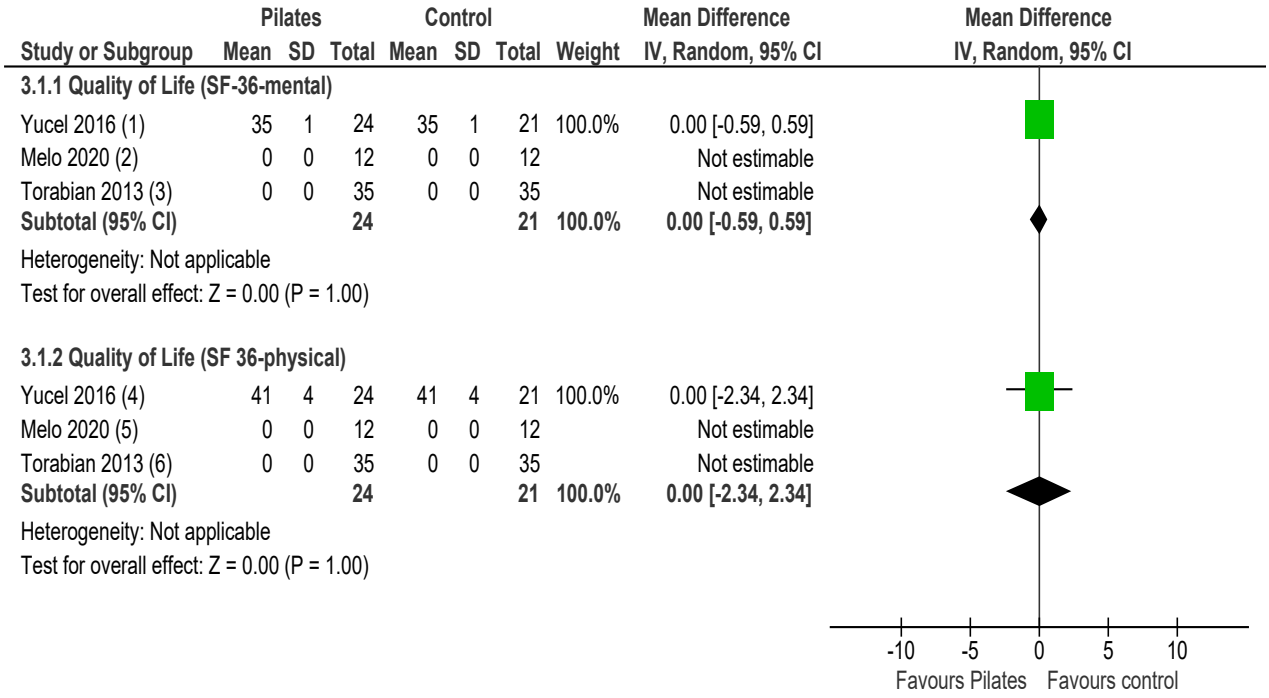
Outcome results related to physical functioning in people with type 2 diabetes are presented in Figure 11.

Outcome results related to body composition in people with type 2 diabetes are presented in Figure 12.

Outcome result related to fatigue in people with type 2 diabetes are presented in Figure 13.

Outcome results related to depression in people with type 2 diabetes are presented in Figure 14.

Figure 10 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Diabetes, type 2 – quality of life



Footnotes

(1) Authors state in the text that presented data are median (IQR) but the table states that the presented values are mean (SD).

(2) Study does not report this outcome, probably because the outcome was not assessed.

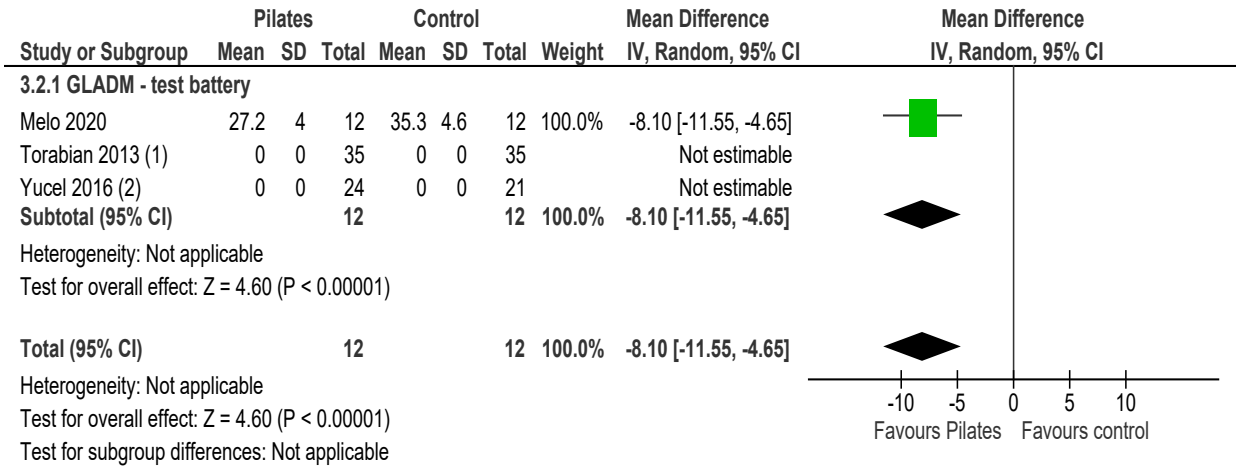
(3) Study does not report this outcome, probably because the outcome was not assessed.

(4) Authors state in the text that presented data are median (IQR) but the table states that the presented values are mean (SD).

(5) Study does not report this outcome, probably because the outcome was not assessed.

(6) Study does not report this outcome, probably because the outcome was not assessed.

Figure 11 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Diabetes, type 2 – activities of daily living

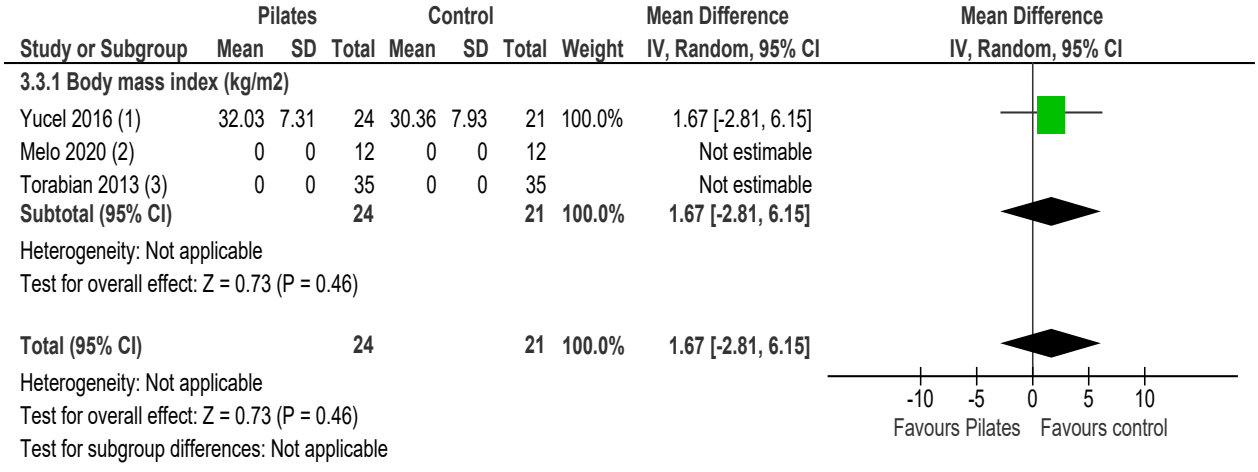


Footnotes

(1) Study does not report this outcome, probably because the outcome was not assessed.

(2) Study does not report this outcome, probably because the outcome was not assessed.

Figure 12 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Diabetes, type 2 – body composition



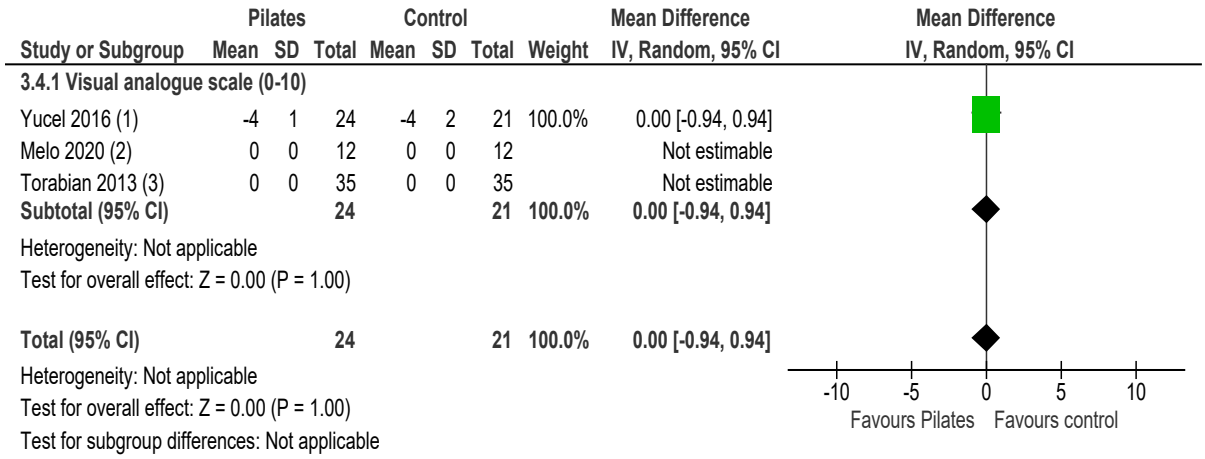
Footnotes

(1) Authors state in the text that presented data are median (IQR) but the table states that the presented values are mean (SD).

(2) Study does not report this outcome, possibly because the P value, magnitude or direction of the results generated were considered...

(3) Study does not report this outcome, Study does not report this outcome, possibly because the P value, magnitude or direction of the results...

Figure 13 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Diabetes. Type 2 – fatigue



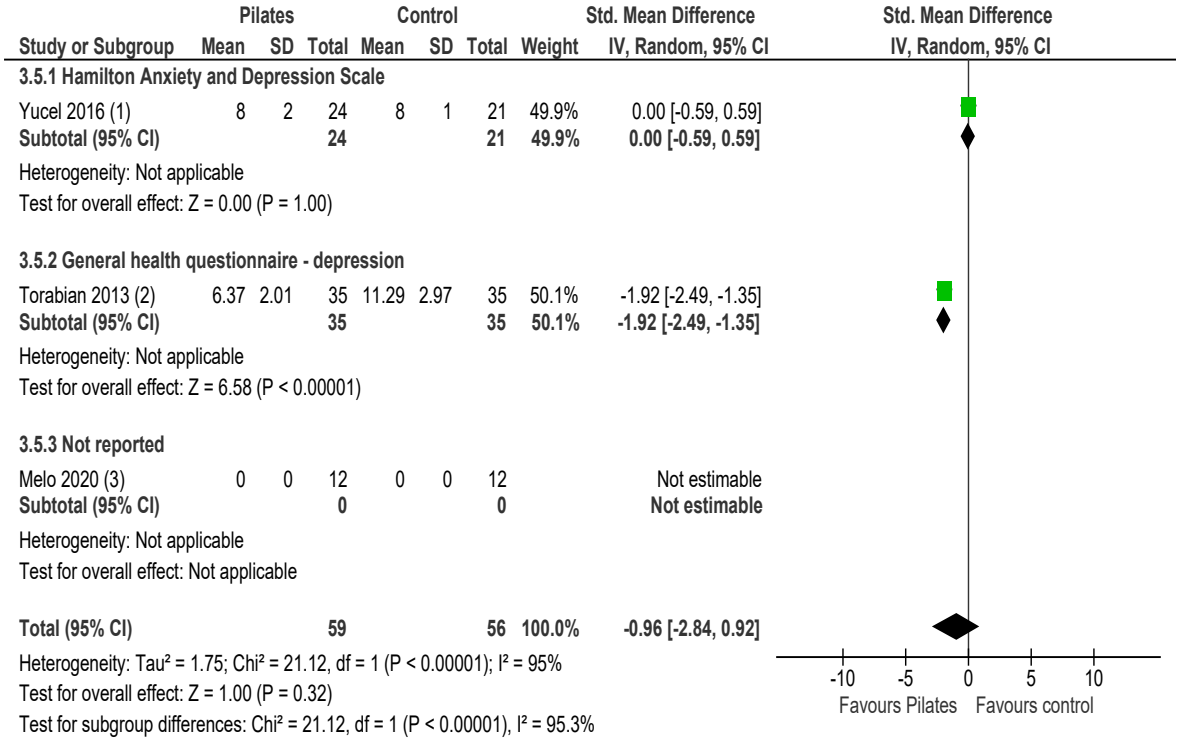
Footnotes

(1) Authors state in the text that presented data are median (IQR) but the table states that the presented values are mean (SD).

(2) Study does not report this outcome, probably because the outcome was not assessed.

(3) Study does not report this outcome, probably because the outcome was not assessed.

Figure 14 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Diabetes, type 2 – depression



Footnotes

(1) Authors state in the text that presented data are median (IQR) but the table states that the presented values are mean (SD).

(2) GHQ-28 subscales are not independent of each other and subscores should not be used to indicate specific psychological diagnoses.

(3) Study does not report this outcome, probably because the outcome was not assessed.

4.5 Multiple sclerosis

4.5.1 Description of the condition

Multiple sclerosis (MS) is a chronic inflammatory, demyelinating and neurodegenerative disease of the central nervous system. A distinctive feature of MS is accumulation of demyelinating plaques in the brain and spinal cord (80, 81). MS symptoms are heterogenous depending on which part of the central nervous system is affected, but can include a combination of motor control issues, fatigue, neurological and neuropsychological symptoms and incontinence. Most people experience relapsing-remitting MS, characterised by neurological episodes known as relapses, which are reversible but leave behind accumulated neurological and clinical disability. Over time the disease progresses to secondary progressive disease. Approximately 5% to 15% of people with MS have a progressive form of disease from onset (80, 81).

MS is the most common nontraumatic disease of the central nervous system in young adults. In Australia, over 25 000 people are living with MS (82). Most people are diagnosed between the ages of 20 and 40 years of age, with three out of every four diagnosed persons likely to be women (82). The quality of life of people with MS in Australia is estimated to be 31% less than that of the general population with reduced quality of life mostly driven by MS-related pain, extreme fatigue, the impact on independent living (related to factors such as balance impairment, dizziness, visual disturbances), mental health and relationships (82).

MS is typically treated with disease modifying therapeutics (DMTs) that act on the immune system to decrease the frequency of relapse and avoid disease progression. In Australia, approximately two-thirds of people with MS are prescribed DMTs, with treatment options more limited for people with the progressive form of disease (82). Use of DMTs is associated with higher QoL but they also contribute the largest economic burden for people living with MS (82). Modifiable lifestyle factors that can slow MS disease progression and prevent or improve associated disabilities are also recommended (83-85), as they provide a mechanism for people with MS to take control and potentially minimise the impact of MS on their lives (86). This includes interventions that focus on falls prevention (87), improvements in diet or gut health (88), and interventions that enhance physical activity (89).

4.5.2 Description of studies

Twenty citations (90-109) corresponding to five RCTs (Duff 2018, Eftekhari 2018, Fleming 2019, Freeman 2012, Kalron 2016) and four quasi RCTs (Abasiyanik 2018, Bulguroglu 2015, Küçük 2015, Marandi 2013) were identified in the literature search. A further two citations (110, 111) corresponding to two NRSIs (Guclu-Gunduz 2014, Kara 2017) were also identified. There are six ongoing studies and nine citations corresponding to eight studies awaiting classification, including six conference abstracts (112-118) and two studies (119, 120) published in a language other than English. The Department's public call for evidence retrieved two additional quasi RCTs (Rezvani 2017, Sisi 2013) (121, 122) and two studies awaiting classification (123, 124) (published in a language other than English). An overview of the PICO criteria of included studies is provided in Appendix D3.1.1.

Twelve of the 13 studies were carried out in single centre settings in Turkey, Canada, Iran, Ireland and Israel, with one study (Freeman 2012) conducted across physical therapy departments of seven recruiting centres in the United Kingdom. The sample size ranged from 18 to 100 participants in the RCTs and quasi RCTs (total 468), while the two NRSIs had 26 and 55 participants. All studies included adults with MS, with four studies (Eftekhari 2018, Fleming 2019, Marandi 2013 and Rezvani 2017) only enrolling female participants, and one study (Hosseini 2013) only including male participants. Most of the studies excluded participants with severe disability by limiting eligibility to those with Expanded Disability Status Scale (EDDS) score of under 4.5 (Bulguroglu 2015, Hosseini Sisi 2013, Marandi 2013, Rezvani 2017), or under 6 (Eftekhari 2018, Freeman

2012, Kalron 2016, Kara 2017, Küçük 2015), or those who were ambulatory (Abasiyanik 2020, Duff 2018, Guclu-Gunduz 2014).

Six studies compared a mat-based Pilates program with no intervention or a wait list control (Duff 2018, Eftekhari 2018, Fleming 2019, Marandi 2013, Rezvani 2017 and Sisi 2013), with Marandi 2013 examining the effect of Pilates delivered as an adjunct to usual care. Participants in Duff 2018 also utilised the CoreAlign apparatus and Fleming 2019 included a second group that performed home-based DVD-guided Pilates. The studies with an active control group compared mat-based Pilates (Freeman 2012 and Kara 2017), Reformer Pilates (Bulguroglu 2015), Pilates that included resistance bands and/or balls (Abasiyanik 2020, Bulguroglu 2015 and Küçük 2015) or an individualised Pilates program (Kalron 2016) with various active controls including home exercise (with breathing and relaxation exercises), standard physiotherapy, physical therapy, aqua exercise and relaxation exercises.

In all studies, the Pilates session were typically one hour in duration lasting for eight (Abasiyanik 2018, Bulguroglu 2015, Eftekhari 2018, Fleming 2019, Freeman 2012, Guclu-Gunduz 2014, Kara 2017, Küçük 2015, Rezvani 2017) or 12 weeks (Duff 2018, Kalron 2016, Marandi 2012) but the intensity varied from one session per week (Abasiyanik 2018, Freeman 2012, Guclu-Gunduz 2014, Kalron 2016) to two (Bulguroglu 2015, Duff 2018, Fleming 2019, Kara 2017, Küçük 2015) or three sessions per week (Eftekhari 2018, Marandi 2012, Rezvani 2017). Post-intervention follow-up occurred in one study (Freeman 2012).

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see 4.5.4.1) (and Appendix F2).

Results of the seven RCTs (Abasiyanik 2018, Bulguroglu 2015, Freeman 2012, Kalron 2016, Küçük 2015, Rezvani 2017, Sisi 2013) and one NRSI (Guclu-Gunduz 2014) that compared Pilates with an active comparator are presented in Appendix F2.

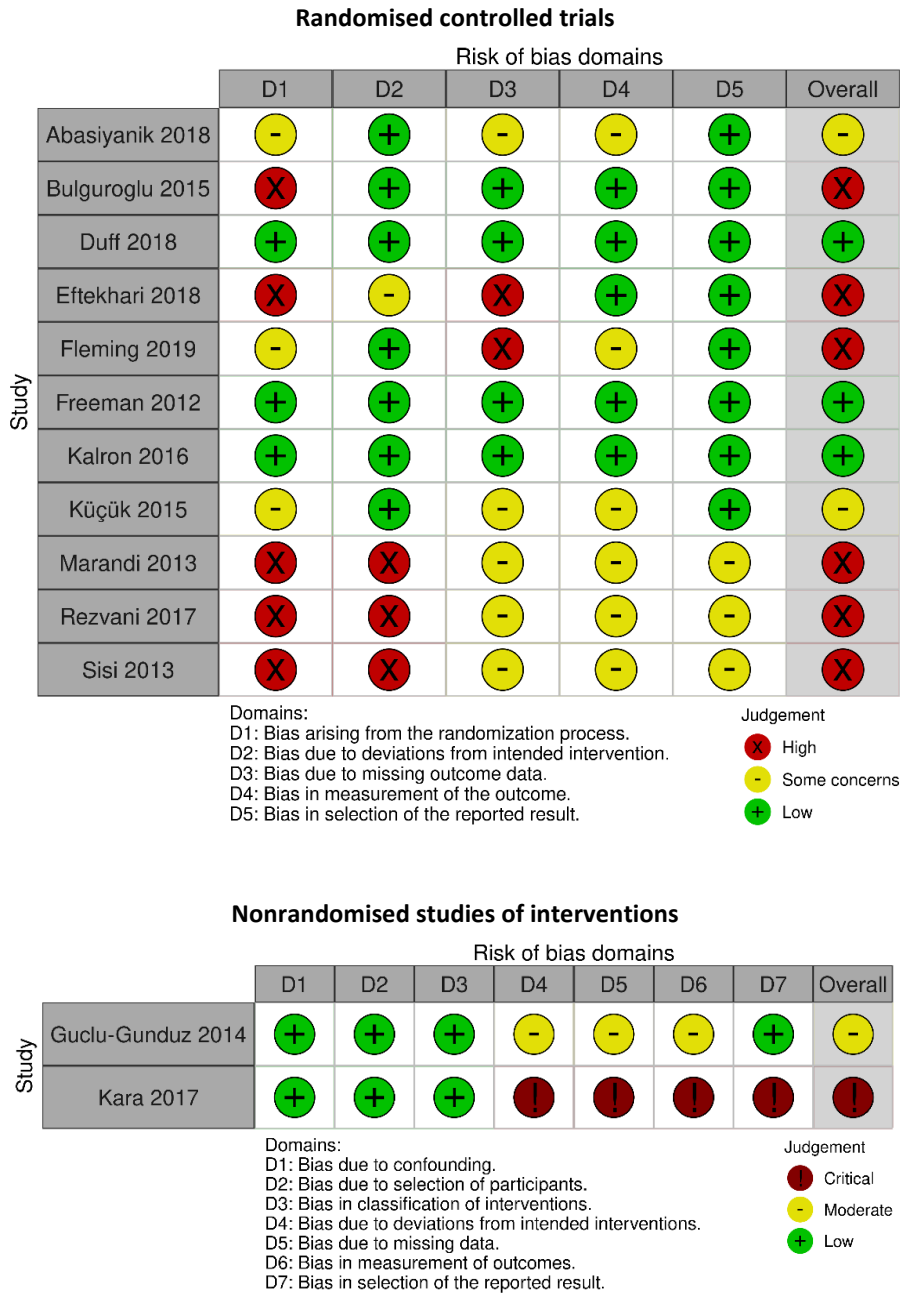
4.5.3 Risk of bias - per item

The risk of bias for each item in the included studies is summarised in Figure 15. Details are provided in Appendix D3.1.2.

Three RCTs (Duff 2018, Freeman 2012, Kalron 2016) were judged to be at overall low risk of bias.

The NRSI by Kara 2017 was judged to be at critical risk of bias due to deviations from the intended intervention and was therefore not included in the data analysis.

Figure 15 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Multiple sclerosis



4.5.4 Main comparison (vs control)

Four out of six eligible RCTs (Duff 2018, Eftekhari 2018, Fleming 2019, Sisi 2013) contributed data relevant to four outcomes. One study (Rezvani 2017) measured one outcome (functional mobility) but did not provide any data and one study (Marandi 2013) could have contributed data to these outcomes, but it was unclear if the outcomes were assessed in the study. There were eight additional studies awaiting classification or ongoing (total 203+ participants) that compared Pilates with no intervention in people with multiple sclerosis that could have contributed data to the critical or important outcomes but there was no information to make a judgment regarding the extent of missing data (see Appendix C6).

4.5.4.1 Summary of findings

Pilates compared to Control (no intervention, waitlist, usual care) for multiple sclerosis

Patient or population: Multiple sclerosis
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Quality of life (mental) assessed with: MSQoL-54 (higher is best) Scale from: 1 to 100 follow-up: 12 weeks	The mean quality of life (mental) was **75.5** points	MD **6.9 points lower** (18.52 lower to 4.72 higher)	-	30 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	The evidence suggests Pilates results in a slight decrease in mental wellbeing in people with multiple sclerosis.**
Quality of life (physical) assessed with: MSQoL-54 (higher is best) Scale from: 0 to 100 follow-up: 12 weeks	The mean quality of life (physical) was **61.7** points	MD **3.4 points lower** (16.69 lower to 9.89 higher)	-	30 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,d,e]	The evidence suggests that Pilates results in little to no difference in physical wellbeing in people with multiple sclerosis.**
Balance (static) assessed with: Berg Balance Scale (higher is best) Scale from: 0 to 56 follow-up: 8 weeks	An effect favouring Pilates reported in two studies. In one trial (MD –7.43; 95% CI –9.35, –5.51; $p < 0.0001$) baseline scores were skewed possibly overstating the effect. In one trial ($p = 0.003$) results were not able to be interpreted as the published data do not correlate with expected values.		-	55 (2 RCTs)	⊕◯◯◯ VERY LOW [e,f,g,h,i]	The evidence is very uncertain about the effect of Pilates on static balance in people with multiple sclerosis.***
Functional mobility assessed with: Timed Up and Go (s) (higher is worse) follow-up: range 8 weeks to 12 weeks	The mean functional mobility ranged from **8.9 to 12.23** seconds	MD **0.55 seconds faster** (2.11 faster to 1.01 slower)	-	80 (2 RCTs)	⊕⊕◯◯ LOW [a,c,e,g,h,j]	The evidence suggests that Pilates results in little to no difference in functional mobility in people with multiple sclerosis.****
Physical performance - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on physical performance in people with multiple sclerosis is unknown.
Fatigue assessed with: MFIS (higher is worse) follow-up: range 8 weeks to 12 weeks	-	SMD **1.13 SD lower^** (1.88 lower to 0.37 lower)	-	34 (2 RCTs)	⊕◯◯◯ VERY LOW [c,e,f,i,j]	The evidence is very uncertain about the effect of Pilates on fatigue in people with multiple sclerosis.
Disability - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on disability in people with multiple sclerosis is unknown.

Pilates compared to Control (no intervention, waitlist, usual care) for multiple sclerosis

Patient or population: Multiple sclerosis
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Social wellbeing - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on social wellbeing in people with multiple sclerosis is unknown.

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

** A change of ≥ 5 points considered to be clinically meaningful (125, 126).

*** The MCID for improvement in balance in people with multiple sclerosis is 3 points (127).

**** The MCID assumed between 2.9 to 3.5 seconds based on MCID in people with chronic stroke (82) or Parkinson's disease (128).

Effect estimates were considered on three levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).
^As a rule of thumb, an SMD of 0.2 is considered a small difference, 0.5 is medium, and 0.8 is large difference (59)
CI: Confidence interval; **MD:** Mean difference; **MFIS:** Modified fatigue impact scale; **SMD:** Standardised mean difference.

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. No serious risk of bias. Certainty of evidence not downgraded.
b. Single study. Heterogeneity not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. Evidence is directly generalisable to the Australian MS population with some caveats. The available evidence is in women with MS who have moderate disability (mean PDDS score of 2.1 to 2.3, range 0 to 6). Certainty of evidence not downgraded.
d. Single study (30 participants). Wide confidence intervals (upper and lower bounds overlap with an important (or no) difference). Certainty of evidence downgraded.
e. Publication bias suspected. Certainty of evidence downgraded.
f. Two studies (100% weight) at high risk of bias for the outcome. Certainty of evidence downgraded
g. No serious heterogeneity. Certainty of evidence not downgraded.
h. No serious indirectness. Evidence is directly generalisable to the Australian population with some caveats. The study is in men with MS with moderate disability (EDDS range 0 to 4). Certainty of evidence not downgraded.
i. No serious imprecision. Certainty of evidence not downgraded.
j. Wide confidence intervals (upper bounds overlaps with an important difference). Certainty of evidence downgraded.

4.5.4.2 Forest plots

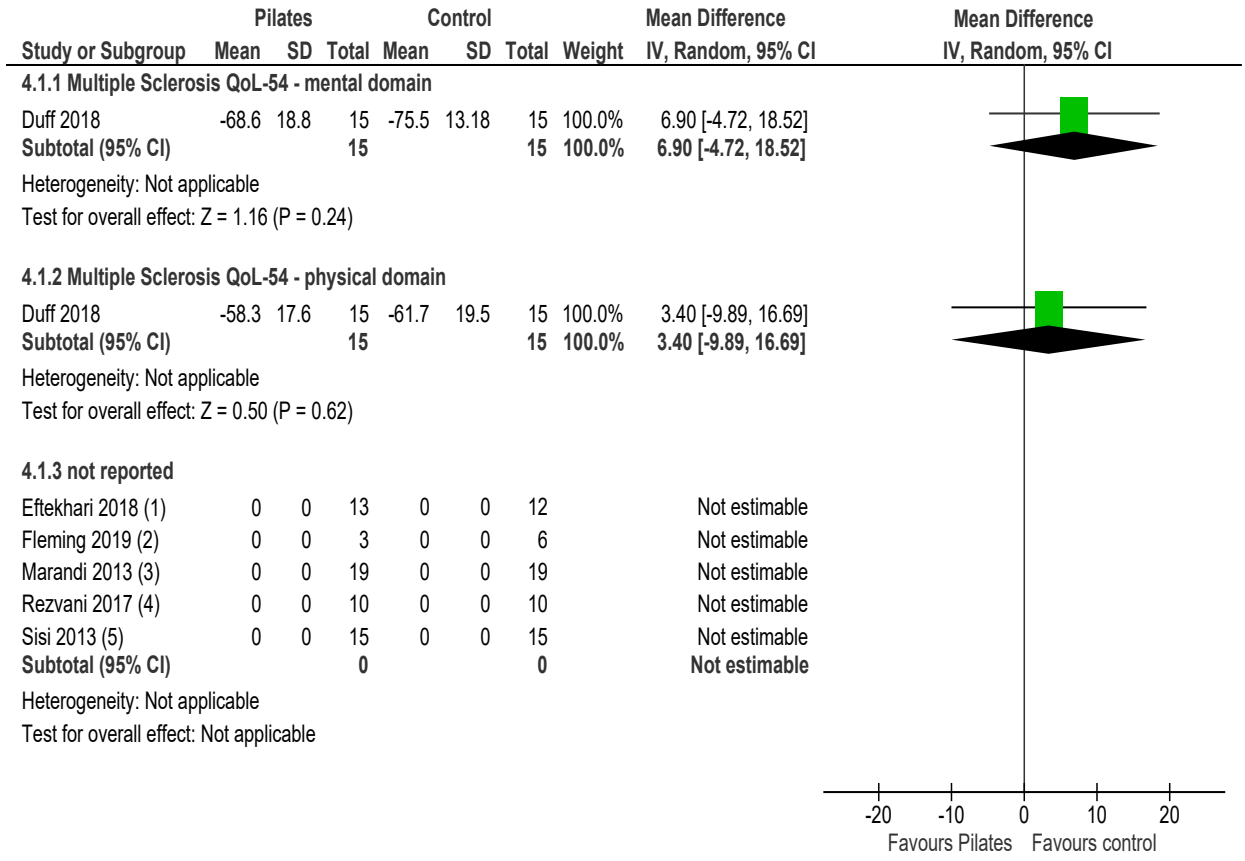
Outcome results related to quality of life for people with MS are presented in Figure 16.

Outcome results related to balance for people with MS are presented in Figure 17.

Outcome results related to functional mobility for people with MS are presented in Figure 18.

Outcome results related to fatigue in people with MS are presented in Figure 19.

Figure 16 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Multiple sclerosis – quality of life



Footnotes

(1) Study does not report this outcome, probably because the outcome was not assessed.

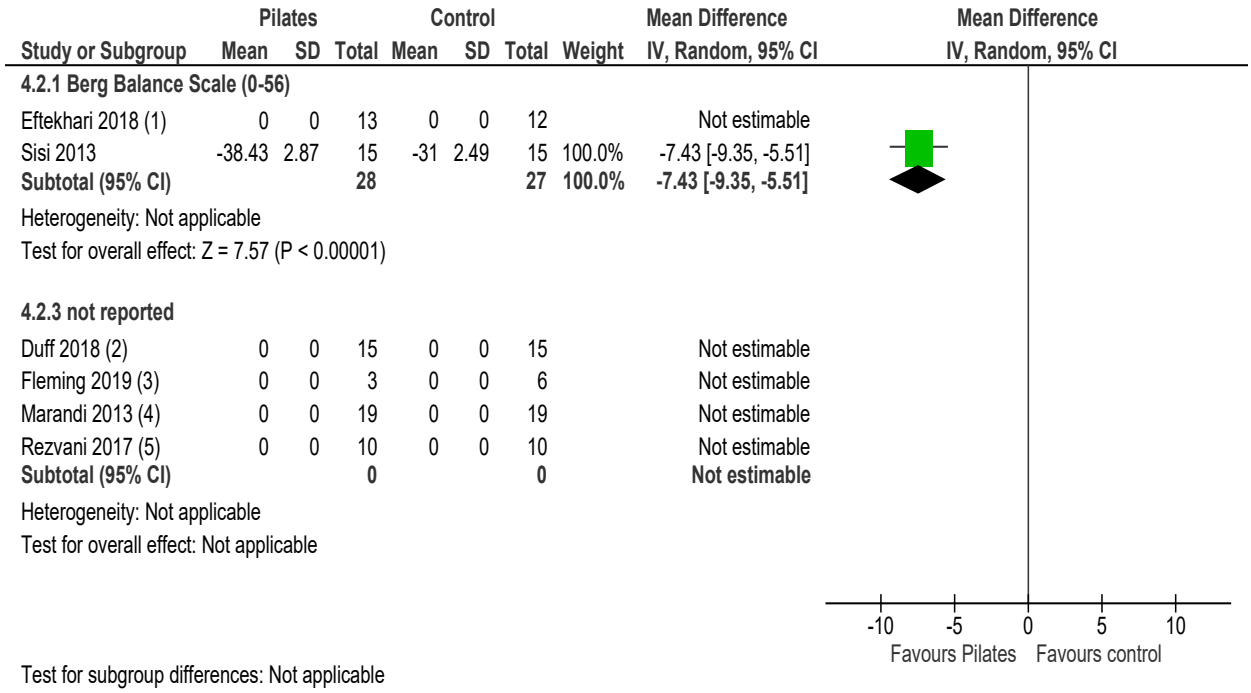
(2) Study does not report this outcome, probably because the outcome was not assessed.

(3) Study does not report this outcome, possibly because the P value, magnitude or direction of the results generated were considered...

(4) Study does not report this outcome, probably because the outcome was not assessed.

(5) Study does not report this outcome, probably because the outcome was not assessed.

Figure 17 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Multiple sclerosis – balance



Test for subgroup differences: Not applicable

Footnotes

(1) Authors report a significant effect (p=0.003) favouring Pilates, but total scores are not able to be interpreted.

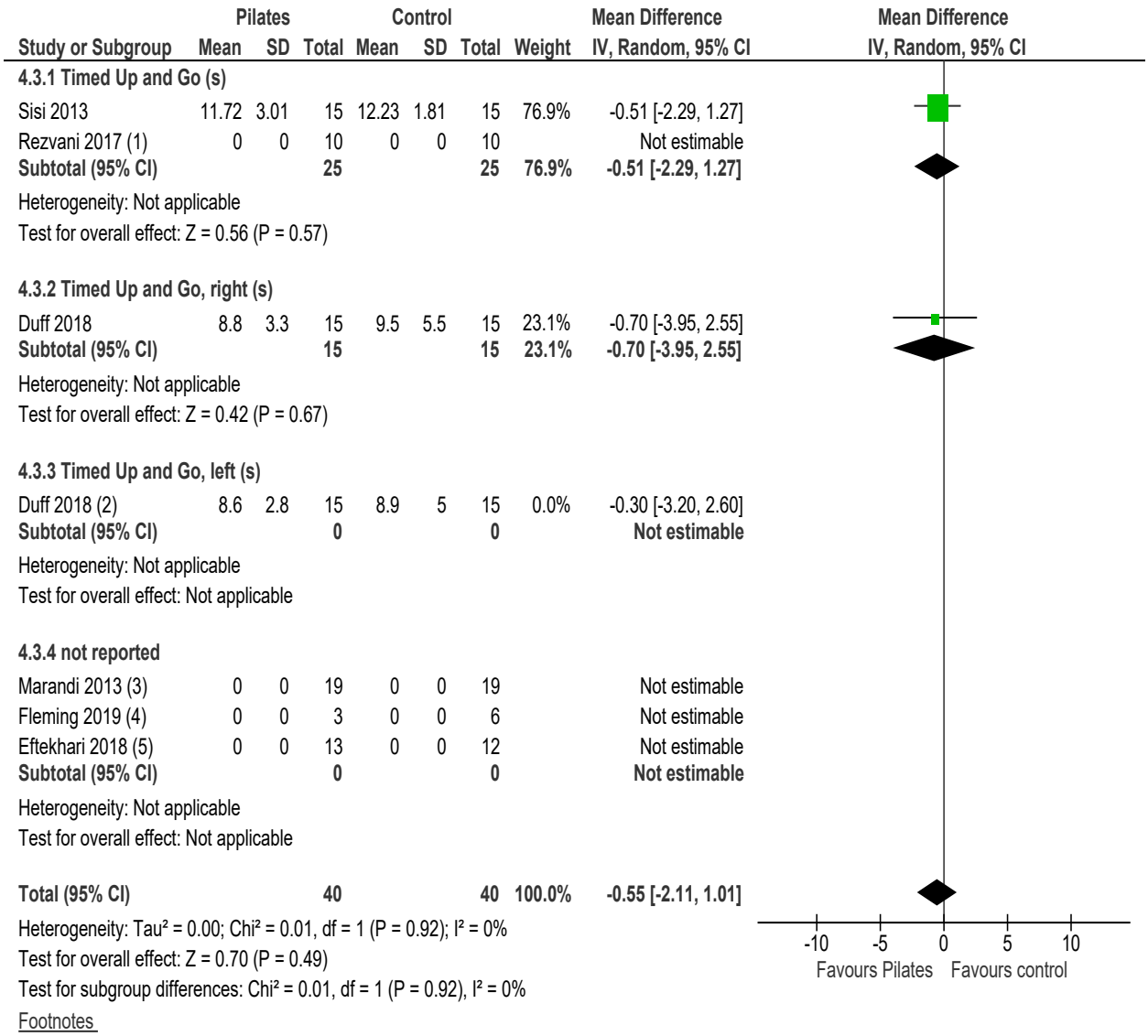
(2) Study does not report this outcome. Balance was measured with the Fullerton Advanced Balance Scale.

(3) Study does not report this outcome, probably because the outcome was not assessed.

(4) Study does not report this outcome. Balance measured using Six Spot Step test.

(5) Study does not report this outcome. Balance measured with the Sharpened Romberg test.

Figure 18 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Multiple sclerosis – functional mobility



Footnotes

(1) The results for this outcome measured but not reported or discussed by the authors.

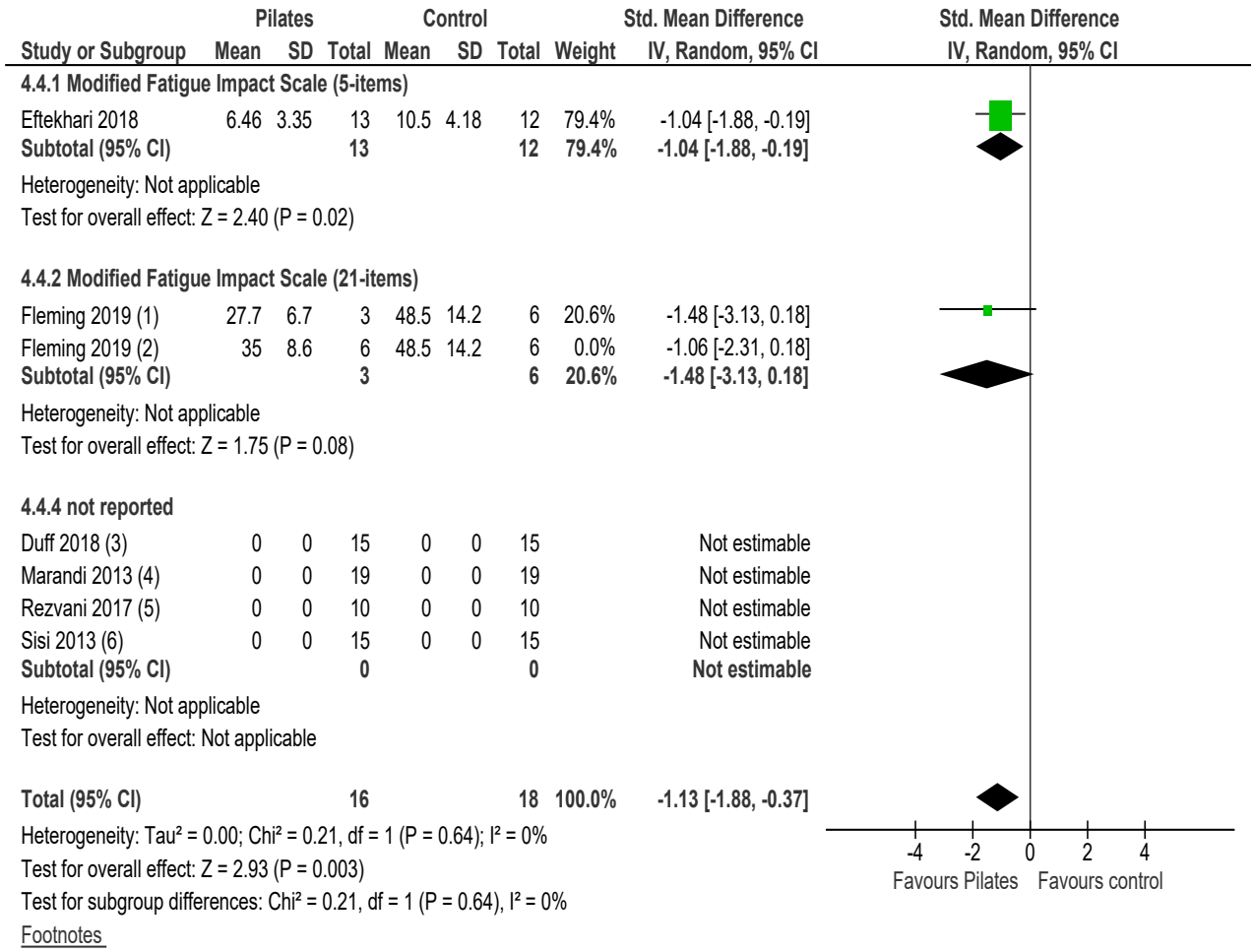
(2) Data not included in summary score to avoid double counting of the participants.

(3) Study does not report this outcome, and it is unclear if the outcome was assessed in the study.

(4) Study does not report this outcome, probably because the outcome was not assessed.

(5) Study does not report this outcome. Aerobic capacity/mobility assessed using the 6-minute and the 10M walk tests.

Figure 19 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Multiple sclerosis – fatigue



Footnotes

(1) Supervised Pilates group. Same control group as Fleming 2019 (2).

(2) Home-based Pilates (DVD-guided). Same control group as Fleming 2019 (1). Not included in the pooled result.

(3) Study does not report this outcome, probably because the outcome was not assessed.

(4) Study does not report this outcome, and it is unclear if the outcome was assessed in the study.

(5) Study does not report this outcome, probably because the outcome was not assessed.

(6) Study does not report this outcome, probably because the outcome was not assessed.

4.6 Myelopathy (HTLV-1 associated)

4.6.1 Description of the condition

Human T-lymphotropic virus 1 (HTLV-1) is a retrovirus that infects T cells. Most people infected with HTLV-1 do not experience any symptoms or ill effects however, approximately 1% of HTLV-1 infected people develop an immune-mediated chronic inflammatory disease known as HTLV-1 associated myelopathy or tropical spastic paraparesis (129). In Australia, HTLV-1 is of greatest concern for Aboriginal and Torres Strait Islander people, with some studies suggesting that HTLV-1 may be highly endemic in Aboriginal groups of inland Australian regions (130, 131). Information regarding the impact of HTLV-1 infection on mortality, illness, and health service utilisation among remote Aboriginal communities in central Australia is lacking (132).

HTLV-1 associated myelopathy is characterised by progressive spastic weakness of the lower limbs, lower back pain and urinary symptoms. There is also a strong association between HTLV-1 and diabetes, and an increased risk of urinary tract infection and chronic kidney disease (133). There are no specific treatments for this condition, with current management is based on the treatment of symptoms (129).

4.6.2 Description of studies

One citation (134) corresponding to one RCT (Borges 2014) was identified in the literature search. There were no ongoing studies and no studies awaiting classification. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D3.2.1.

Borges 2014 was carried out in a single centre setting in Brazil and included 22 adult participants who had been infected by HTLV-1 and reported low back pain. The participants had a mean age of 48.73 (SD 10.07) years with a mean BMI of 25.18 (SD4.07) and the majority were females (72.7%).

Borges 2014 was a randomised crossover trial that compared Pilates with no intervention for 15 weeks before the participants crossed over into the comparator group for 15 additional weeks. The Pilates exercise regime consisted of two one-hour sessions per week with the first session consisting of Reformer Pilates and the second session on the Cadillac and mat Pilates.

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see 4.6.4.1) (and Appendix F2).

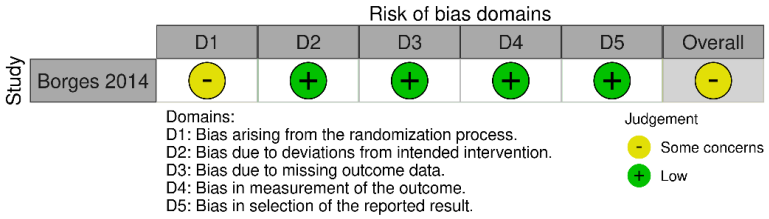
No studies were identified comparing Pilates with an active intervention in people with HTLV-1 associated myelopathy.

4.6.3 Risk of bias - per item

The risk of bias for each item in the included study is summarised in Figure 20. Details are provided in Appendix D3.2.2.

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

Figure 20 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Myelopathy (HTLV-1 associated)



4.6.4 Main comparison (vs control)

One RCT (Borges 2014) was eligible for this comparison and contributed data to six of seven outcomes. There were no additional studies identified (awaiting classification or ongoing) that could have contributed data to these outcomes (see Appendix C6).

4.6.4.1 Summary of findings

Pilates compared to Control (no intervention, waitlist, usual care) for myelopathy (HTLV-1 associated)

Patient or population: Myelopathy (HTLV-1 associated)
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with Control	Risk with Pilates				
Pain intensity assessed with: Visual analogue scale (higher is worse) Scale from: 0 to 10 follow-up: 15 weeks	The mean pain intensity was **7.5** cm	MD **4.05 cm lower** (6.16 lower to 1.94 lower)	-	22 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on pain intensity in people with HTLV-1 associated myelopathy.**
Physical function assessed with: SF-36 - physical function (higher is best) Scale from: 0 to 100 follow-up: 15 weeks	The mean physical function score was **32** points	MD **9.82 points higher** (5.14 lower to 24.78 higher)	-	22 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on physical function in people with HTLV-1 associated myelopathy.***
Role - physical assessed with: SF-36 Role-physical (higher is best) Scale from: 0 to 100 follow-up: 15 weeks	The mean role - physical score was **10** points	MD **62.73 points higher** (40.92 higher to 84.54 higher)	-	22 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on activities of daily living in people with HTLV-1 associated myelopathy.
Fatigue assessed with: SF-36 - vitality (higher is best) Scale from: 0 to 100 follow-up: 15 weeks	The mean vitality score was **28** points	MD **28.36 points higher** (8.96 higher to 47.76 higher)	-	22 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on fatigue in people with HTLV-1 associated myelopathy.

Pilates compared to Control (no intervention, waitlist, usual care) for myelopathy (HTLV-1 associated)

Patient or population: Myelopathy (HTLV-1 associated)
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statements
	Risk with Control	Risk with Pilates				
Mental health assessed with: SF-36 - Mental health (higher is best) Scale from: 0 to 100 follow-up: 15 weeks	The mean mental health score was **54** points	MD **15.82 points higher** (4.16 lower to 35.8 higher)	-	22 (1 RCT)	⨁◯◯◯ VERY LOW [a,b,c,d,e]	The evidence is very uncertain about the effect of Pilates on mental health in people with HTLV-1 associated myelopathy.
Social function assessed with: SF-36 - Role-social (higher is best) Scale from: 0 to 100 follow-up: 15 weeks	The mean social function score was **55** points	MD **14.32 points higher** (5.14 lower to 33.78 higher)	-	22 (1 RCT)	⨁◯◯◯ VERY LOW [a,b,c,d,e]	The evidence is very uncertain about the effect of Pilates on social functioning in people with HTLV-1 associated myelopathy.
Mental function assessed with: SF-36 - Role-emotional (higher is best) Scale from: 0 to 100 follow-up: 15 weeks	The mean role - emotional score was **70.51** points	MD **6.86 points lower** (34.97 lower to 21.25 higher)	-	22 (1 RCT)	⨁◯◯◯ VERY LOW [a,b,c,d,e]	The evidence is very uncertain about the effect of Pilates on emotional functioning in people with HTLV-1 associated myelopathy.

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

** MCID assumed around 2.0 cm based on MCID in people with chronic pain (135).

*** MCID in unknown.#

In the absence of an MCID, effect estimates were considered on three levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).

CI: Confidence interval; **MD:** Mean difference; **SF-36**: 36-item short-form

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. No serious risk of bias. Certainty of evidence not downgraded.
b. Single study. Imprecision not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is applicable to the Australian population with few caveats. The available evidence is in people with HTLV-1 associated myelopathy with low back pain and may not be applicable to the broader population with HTLV-1 associated myelopathy. Certainty of evidence not downgraded.
d. Small study (fewer than 25 participants). Wide confidence intervals (upper and lower bounds overlap with no important difference). Certainty of evidence downgraded.

e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.

4.6.4.2 Forest plots

Outcome results related to pain in people with HTLV-1 associated myelopathy are presented in Figure 21.

Outcome results related to health-related quality of life in people with HTLV-1 associated myelopathy are presented in Figure 22.

Figure 21 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Myelopathy, HTLV-1 associated – pain intensity

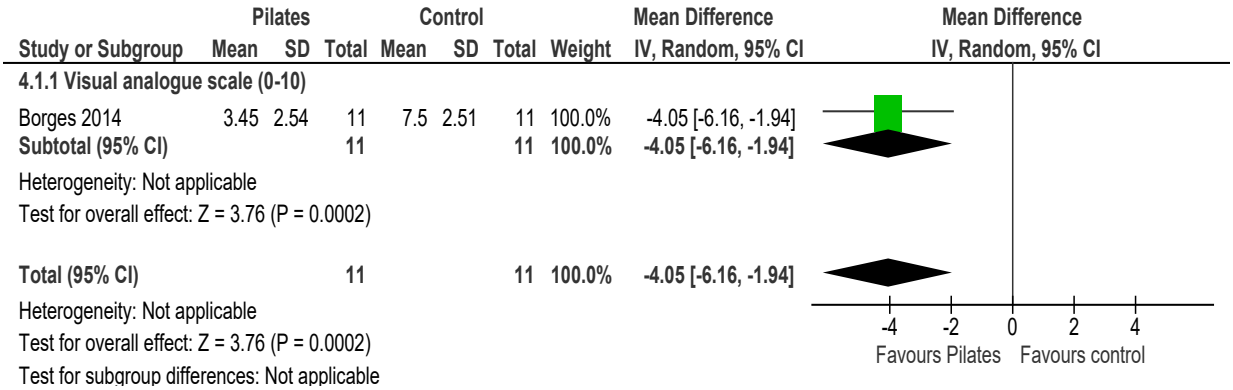
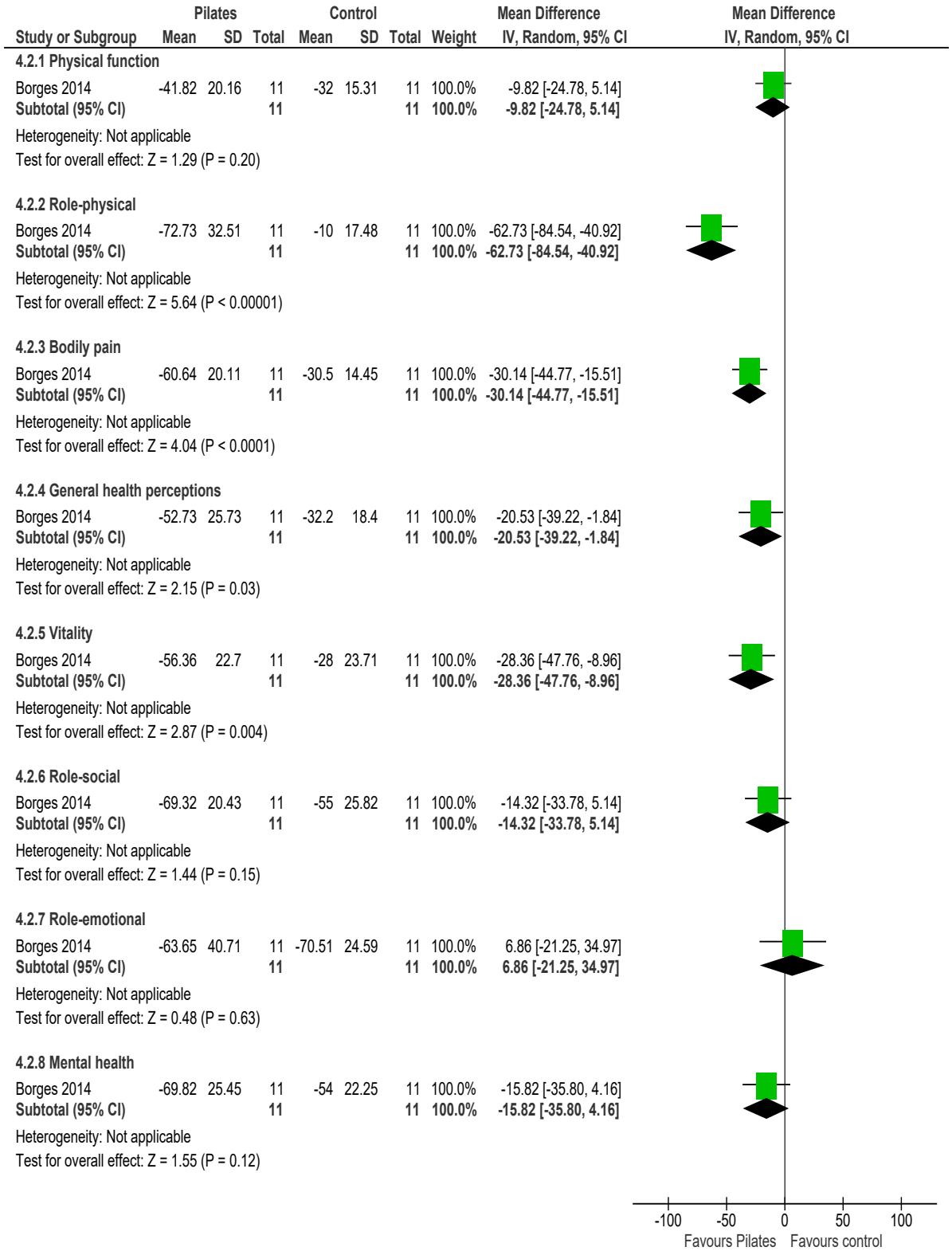


Figure 22 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Myelopathy, HTLV-1 associated – quality of life



4.7 Parkinson's disease

4.7.1 Description of the condition

Parkinson's disease (PD) is a complex neurodegenerative disease characterised by death of dopaminergic neurons. PD is a progressive disease with affected persons facing increasing levels of disability caused by motor (tremor, stiffness, slowness and imbalance) and nonmotor symptoms (sleep disorder, cognitive decline, depression, anxiety, constipation, bladder and bowel dysfunction, fatigue and trouble swallowing) affecting many organ systems (136). PD is one of the most common neurodegenerative diseases, with estimates ranging between 84 000 and 212 000 people living with PD in Australia (137, 138). Approximately 18% of affected persons are of working age, with the majority of people living with PD diagnosed after the age of 65. A dramatic rise in number of people living with PD is expected as the Australian population ages (137).

Traditionally, treatment of PD involves pharmacologic approaches (typically levodopa with or without other medications). However, even with optimal pharmacologic management, people living with PD experience progressive disability. For this reason, there has been growing support for the addition of nonpharmacologic approaches to PD management including exercise such as Pilates, and physical, occupational and speech therapies (136, 139).

4.7.2 Description of studies

One citation (140) corresponding to one RCT (Mollinedo-Cardalda 2018) was identified in the literature search. There are four ongoing studies and no studies awaiting classification. The Department's public call for evidence resulted in three additional citations (141-143) corresponding to two quasi RCTs (Daneshmandi 2017, Pandya 2017), and one study awaiting classification (Alavi 2018) (141) that was published in a language other than English . An overview of the PICO criteria of included studies is provided in Appendix D3.3.1.

All three studies were carried out in single centre settings in Iran (Daneshmandi 2017), Spain (Mollinedo-Cardalda 2018) and India (Pandya 2017) and included participant over the age of 50 years diagnosed with PD. Participants in Daneshmandi 2017 and Mollinedo-Cardala 2011 had no major motor disability (i.e., ability to walk and stand independently) while Pandya 2017 enrolled participants with a prior history of one or more falls in the preceding years. Sample sizes ranged from 26 to 32 participants (total 88 participant), with more women than men (65.4%) enrolled in Mollinedo-Cardalda 2018.

Two studies (Daneshmandi 2017, Mollinedo-Cardala 2011) compared mat Pilates using TheraBand with active controls (walking and aerobic exercise, respectively), while one study (Pandya 2017) assessed the effect of Pilates (with TheraBand) as an adjunct to conventional balance training. In all studies, the Pilates session were typically one hour in duration, with the program intensity and duration being three times per week for 7 weeks (Pandya 2017) or 8 weeks (Daneshmandi 2017) or two sessions per week for 12 weeks (Mollinedo-Cardalda 2018). Post-intervention follow-up after 4 weeks occurred in one study (Mollinedo-Cardala 2018).

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see 4.7.4.1) (and Appendix F2).

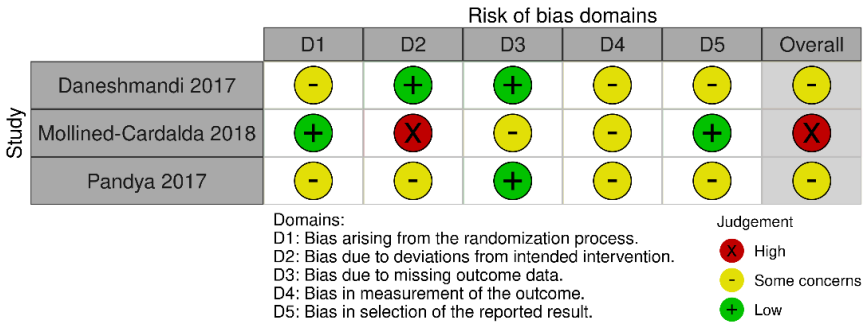
Results of the two studies (Daneshmandi 2017, Mollinedo-Cardala 2011) that compared Pilates with an active comparator are presented in Appendix F2.

4.7.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 23. Details are provided in Appendix D3.3.2.

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

Figure 23 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Parkinson's disease



4.7.4 Main comparison (vs control)

One study (Pandya 2017) was eligible for this comparison and contributed data relevant to two outcomes. There was one additional study published in a language other than in English that compared Pilates with no intervention in Parkinson's disease (total 106 participants) that could have contributed data to one outcome (balance) (see Appendix C6).

4.7.4.1 Summary of findings

Pilates compared to Control (no intervention, waitlist, usual care) for Parkinson's disease

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

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with Control	Risk with Pilates				
Quality of life, disease specific - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on quality of life in people with Parkinson's disease is unknown.
Motor function - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on motor function in people with Parkinson's disease is unknown.
Functional mobility assessed with: Timed Up and Go (higher is worse) follow-up: 7 weeks	The mean functional mobility was **26.53** seconds	MD **8.53 seconds faster** (13.37 faster to 3.69 faster)	-	30 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on functional mobility in people with Parkinson's disease.**
Gait - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on gait in people with Parkinson's disease is unknown.

Pilates compared to Control (no intervention, waitlist, usual care) for Parkinson's disease

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

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with Control	Risk with Pilates				
Disability - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on disability in people with Parkinson's disease is unknown.
Balance assessed with: Berg Balance Test (higher is best) Scale from: 0 to 56 follow-up: 7 weeks	The mean balance score was **37.066** points	MD **5.07 points higher** (1.24 higher to 8.9 higher)	-	30 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on static balance in people with Parkinson's disease.***
Falls - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on incidence of falls in people with Parkinson's disease is unknown.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
** The MCID for improvement in functional mobility is 3.5 seconds (128)
*** MCID for improvement in balance stability is 5 points, but a total score of less than 45 indicates people in the Pilates group continue to be at greater risk of falling.

Effect estimates were considered on three levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).
CI: Confidence interval; **MD:** Mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. No serious bias. Certainty of evidence not downgraded.
b. Single study. Heterogeneity not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is applicable to the Australian population with some caveats. The study is in people aged younger than 65 with Parkinson's disease and a history of falls/near falls. In addition, Pilates was delivered as an adjunct to conventional balance training, which is not reflective of usual practise in Australia. The evidence may not be applicable to older people with Parkinson's disease or those with no falls history or gait impairment.
d. Serious imprecision. Small study (30 participants). Wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.

4.7.4.2 Forest plots

Outcome results related to functional mobility for people with PD are presented in Figure 24.

Outcome results related to balance stability for people with PD are presented in Figure 25.

Figure 24 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Parkinson's disease – Functional mobility

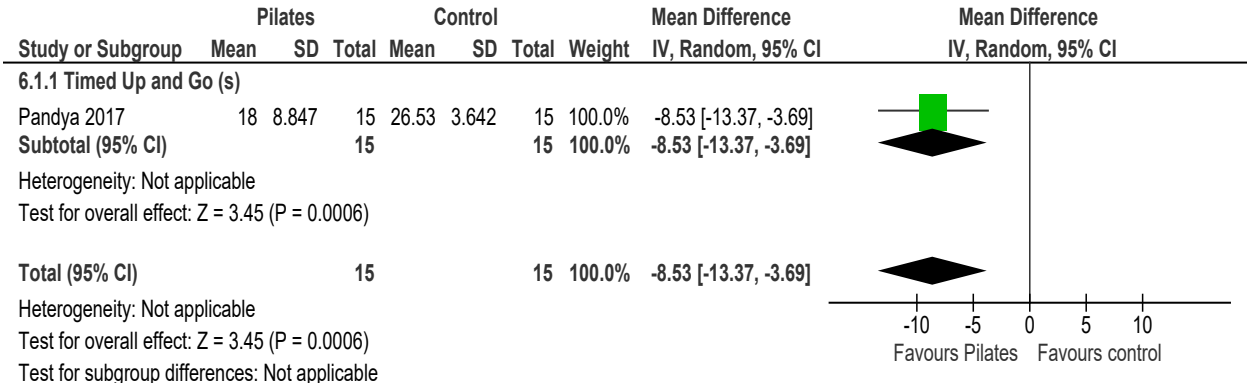
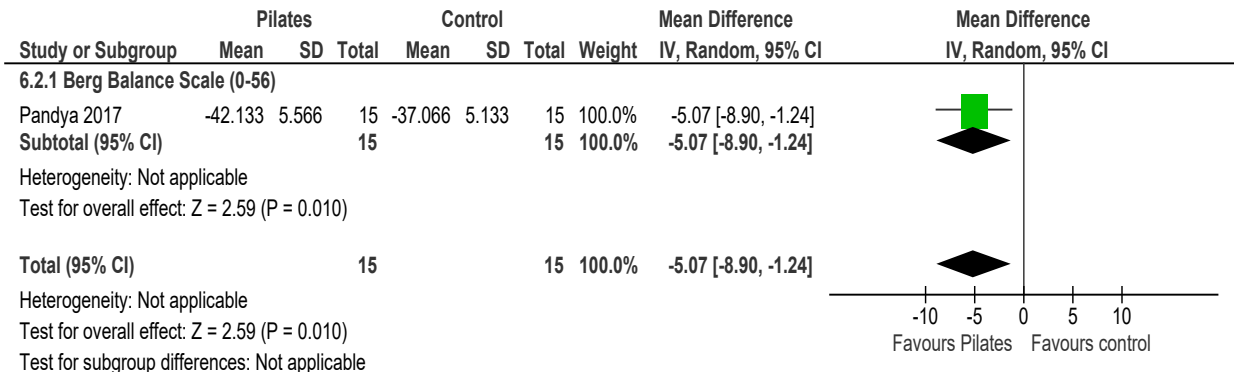


Figure 25 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Parkinson's disease – Balance



4.8 Rehabilitation after stroke

4.8.1 Description of the condition

Stroke occurs when blood supply to the brain either suddenly becomes blocked (ischaemic stroke) or a blood vessel ruptures and begins to bleed (haemorrhagic stroke) (144). In Australia, there were more than 100 stroke events every day in 2017 and stroke accounted for 5.3% of all deaths in 2018 (144). Every stroke is different depending on where in the brain stroke occurs and the severity. As a result of stroke, part of the brain may die which can lead to the impairment of various function, including partial paralysis and difficulties with speech, swallowing, vision and thinking (145).

People with chronic stroke[c] are hospitalised during the acute or subacute phase and go on to receive rehabilitation treatment in the months following (3). Australian Clinical Guidelines for Stroke Management (146) suggest holistic rehabilitation beginning the first day after stroke with the aim of maximising the participation of the person with stroke in the community. An important part of the rehabilitation process is improving muscle strength and coordination. The Pilates method is thought to be effective for the recovery of physical functions including balance, strength and flexibility in various age groups (147). The method can be adapted to the persons abilities and needs and has been suggested to be a valuable part of rehabilitation for persons following stroke (147).

4.8.2 Description of studies

Four citations (147-150) corresponding to one RCT (Lim 2017), two quasi RCTs (Lim 2016, Roh 2016) and one NRSI (Yun 2017) were identified in the literature search. There was one ongoing study, and one study awaiting classification (Abedini 2015)(151) that was published in a language other than English and identified through the Department's public call for evidence. One further study (Sathe 2018) (152) was also identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D3.4.1.

Five studies were conducted in local rehabilitation centres in Korea (Lim 2016, Lim 2017, Roh 2016, Yun 2017) or India (Sathe 2018). Sample sizes ranged between 10 and 40 participants (total 109). All five studies included participants from 6 months to two years post stroke who were medically stable and able to walk independently without an assistive device. There were no limitations on age or gender specified in any of the studies.

Two studies (Lim 2016, Roh 2016) compared mat-based Pilates exercises to no intervention. Two studies compared Pilates delivered as an adjunct to conventional balance exercises (Sathe 2018) or conventional stroke rehabilitation (Lim 2017) and one study (Yun 2017) compared Pilates with occupational therapy sessions.

In three studies (Lim 2016, Lim 2017, Roh 2016) Pilates exercises were delivered three times a week for eight weeks, with the treatment duration being 60 minutes each session. In Lin 2017, the conventional stroke rehabilitation sessions were carried out 5 days a week for 30 minutes over eight weeks. The duration of Pilates exercises was not specified by Sathe 2018 however, they were performed three times a week for up to six weeks and lasted as long as needed to complete the program. Details of duration and frequency of conventional balance therapy sessions were not specified. The Pilates sessions in the study by Yun 2017 were 60 minutes twice a week for 12 weeks, with occupational therapy sessions being 50 minutes three times a week.

[c] Usually defined as at least six months after the initial stroke incident.

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see 4.8.4.1) (and Appendix F2). Two RCTs (Lim 2017, Roh 2016) contributed data relevant to one outcome. The other two studies (Lim 2016, Sathe 2018) did not report any outcomes measures considered to be critical or important for decision making.

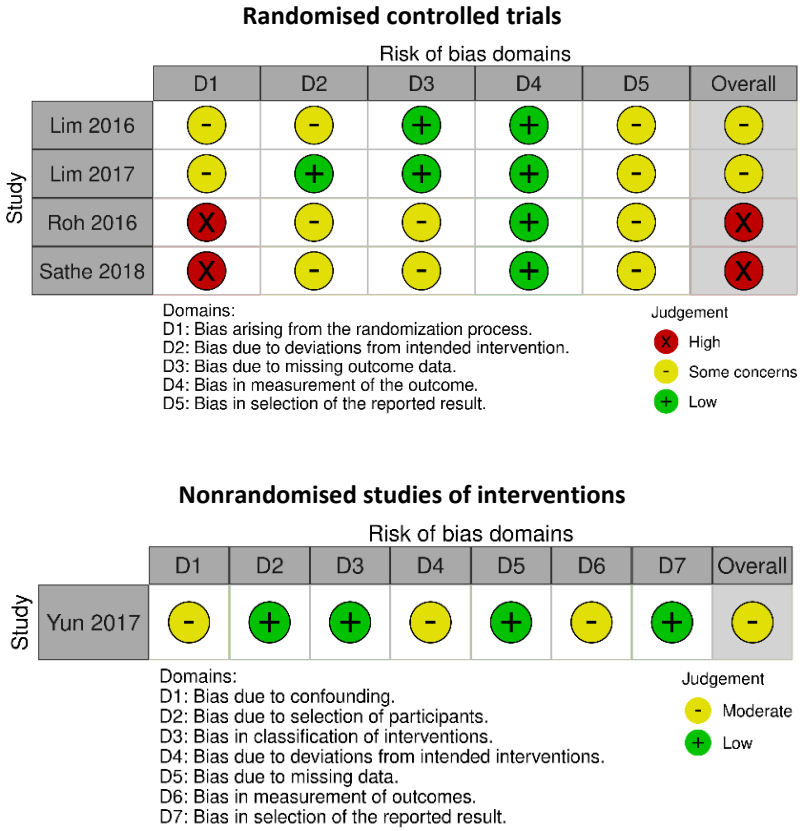
Results of the study (Yun 2017) that examined Pilates versus an active comparator are presented in Appendix F2.

4.8.3 Risk of bias – per item

The risk of bias for each item in the included studies is summarised in Figure 26. Details are provided in Appendix D3.4.2.

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

Figure 26 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Rehabilitation after stroke



4.8.4 Main comparison (vs control)

Four RCTs were eligible for this comparison. Two RCTs (Lim 2017, Roh 2016) contributed data relevant to one outcome. The other two RCTs (Lim 2016 Sathe 2018) did not measure or assess any outcomes considered critical or important to this review.

There was one additional study published in a language other than English (awaiting classification) that compared Pilates with no intervention in people with chronic stroke (6 participants) that could have contributed data to one outcome (balance) (see Appendix C6).

4.8.4.1 Summary of findings

Pilates compared to Control (no intervention, waitlist, usual care) for rehabilitation after stroke

Patient or population: Rehabilitation after stroke
Setting: Rehabilitation/Occupational therapy centre
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Disability – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on disability in people recovering from stroke is unknown.
Quality of life, global – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on quality of life in people recovering from stroke is unknown.
Quality of life, disease specific – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on quality of life in people recovering from stroke is unknown.
Activities of daily living – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on activities of daily living in people recovering from stroke is unknown.
Functional mobility assessed with: Gait speed (higher is better) follow-up: 8 weeks	The mean functional mobility was **21.54** cm/s	MD **9.94 cm/s faster** (18.16 faster to 1.72 faster)	-	20 (1 RCT)	⨁◯◯◯ VERY LOW [a,b,c,d,e]	The evidence is very uncertain about the effect of Pilates on gait speed in people recovering from stroke.**
Functional mobility assessed with: Timed Up and Go (higher is worse) follow-up: 8 weeks	The mean functional mobility was **21.7** seconds	MD **2.5 seconds faster** (19.43 faster to 14.43 slower)	-	20 (1 RCT)	⨁⨁◯◯ LOW [b,d,e,f]	The evidence suggests that Pilates results in little to no difference in functional mobility in people recovering from stroke.***
Balance – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on balance in people recovering from stroke is unknown.
Cardiovascular disease risk – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on cardiovascular disease risk in people recovering from stroke is unknown.

Pilates compared to Control (no intervention, waitlist, usual care) for rehabilitation after stroke

Patient or population: Rehabilitation after stroke
Setting: Rehabilitation/Occupational therapy centre
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual care)

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

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
** The MCID in people with stroke is 10 cm/s (153).
*** The MCID in people with stroke is 2.9 seconds (154).

Effect estimates were considered on three levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).
CI: Confidence interval; **MD:** Mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

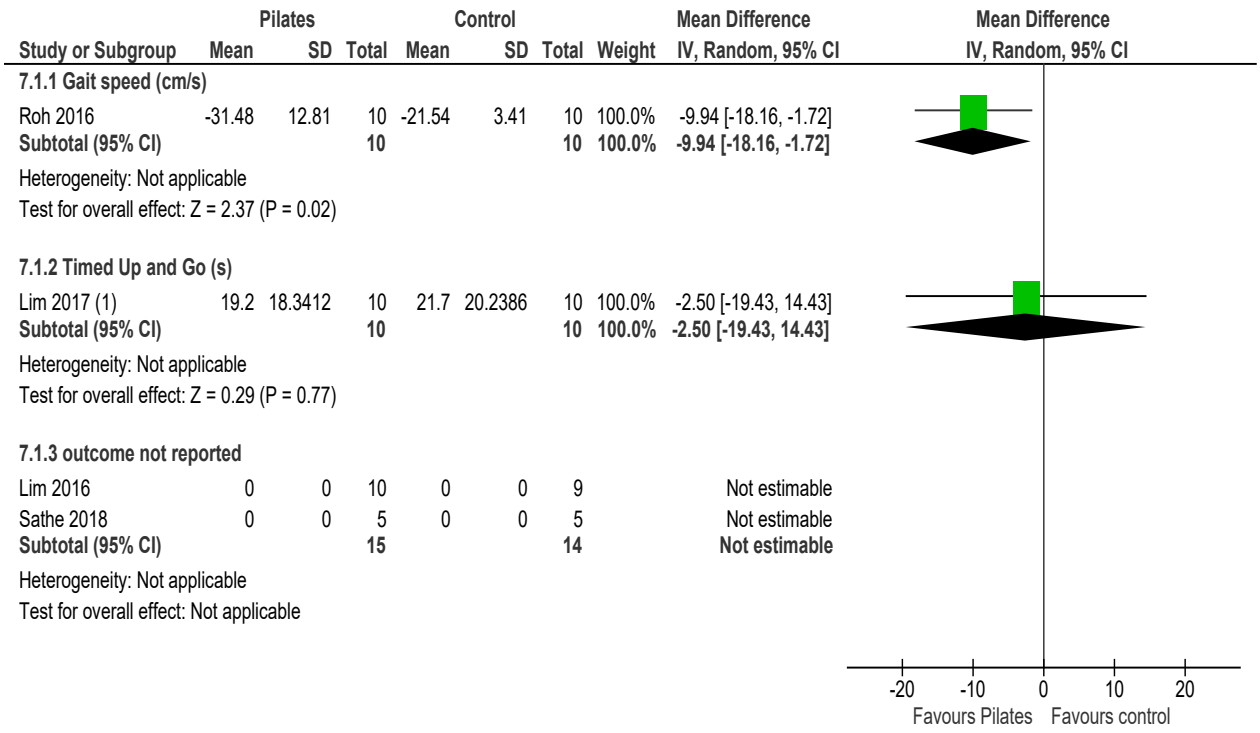
Explanations

a. One study (100% weight) at high risk of bias for the outcome. Certainty of evidence downgraded.
b. Single study. Heterogeneity not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The available evidence is directly generalisable to the Australian population with some caveats. The evidence is in people with unilateral hemiparetic stroke who are ambulant and medically stable. Certainty of evidence not downgraded.
d. Serious imprecision. Small study (fewer than 25 participants). Wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.
f. No serious indirectness. The evidence is generalisable to the Australian population with some caveats. The study is in people 2-years post stroke who are medically stable and ambulant. All participants also received stroke rehabilitation therapy (consisting of joint mobility, muscle strengthening and walking exercise). Certainty of evidence not downgraded.

4.8.4.2 Forest plots

Outcome results related to functional mobility for people recovering after stroke are presented in Figure 27.

Figure 27 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Rehabilitation after stroke – Functional mobility



Footnotes

(1) SD calculated from reported standard error

4.9 Hypertensive heart disease

4.9.1 Description of the condition

Elevated blood pressure is a significant contributor to global burden of cardiovascular disease and mortality (155). Approximately 1 in 3 Australians over 18 years have high blood pressure, 23% of which are uncontrolled (BP remains above 140/90 mmHg whether or not a person is taking medication) (156). As an independent risk factor for stroke, heart failure, chronic kidney disease and premature death, uncontrolled hypertension poses a significant burden to Australia's health care system (157). Structural changes to the left atrial, responsible for regulating left ventricular functioning during systole and diastole, can occur as an adaptive process in response to prolonged elevated blood pressure. This may lead to reduced functioning and myocardium fibrosis (158).

Different categories and grades are used to assist in the diagnosis and management of BP (157). In adults, normal BP is defined as systolic 120-129 mmHg and diastolic 80-84 mmHg, whereas an optimal blood pressure is 120/80 mmHg. High to normal BP is classified as systolic 130-139 mmHg and diastolic 85-89 mmHg. Hypertension is classified into three grades as follows:

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

Appropriately controlling, managing and reducing hypertension is imperative to reducing CVD burden. Studies have demonstrated the benefits of regular exercise on cardiovascular health, with regular physical activities and progressive resistance exercises demonstrated to reduce blood pressure (159, 160) and improve cardiovascular function in those with cardiovascular disease (e.g. heart failure) (160, 161). However, there is insufficient evidence regarding the frequency, intensity, time, and duration of physical activity to influence the associations between physical activity and BP (160). The National Heart Foundation of Australia Guidelines recommend regular physical exercise, including muscle strengthening activities at least two days a week to aid in the management and reduction of blood pressure (157).

4.9.2 Description of studies

One citation (162) corresponding to one NRSI (Martins-Meneses 2015) was identified in the literature. There were two ongoing studies and one study awaiting classification (Eghbali 2017) (163) that was published in a language other than English. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D4.1.1.

Martins-Meneses 2015 was carried out in a community dwelling in Brazil and included 44 women aged 30-59 years with hypertension who use antihypertensive medication and had not been physically active in the past 6 months. The mat Pilates sessions were delivered twice per week and consisted of about 12 exercises performed to sounds of calm and relaxing music over 60 minutes. Participants in the control group continued their usual daily activities and were able to participate in the Pilates exercise training program after completion of the 16-week trial. Participants in both groups continued with their antihypertensive medication.

The study reported data relevant to one outcome (cardiovascular disease-risk) but was judged to be at critical risk of bias due to substantial attrition (more than 35% missing data) and was therefore not considered in the reporting of results, evidence synthesis or conclusions.

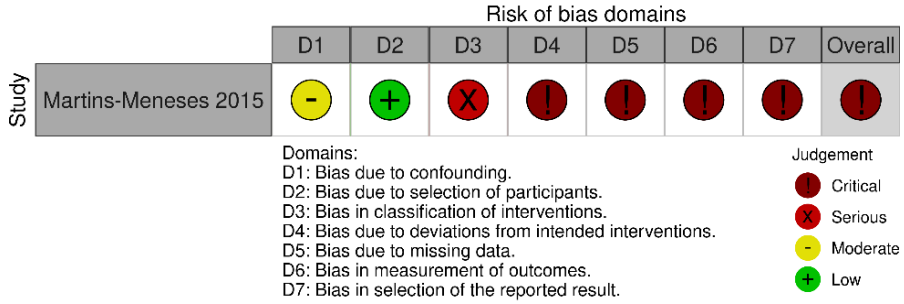
4.9.3 Risk of bias – per item

The risk of bias for each item in the included studies is summarised in Figure 28. Details are provided in Appendix D4.1.2.

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

The NRSI by Martins-Meneses 2015 was judged to be at critical risk of bias due high dropout and nonadherence to assigned interventions (total 37%) and no adjustment for missing data. Participants who did not attend more than 75% of sessions were not included in the data analysis, which would likely seriously overstate the treatment effect. Notably, participants who had systolic BP above 160 mm Hg and/or diastolic BP above 105 mm Hg before a Pilates session, were exempted from the session, increasing the likelihood that nonadherence was linked to health state.

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



4.9.4 Main comparison (vs control)

4.9.4.1 Summary of findings

There were no studies found for outcomes selected *a priori* as critical or important, thus the effect of Pilates compared with control on these outcomes in people with hypertension is unknown.

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

- quality of life
- cardiovascular disease risk
- disease progression
- fitness/exercise capacity
- physical performance
- body composition

4.10 Osteoarthritis

4.10.1 Description of the condition

Osteoarthritis (OA) is a chronic disease that primarily impacts the articular cartilage and the subchondral bone of a synovial joint, which eventually results in joint failure (164). Individuals with OA experience joint pain, stiffness and swelling that mainly affects the hands, knees and hips (165). As OA progresses it can impact a person's quality of life as it becomes difficult to perform everyday tasks (165).

OA is the most common form of arthritis in Australia (165, 166). In 2007 to 2008, it was estimated 2.2 million (9.3%) Australians were living with OA (166). There is no specific cause of OA, however, several factors are associated with the onset and progression of disease, including physical wear and tear of a joint over time, being female, overweight or obese and older age. Although younger people can be affected by OA, it most frequently occurs in people over 55 years of age with just over one-third of all adults aged 75 years and over experiencing this condition (165, 166).

There is no cure for OA (166) with recommended treatments focused on relieving pain and improving joint function. International guidelines (167-169) recommend routine aerobic exercise and/or physiotherapy to assist in improving pain and maintain and strengthen joint function and range of motion. Australian guidelines (165) strongly recommend regular land based exercise such as muscle strengthening exercises, Pilates, walking and Tai Chi.

4.10.2 Description of studies

One citation (170) corresponding to one quasi RCT (Mazloum 2018) was identified in the literature search. No additional studies were identified in the Department's public call for evidence. There were two ongoing studies (IRCT201604041552N6, NCT04183933) and two studies awaiting classification (Baltaci 2010, Kisacik 2015) (171, 172), one of which was published in a language other than English. An overview of the PICO criteria of included studies is provided in Appendix D5.1.1.

One study (Mazloum 2018), conducted in Iran, was carried in a university setting. The study enrolled 41 participants aged 40 years or older with OA of the knee, presenting with pain on most days of the previous month. Participants in Mazloum 2018 were middle-aged (mean 55 years) and predominantly male (69%).

The effectiveness of Pilates exercise compared to no intervention was examined in one study (Mazloum 2018). The Pilates sessions were typically one hour in duration, and the treatment program was delivered three times per week for 8 weeks. Participants in the control group were allowed to maintain their usual activities and were offered the therapeutic exercises at the end of the trial. One study (Mazloum 2018) also included an active comparator group, described as conventional therapeutic exercise, with sessions starting at 30 minutes duration, increasing to 60 minutes based on the participants ability to perform the exercises.

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see 4.10.4.1) (and Appendix F2).

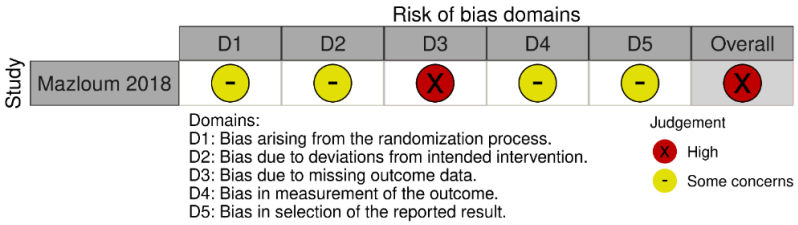
Results of the study (Mazloum 2018) comparing Pilates with an active comparator are presented in Appendix F2.

4.10.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 29. Details are provided in Appendix D5.1.2.

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

Figure 29 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Osteoarthritis



4.10.4 Main comparison (vs control)

One study (Mazloum 2018) comparing Pilates with no intervention in people with osteoarthritis of the knee was eligible for this comparison and contributed data to two of the seven outcomes. There was one additional study published in a language other than English (awaiting classification) that compared Pilates with no intervention in people with knee osteoarthritis (total participants unknown) that could have contributed data to these outcomes but there was no information to make a judgment regarding the extent of missing data (see Appendix C6).

4.10.4.1 Summary of findings

Pilates compared to Control (no intervention, waitlist, usual care) for osteoarthritis

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

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Pain - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on pain in people with osteoarthritis is unknown.
Quality of life - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on quality of life in people with osteoarthritis is unknown.
Global function/disability assessed with: Lequesne index (higher is worse) follow-up: 8 weeks	The mean global function/ disability was **10.5** points	MD **2.1 points lower** (3.36 lower to 0.84 lower)	-	33 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on global function/disability in people with osteoarthritis.**
Physical performance assessed with: Time to complete activities[f] (faster is better) follow-up: 8 weeks	The mean physical performance was **58.5** seconds	MD **9.6 seconds faster** (13.5 faster to 5.7 faster)	-	33 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on physical performance in people with osteoarthritis.***

Pilates compared to Control (no intervention, waitlist, usual care) for osteoarthritis

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

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Proprioception - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on proprioception in people with osteoarthritis is unknown.
Work status - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on work status in people with osteoarthritis is unknown.
Anxiety - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on anxiety in people with osteoarthritis is unknown.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
** The MCID of the Lequesne Index in people with knee osteoarthritis is 2.75 (173). A score higher than eight in the Pilates group indicates people continue to have high pain and disability
*** MCID in unknown.^

Effect estimates were considered on three levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).
^ In the absence of an MCID, effect estimates were considered based on the SMD: where an SMD of 0.2 represents a small difference, 0.5 is moderate, and 0.8 is a large difference.

CI: Confidence interval; **MD:** Mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. One study (100% weight) at high risk of bias for the outcome. Certainty of evidence downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is directly generalisable to the Australian population with some caveats. The study is in mostly male participants with knee osteoarthritis, which may not be generalisable to those with other osteoarthritis (e.g., upper extremity). Certainty of evidence not downgraded.
d. Single study (33 participants). Wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.
f. Activities include walking for 15m, standing up from a chair and walking 15m, and going up and down 11 stairs.

4.10.4.2 Forest plots

Outcome results related to physical function/disability for people with osteoarthritis are presented in Figure 30.

Outcome results related to physical performance for people with osteoarthritis are presented in Figure 31.

Figure 30 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): knee osteoarthritis – global physical functioning

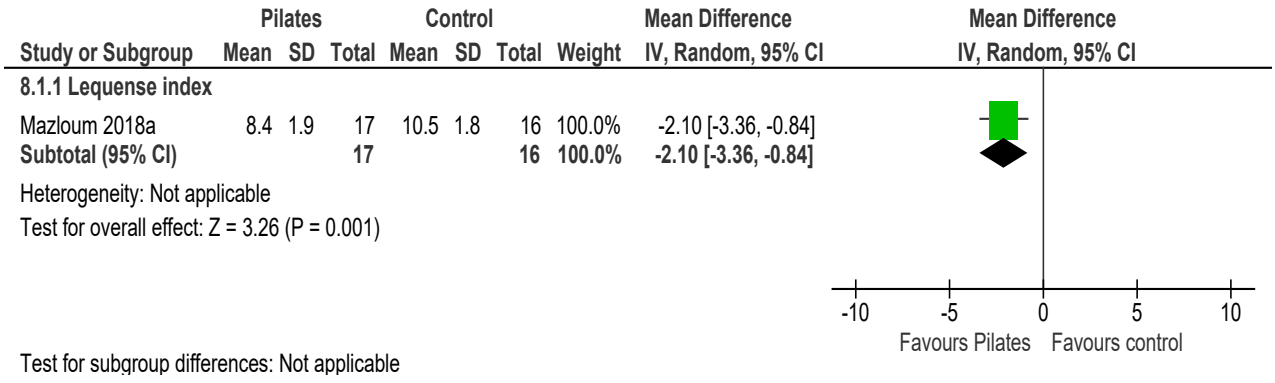
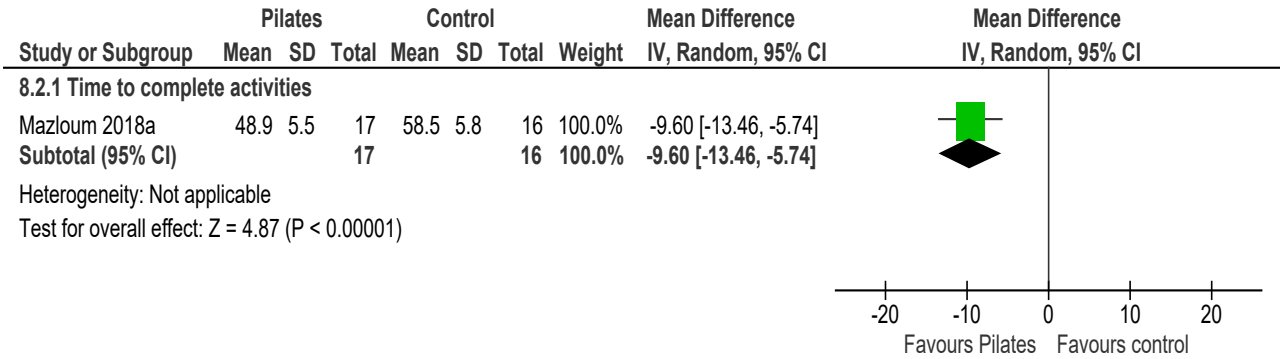


Figure 31 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): knee osteoarthritis - physical performance



4.11 Postviral arthropathies

4.11.1 Description of the condition

Viral infections can be associated with an acute form of arthritis that occur due to direct infection of the joint (virus is present) or through an indirect process (virus is absent with or without the presence of antigens) (174). Viruses that are typically associated with an acute arthritis include parvovirus B-19, hepatitis B, hepatitis C, Epstein-Barr virus, HIV, the mosquito-borne alphaviruses such chikungunya virus, Ross River virus, Barmah Forest virus, and the mosquito-borne flaviviruses such as Dengue and Zika virus (175). In Australia, Ross River virus is of the main concern with, around 8000 cases reported annually (176) but in recent times the chikungunya virus has become an emerging travel-related health threat that is found in Africa, South-East Asia and the Western Pacific (175, 177-180).

Many viral arthralgias are self-limiting or can be resolved through treatment of the underlying infection (174), however, a small proportion of people will develop a chronic arthritis that lasts more than six weeks (177, 178). Postviral arthralgias are associated with cross-reactivity of the immune response, leading to inflammation of joint tissues and damage to the cells. Changes in the joint can cause pain and swelling, long after the virus has been removed. Among the alphaviruses, acute infection usually occurs between four and 15 days after being bitten by an infected mosquito (176-178). Symptomatic infection can be characterised by a debilitating arthritic disease with fever and joint pain in the acute phase (176, 177, 181). Other common signs and symptoms include headache, nausea, fatigue and rash (176, 178). Chronic postviral arthritis is characterised by persistent musculoskeletal and/or joint pain with limited movement for several months or years (177, 178, 181, 182). People with chronic postviral arthritis experience a reduced quality of life associated with reduced function, debilitating pain and joint stiffness (175, 177-181).

Most cases of viral arthritis are identified through serological tests or blood tests; however, the infection may go unrecognised or misdiagnosed because of mild symptoms (177-180). There are no vaccinations available and there are often no specific antiviral drug treatments (174, 175, 178). Prevention of mosquito-borne viruses includes minimising skin exposure, using repellents and basic precaution in high risk areas (178). International guidelines (182-184) encourage physical therapy, aerobic exercise, stretching and manual therapy to combat mental, functional and physical health effects experienced by people with postviral arthropathies, particularly in the subacute and chronic phases of the disease.

4.11.2 Description of studies

Two citations (185, 186) corresponding to one RCT (de Oliveira 2019) were identified in the literature search. There were no studies awaiting classification and no ongoing studies. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D5.2.1.

One study (de Oliveira 2019) was carried out in a single centre setting in Brazil. Participants had a confirmed diagnoses of chronic Chikungunya fever (symptoms lasting more than three months) and were receiving routine treatment through the rheumatology outpatient clinic. Most participants in the trial were middle-aged (mean 57 years) and were predominantly female (93%).

One study (de Oliveira 2019) assessed the effectiveness of Pilates exercise compared to no intervention, delivered as an adjunct to standard medical care. The Pilates sessions (in groups of six) were provided by a physical education professional trained in the Pilates method over 50 minutes, two-times per week for 12 weeks. Exercises were of light to moderate intensity (increasing from 6 to 12 repetitions) and included using Swiss ball and elastic bands of medium (upper body) and strong (lower body) intensity.

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see 4.11.4.1) (and Appendix F2).

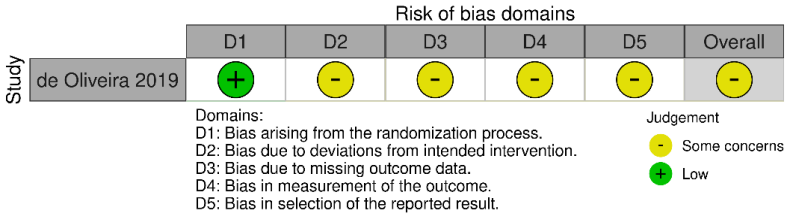
There were no studies identified comparing Pilates with an active intervention in people with post viral arthropathies.

4.11.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 32. Details are provided in Appendix D5.2.2.

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

Figure 32 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Postviral arthropathies



4.11.4 Main comparison (vs control)

One study (de Oliveira 2019) comparing Pilates with no intervention (delivered as an adjunct to standard medical care) in people with chronic Chikungunya fever was eligible for this comparison and contributed data relevant to two outcomes.

There were no studies awaiting classification or ongoing that compared Pilates with no intervention in people with post-viral arthropathies that could have contributed data to these outcomes (see Appendix C6).

4.11.4.1 Summary of findings

Pilates compared to Control (no intervention, waitlist, usual care) for postviral arthropathies

Patient or population: Postviral arthropathies
Setting: Community or Outpatient clinic
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Pain assessed with: Visual analogue scale (higher is worse) Scale from: 0 to 10 follow-up: 12 weeks	The mean pain was **7.8** points	MD **3.4 points lower** (4.85 lower to 1.95 lower)	-	42 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates in peoples with postviral arthropathies.**

Pilates compared to Control (no intervention, waitlist, usual care) for postviral arthropathies

Patient or population: Postviral arthropathies
Setting: Community or Outpatient clinic
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Quality of life assessed with: SF-12 - Physical component score (higher is better) Scale from: 0 to 100 follow-up: 12 weeks	The mean quality of life was **28.9** points	MD **11 points higher** (15.35 higher to 6.65 higher)	-	42 (1 RCT)	⊕⊕◯◯ LOW [a,b,c,e]	The evidence suggests Pilates improves physical wellbeing in people with postviral arthropathies.***
Fatigue - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on fatigue in people with postviral arthropathies is unknown.
Functional capacity - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on functional capacity in people with postviral arthropathies is unknown.
Global disease assessment - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on global disease assessment in people with postviral arthropathies is unknown.
Peripheral joints and entheses - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on peripheral joints and entheses in people with postviral arthropathies is unknown.
Acute-phase reactant - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on acute-phase reactant in people with postviral arthropathies is unknown.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
** The MCID for improvement in pain is reported to be 2-points (187).
** The MCID for improvement in physical wellbeing is reported to be 3.29 points (91).

Effect estimates were considered on three levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).
CI: Confidence interval; **MD:** Mean difference.

Pilates compared to Control (no intervention, waitlist, usual care) for postviral arthropathies

Patient or population: Postviral arthropathies
Setting: Community or Outpatient clinic
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual care)

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

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. No serious risk of bias. Certainty of evidence not downgraded.
b. Single study. Heterogeneity not formally assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is generalisable to the Australia population with some caveats. The available evidence is in people (predominantly women) with postviral arthropathy (due to Chikungunya virus), which may not be generalisable to postviral arthropathies found in Australia but could be sensibly applied. Certainty of evidence not downgraded.
d. Single study (fewer than 50 participants). Wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.

4.11.4.2 Forest plots

Outcome results related to pain for people with postviral arthropathies are presented in Figure 33.

Outcome results related to physical wellbeing for patients with postviral arthropathies are presented in Figure 34.

Figure 33 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): postviral arthropathies - pain

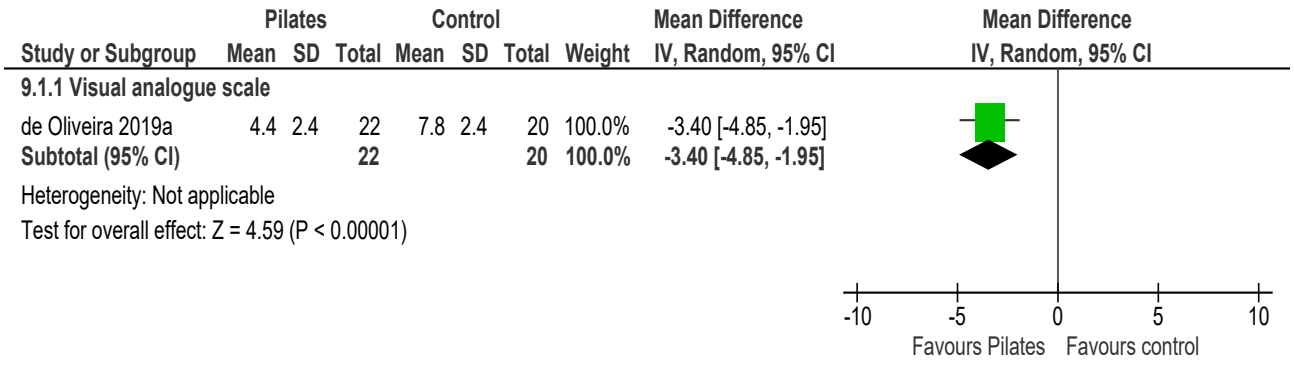
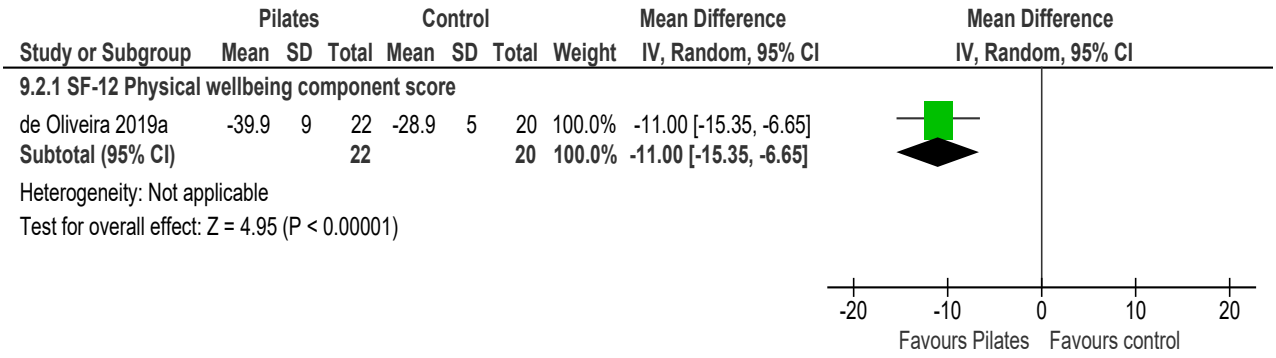


Figure 34 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): postviral arthropathies – quality of life



4.12 Spondyloarthritis

4.12.1 Description of the condition

Spondyloarthritis (SpA), which comprises axial spondyloarthritis (axSpA), peripheral SpA (e.g., psoriatic arthritis) and undifferentiated SpA, is a chronic, progressive, immune-mediated arthritis classified by the absence of rheumatoid factor (188). axSpA (or ankylosing spondylitis) mainly affects the spine and is characterised by the progressive loss of flexibility in the spine, due to bony overgrowth and inflammation of ligaments that may lead to the bones of the spine to fuse (ankylose) (189, 190).

Approximately 1-2% of Australians are affected by axSpA and it is about three times more common in men than women (191). The cause of axSpA remains unknown, however, there is a strong genetic and familial component, with interactions between genes, intestinal microbes, mechanical stress and lifestyle likely playing a role in disease development (188). Persons carrying the major histocompatibility complex class 1 antigen HLA-B27, and who have a parent or sibling with axSpA, are at increased risk (one in five) of developing axSpA(188, 191). axSpA first presents between the ages of 15 and 40 years, with disease duration, increasing age, and nicotine exposure associated with increased disease activity (188). People living with axSpA mainly present with significant back pain, reduced mobility and decreased quality of life, however, symptoms may vary and the disease affects people in different ways (191). Besides stiffness, pain and swelling of the spine, some people may also experience inflammation in peripheral joints such as hips, shoulders, hands and the chest wall (192, 193). Extra-articular manifestations also typical of axSpA are include acute anterior uveitis, psoriasis (PsO), and inflammatory bowel disease (IBD) (192-194).

There is no known cure for axSpA, with treatment and management of the disease focused on supressing inflammation to prevent disability and structural damage (using nonsteroidal anti-inflammatory drugs [NSAIDs]), glucocorticoids or bDMARDs and to maintain work productivity (195, 196). Like rheumatoid arthritis, regular exercise and physiotherapy are essential for people with SpA (197) but there are no specific guidelines available that outline the optimum physical activities for people with spondyloarthropathies. Therapies including stretches and exercises can keep the spine and joints as flexible, strong and pain-free as possible (191, 197).

4.12.2 Description of studies

One citation (198) corresponding to one RCT (Altan 2012) was identified in the literature search. There were two ongoing studies (NCT04292028, NCT03904953) and three studies awaiting classification (Brayjani 2019, Martínez-Pubil 2017, Oksuz 2018) (199-202), two of which were published in a language other than English. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D5.3.1.

One study (Altan 2012) was carried out in outpatient clinic in Turkey and enrolled 55 adults with axSpA aged 28 to 69 years (mean age 45.23 years). Disease duration ranged from 2 to 22 years (mean 8.84 years). People with active peripheral arthritis, total spinal ankylosis, ESR over 50mm/h, CRP more than 10 times normal values, or changes to treatment in the last two months prior to the study were excluded.

One study (Altan 2012) assessed the effectiveness of Pilates exercise delivered as an adjunct the standard medical care compared to usual activities. The 60-minute Pilates sessions were provided by a certified trainer three times a week for 12 weeks. Participants in the control group were advised to continue with their usual physical activities.

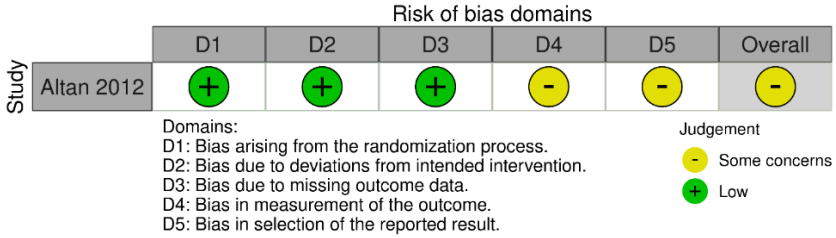
Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see 4.12.4.1) (and Appendix F2). There were no studies identified comparing Pilates with an active intervention in people with spondyloarthropathies.

4.12.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 35. Details are provided in Appendix D5.3.2.

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

Figure 35 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Spondyloarthropathies



4.12.4 Main comparison (vs control)

One study was eligible for this comparison and contributed data to four outcomes. There were three additional studies awaiting classification (two published in a language other than English) that compared Pilates with no intervention in people with ankylosing spondylitis (total 82 participants) that could have contributed data to all four outcomes (see Appendix C6).

4.12.4.1 Summary of findings

Pilates compared to Control (no intervention, waitlist or usual care) for spondyloarthropathies

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

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Global assessment assessed with: Bath Ankylosing Spondylitis Disease Activity Index (higher is worse) Scale from: 0 to 10 follow-up: 12 weeks	The mean global assessment was **3.1** points	MD **1.0 points lower** (1.98 lower to 0.02 lower)	-	55 (1 RCT)	⨁⨁◯◯ LOW [a,b,c,d,e]	The evidence suggests that Pilates results in little to no effect on global disease assessment in people with spondyloarthropathies.**

Pilates compared to Control (no intervention, waitlist or usual care) for spondyloarthropathies

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

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Physical function assessed with: Bath Ankylosing Spondylitis Functional Index (higher is worse) Scale from: 0 to 10 follow-up: 12 weeks	The mean physical function was **2.3** points	MD **0.6 points lower** (1.48 lower to 0.28 higher)	-	55 (1 RCT)	⨁⨁◯◯ LOW [a,b,c,d,e]	The evidence suggests that Pilates results in little to no effect on physical function in people with spondyloarthropathies.***
Quality of life assessed with: Ankylosing Spondylitis Quality of Life (higher is worse) Scale from: 0 to 18 follow-up: 12 weeks	The mean quality of life was **4.0** points	mean **0.00 points** (2.57 lower to 2.57 higher)	-	55 (1 RCT)	⨁⨁◯◯ LOW [a,b,c,d,e]	The evidence suggests that Pilates results in little to no difference in quality of life in people with spondyloarthropathies.****
Pain - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on pain in people with spondyloarthropathies is unknown.
Spinal mobility assessed with: Bath Ankylosing Spondylitis Metrology Index (higher is worse) Scale from: 0 to 10 follow-up: 12 weeks	The mean spinal mobility was **8.7** points	**0.3 points lower** (1.28 lower to 0.68 higher)	-	55 (1 RCT)	⨁⨁◯◯ LOW [a,b,c,d,e]	The evidence suggests that Pilates results in little to no difference on spinal mobility in people with spondyloarthropathies. *****
Fatigue - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on fatigue in people with spondyloarthropathies is unknown.
Symptoms of peripheral joints and entheses - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on peripheral joints and entheses in people with spondyloarthropathies is unknown.

Pilates compared to Control (no intervention, waitlist or usual care) for spondyloarthropathies

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

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

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
** The MCID for improvement in BASDAI score is 0.7 points, increasing to 1.1 in people with active disease (203).
*** The MCID for improvement in BASFI score is 0.4 points, increasing to 0.6 in patients with active disease (94).
**** The MCID for improvement in ASQoL score is 3 points (204).
***** MCID is unknown.^

Effect estimates were considered on three levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).
^ In the absence of an MCID, effect estimates were considered based on the SMD: where an SMD of 0.2 represents a small difference, 0.5 is moderate, and 0.8 is a large difference.

CI: Confidence interval; **MD:** Mean difference; **BASDAI:** Bath Ankylosing Spondylitis Functional Index

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. One RCT (100% weight) with no serious risk of bias. Certainty of evidence not downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is generalisable to the Australian population with some caveats. The study is in people with ankylosing spondylitis and does not include people with active peripheral arthritis or those nonresponsive to prescribed treatments. The evidence may not be generalisable to people with other spondyloarthropathies but could be sensibly applied. Certainty of evidence not downgraded.
d. Single study (fewer than 60 participants). Wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.

4.12.4.2 Forest plots

Global assessment results in people with spondyloarthropathies are presented in Figure 36.

Outcome results related to physical functioning in people with spondyloarthropathies are presented in Figure 37.

Outcome results related to quality of life in people with spondyloarthropathies are presented in Figure 38.

Outcome results for spinal mobility in people with spondyloarthropathies are shown in Figure 39.

Figure 36 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Spondyloarthropathies - global assessment

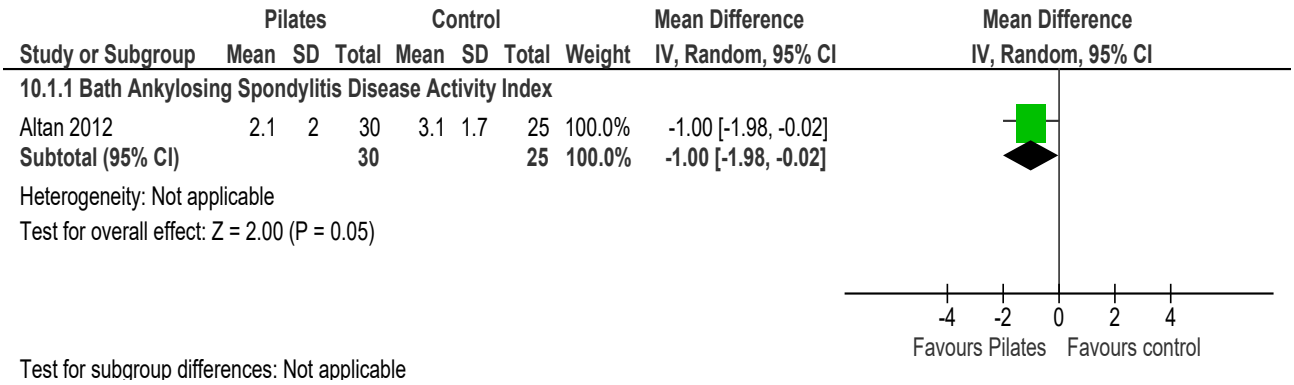


Figure 37 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Spondyloarthropathies – global physical functioning

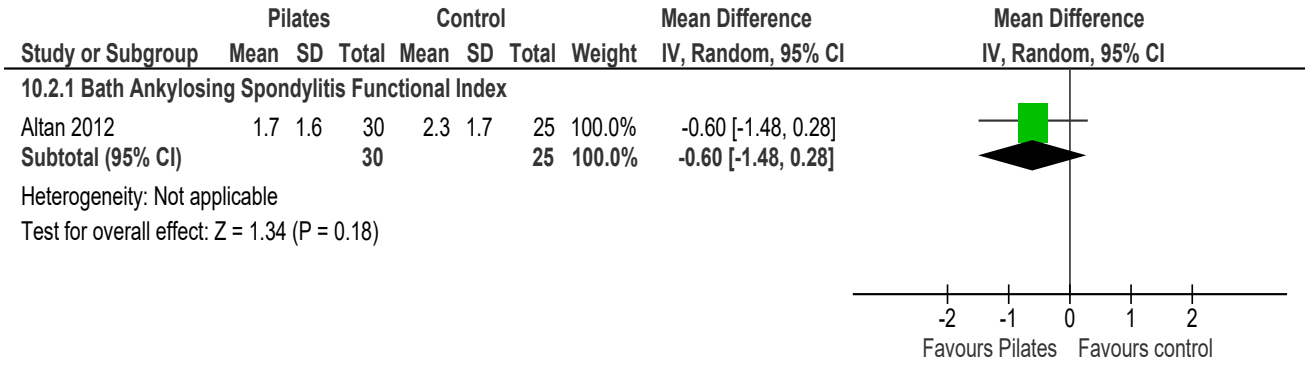


Figure 38 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Spondyloarthropathies - quality of life

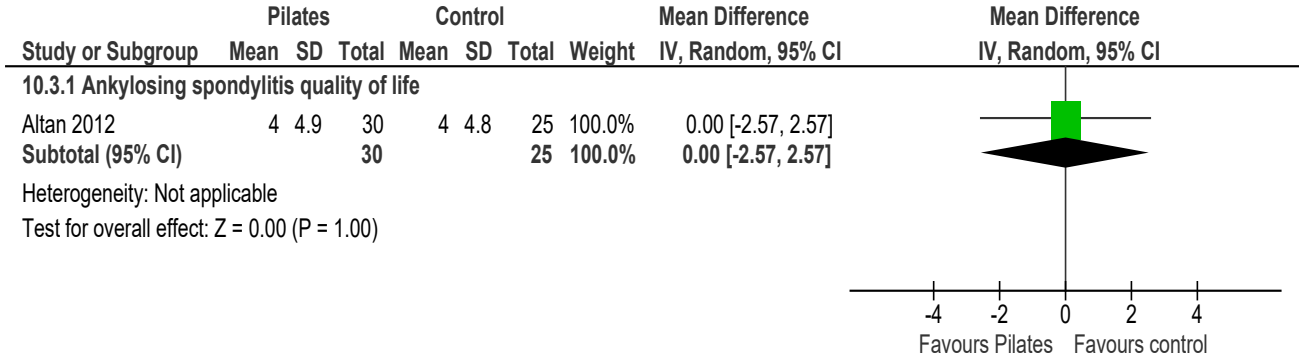
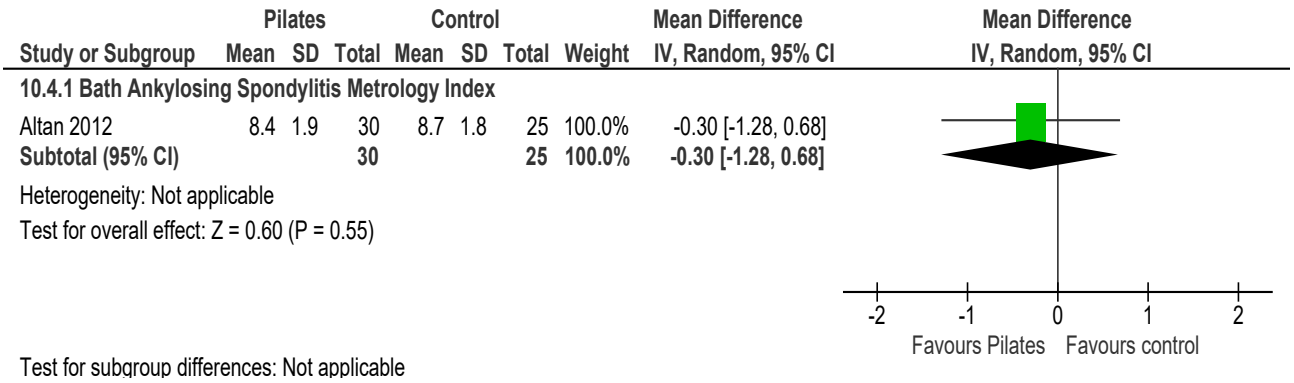


Figure 39 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Spondyloarthropathies - spinal mobility



4.13 Spinal deformities

4.13.1 Description of the conditions

Structural disorders of the spine involve abnormalities in the alignment, formation or curvature of one or more portions of the spine and can involve any combination of the axial, coronal and sagittal planes (205, 206). Deformities or malalignment typically occur along one of the three curvatures of the spine – the neck, the upper back or the lower back – and include conditions such as scoliosis (side-to-side with or without rotation), hyperkyphosis of the thoracic spine (round back), hyperlordosis of the lumbar spine (swayback) or hyperlordosis of the cervical spine (forward head). In the normal spine, the opposing curvatures work together to balance the trunk and head over the pelvis and allow for optimal functioning of the muscles (206). When a person's ability to stand upright is compromised, other parts of the spine compensate to maintain upright posture, which requires more effort and energy to both stand and walk (206). In the presence of deformities, spinal curvatures result in decreased function, and can cause pain, fatigue, respiratory compromise, poor balance and increased risk of falls, and overall lower quality of life (207-210).

Scoliosis is defined as a progressive, lateral curvature of the spine. A diagnosis of scoliosis is confirmed when the Cobb angle – a measurement of the angle or curve of the spine (211) – is greater than 10 degrees and axial rotation can be recognised (207). Classification of scoliosis varies according to age of onset, aetiology, severity and type of curvature. Scoliosis can be concomitant with reduced kyphosis (forward bend) in the thoracic curve or lordosis in the lumbar curve (205, 212). The two major types are idiopathic scoliosis (infantile, juvenile, adolescent, adult) and nonidiopathic scoliosis (congenital, neuromuscular, mesenchymal) (211, 212). The cause of idiopathic scoliosis is unknown, whereas scoliosis in adults is often due to spinal degeneration and advancing age. Adolescent idiopathic scoliosis is a common disease with estimates of prevalence ranging between 0.47% and 5.2% (212).

In children and adolescents, treatment of scoliosis is aimed at avoiding fusion, with approximately 3 to 5 in every 1000 children developing scoliosis severe enough to require treatment (208, 213). Management is typically focused on regular physical examination during the growth phase, and active nonsurgical treatment. Although brace treatments do not cure scoliosis, success rates are approximately 80% in people who are compliant, avoiding the need for surgery (211, 213). The Scoliosis Research Society also recommends exercises to improve respiratory function during brace treatment, with physiotherapeutic scoliosis-specific exercises (PSSE) developed to promote the expansion and ventilation of specific lung compartments (207). For adult scoliosis, the effectiveness of PSSEs is uncertain (213).

Hyperkyphosis occurs when the 'rounding' of the upper spine increases past 40 or 45 degrees (depending on age) (206). Hyperlordosis occurs when inward curvature of the lumber or cervical spine goes beyond normal, the degree of which being specific to each person (206). The most frequent form, known as postural (degenerative or age-related) kyphosis or lordosis, is flexible and often occurs because of weakened muscles and ligaments, or wear in the discs and the facet joints leading to misalignment of the vertebrae (209, 210). People with postural kyphosis or lordosis have no visible abnormalities in their vertebrae (206). Other types of primary hyperkyphosis are considered 'rigid' and include Scheuermann's Disease (a juvenile form related to a defect of the vertebral growth plate), congenital kyphosis (bone defect detected at birth), and posttraumatic kyphosis (typically related to severe neurologic injury such as quadriplegia). Hyperkyphosis or hyperlordosis can also occur secondary to diseases such as osteoporosis, Parkinson's disease, stroke, and inflammatory spondyloarthritis (206).

Treatment strategies for postural hyperkyphosis or hyperlordosis are variable (206, 209) and include conservative treatments such as pain medication, supervised physical therapy or bracing. Other

interventions may include chiropractic care, acupuncture or unsupervised exercise programs such as Pilates and yoga. Invasive surgery (i.e., spinal fusion) may be indicated in adolescents and adults in the presence of progressive deformities, and in those with refractory pain and dysfunction (213).

4.13.2 Description of studies

Twelve citations (214-225) corresponding to two RCTs (Alves de Araujo 2010, Kudchadhar 2019) and four quasi RCTs (Junges 2012, Kim 2016, Lee 2016b, Navega 2016) were identified in the literature search. There was one ongoing study (IRCT20180506039562N1) and four studies awaiting classification (Hurer 2019, Rezaei 2015, Shahrjerdi 2014, Uzun 2018) (226-229), three of which were published in a language other than English. One additional study awaiting classification (Afroundeh 2017) (230) was identified in the Department's public call for evidence and was also published in a language other than English. An overview of the PICO criteria of included studies is provided in Appendix D5.4.1.

Three studies were conducted in local community settings in either Brazil (Junges 2012, Navega 2016) or Korea (Lee 2016). The other three studies were carried out in the university setting in Brazil (Alves de Araujo 2010), Korea (Kim 2016) or India (Kudchadhar 2019). Sample sizes ranged between 24 to 51 participants (total 178).

One study (Lee 2016) included sedentary females aged 20-39 years with forward head posture. Two studies (Junges 2012, Navega 2016) included women with hyperkyphosis of the thoracic spine (spinal curvature angle greater than 45 degrees). Participants in Junges 2012 were aged over 45 years, whereas participant in Navega 2016 were aged between 60 and 75 years. One study (Kudchadhar 2019) included young adults aged between 18 to 40 years with hyperlordosis and an anterior pelvic tilt angle of greater than 13 degrees. There were two studies in people with scoliosis (Alves de Araujo 2010, Kim 2016). Participants in Alves de Araujo 2010 were aged between 18 and 25 years and had nonstructural dorsolumbar scoliosis with rightward or leftward convexity. Participants in Kim 2016 were female, aged between 14 and 16 years and had idiopathic scoliosis with a Cobb angle greater than or equal 20 degrees.

One study (Junges 2012) examined the effectiveness of Pilates compared with no exercise. The 60-minute Pilates sessions were conducted twice a week for 30-weeks (Junges 2012). Junges 2012 allowed participants in the control group to continue with normal daily activities.

Five studies (Alves de Araujo 2010, Kim 2016, Kudchadhar 2019, Lee 2016, Navega 2016) compared the effectiveness of Pilates to another intervention. In two studies, the control group received postural education; with control group participants in Alves de Araujo 2010 attending weekly meetings with the therapist, and in Navega 2016 they attended four 45-minute lectures. The 60-minute Pilates sessions were conducted twice a week for eight (Navega 2016) and 12 weeks (Alved de Araujo 2010). In three studies the comparator was 'active', with participants in Lee 2016 receiving a combined exercise program that included using TheraBands. The sessions were 50-mins in duration and were delivered three times a week for 10 weeks. Kim 2016 compared 60-minute Pilates exercises to physical therapy exercises tailored to each participants spine curvature (Schroth method for scoliosis), both were performed three times a week for 12 weeks. Kudchadhar 2019 assessed a set number of mat Pilates exercises delivered three times a week for four weeks. Pilates was compared to a series of 10 gentle exercises and stretches (The Egoscue Method) or Lumbar stabilisation exercises. All interventions in Kudchadhar 2019 also included stretching for hamstring, rectus femoris, iliopsoas and tendoachillis muscles.

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings tables (see 4.13.4.1) (and Appendix F2).

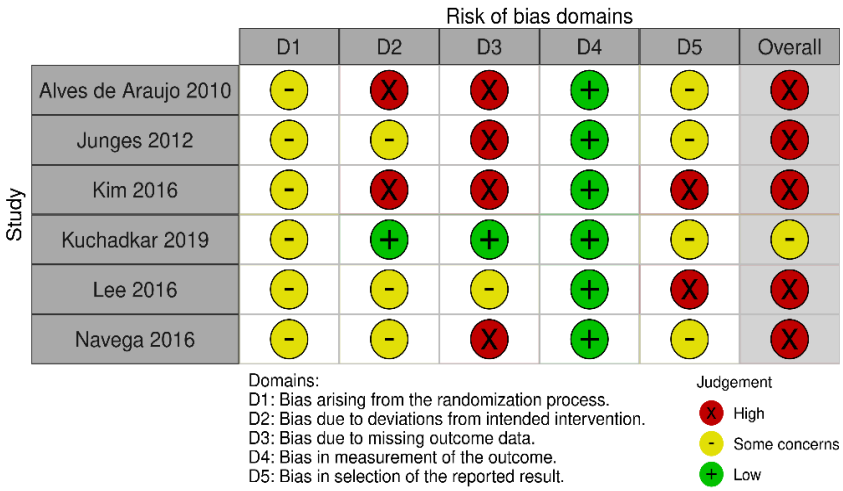
Results of the fours studies (Kim 2016, Kudchadkar 2019, Lee 2016b, Navega 2016) comparing Pilates with an active comparator are presented in Appendix F2.

4.13.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 40. Details are provided in Appendix D5.4.2.

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

Figure 40 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Spinal deformities



4.13.4 Main comparison (vs control)

Two RCTs (Alves de Araujo 2010, Junges 2012) were eligible for this comparison and contributed data relevant to three outcomes specific to people either with non-structural scoliosis (one study) or hyperkyphosis (one study). There were two additional studies identified (awaiting classification of ongoing) that compared Pilates with no intervention people with hyperlordosis (total 30+ participants) that could have contributed data to outcomes specific to people with hyperlordosis (see Appendix C6).

4.13.4.1 Summary of findings

Scoliosis

Pilates compared to control (no intervention, wait list or usual care) for Spinal Deformities-Scoliosis

Patient or population: Spinal deformities - Scoliosis
Setting: Community
Intervention: Pilates
Comparison: control (no intervention, wait list or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with control	Risk with Pilates				
Pain assessed with: Numeric rating scale (Borg CR10) (Higher is worse) Scale from: 0 to 10 follow-up: 3 months	The mean pain was **3.8 points**	MD **2 points lower** (3.8 lower to 0.2 lower)	-	31 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on pain in people with scoliosis.**
Disability - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on disability in people with scoliosis is unknown.
Quality of life - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on quality of life in people with scoliosis is unknown.
Flexibility/Range of motion - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on flexibility/range of motion in people with scoliosis is unknown.
Psychological wellbeing - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on psychological wellbeing in people with scoliosis is unknown.
Deformity progression assessed with: Degree of curvature (Cobb angle) (higher is worse) follow-up: 3 months	The mean deformity progression was **6.9** degrees	MD **2.1 degrees lower** (4.13 lower to 0.07 lower)	-	31 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on deformity progression in people with scoliosis.***
Balance - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on balance in people with scoliosis is unknown.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
**The MCID for pain in people with non-structural scoliosis is assumed to be 2 points (187)
*** MCID is unknown. A change of 2.10 degrees was not considered clinically important.

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

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

Pilates compared to control (no intervention, wait list or usual care) for Spinal Deformities-Scoliosis

Patient or population: Spinal deformities - Scoliosis
Setting: Community
Intervention: Pilates
Comparison: control (no intervention, wait list or usual care)

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

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. One RCT (100% weight) at high risk of bias for the outcome. Certainty of evidence downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is generalisable to the Australian population with some caveats. The available evidence is in women with nonstructural scoliosis (no spinal rotation) so may not be directly generalisable to people with structural scoliosis. Evidence in men is not available. Certainty of evidence not downgraded.
d. Small study (31 participants). Wide confidence intervals (lower bounds overlap with no important difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.

Other spinal deformities (hyperkyphosis, hyperlordosis, forward head) –specific outcomes

Pilates compared to control (no intervention, wait list or usual care) for Dorsopathies-Hyperkyphosis

Patient or population: Spinal deformities (hyperkyphosis, hyperlordosis, forward head)
Setting: Community
Intervention: Pilates
Comparison: control (no intervention, wait list or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Deformity progression assessed with: Degree of curvature (Cobb angle) (higher is worse) follow-up: 30 weeks	The mean deformity progression was **58.22** degrees	MD **2.72 degrees lower** (9.04 lower to 3.6 higher)	-	41 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on deformity progression in people with hyperkyphosis.**
Flexibility - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on flexibility in people with hyperkyphosis is unknown.

Pilates compared to control (no intervention, wait list or usual care) for Dorsopathies-Hyperkyphosis

Patient or population: Spinal deformities (hyperkyphosis, hyperlordosis, forward head)
Setting: Community
Intervention: Pilates
Comparison: control (no intervention, wait list or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Degrees of lumbar lordosis - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on degrees of lumbar lordosis in people with hyperlordosis is unknown.
Anterior pelvic tilt - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on anterior pelvic tilt in people with hyperlordosis is unknown.
Physical functioning - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on physical functioning in people with forward head is unknown.
Deformity progression - not reported assessed with: Craniovertebral angle	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on deformity progression in people with forward head is unknown.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
**MCID is unknown. A change of 2.10 degrees was not considered clinically important.

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

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

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. One study (100% weight) at high risk of bias for the outcome. Certainty of evidence downgraded
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is probably generalisable to the Australian population with few caveats The available evidence is in women with hyperkyphosis. Evidence in men is not available. Certainty of evidence not downgraded.
d. Small study (41 participants). Wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.

Other spinal deformities (hyperkyphosis, hyperlordosis, forward head) – shared outcomes

There were no studies found for shared outcomes selected *a priori* as critical or important, thus the effect of Pilates compared with control on these outcomes in people with hyperkyphosis, hyperlordosis, forward head.

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

- pain
- disability
- quality of life
- global perceived effect
- work status

4.13.4.2 Forest plots

Outcome results related to pain for people with scoliosis are presented in Figure 41.

Outcome results related to deformity progression for people with scoliosis are presented in Figure 42.

Outcome results related to deformity progression in people with hyperkyphosis are presented in Figure 43.

Figure 41 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Spinal deformities - Scoliosis (postural) – Pain

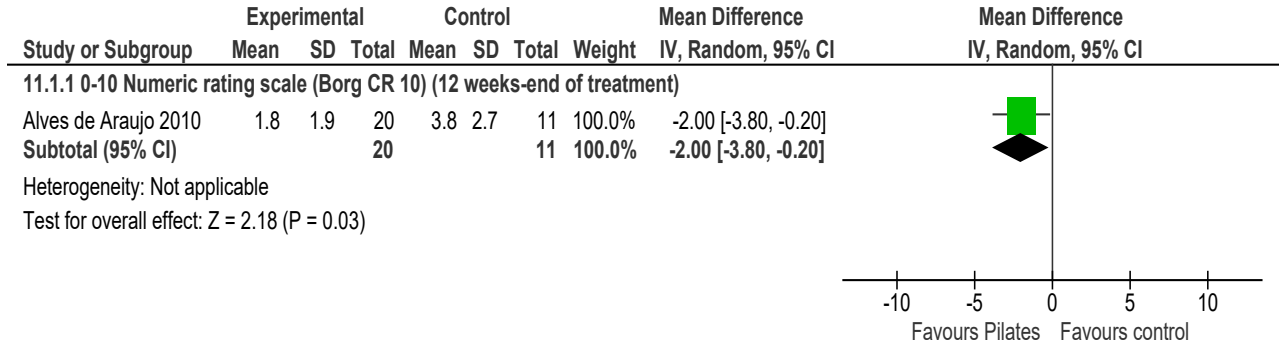


Figure 42 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Spinal deformities - Scoliosis (postural) – Deformity progression

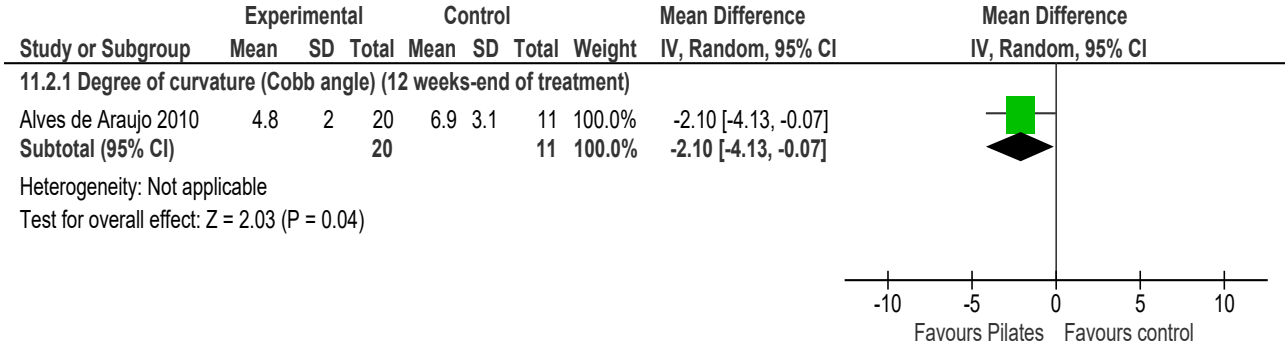
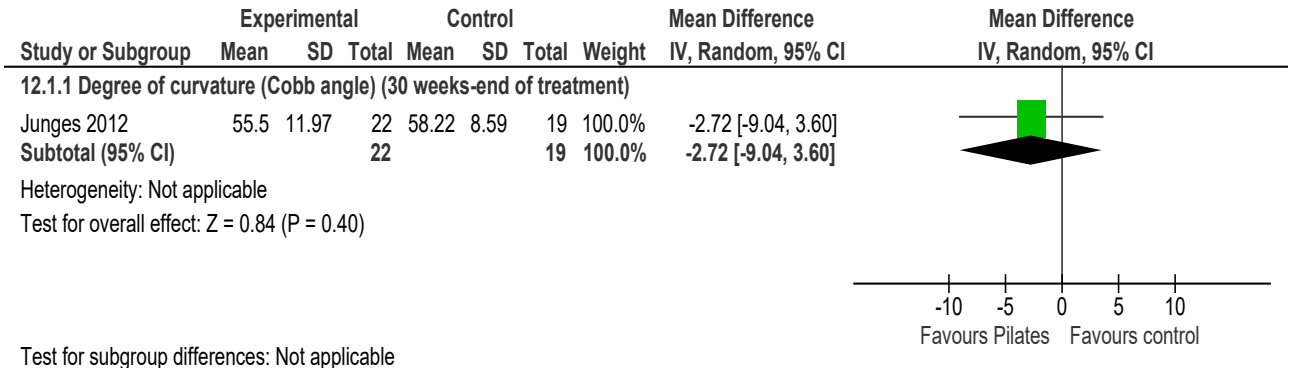


Figure 43 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Spinal deformities (hyperkyphosis) – Deformity progression



4.14 Osteoporosis

4.14.1 Description of the condition

Osteoporosis occurs when the bones lose minerals such as calcium faster than the body can replace them, causing the bones to become thin and weak (231, 232). A decrease in bone mineral density (BMD) and the changes in bone quality result in an increased risk of skeletal fractures (231, 232). These fractures can often occur from a minor bump or fall that can have a significant impact on the individual (232). Fractures can lead to chronic pain, disability, excess mortality and morbidity and a reduction in overall quality of life (231, 233). Most risk factors associated with the development of osteoporosis (such as low vitamin D levels, low intake of calcium, low body weight, smoking, low physical inactivity) are modifiable (234). However, there are also nonmodifiable risk factors that are associated with osteoporosis, including age, sex and family history of the condition (234).

Osteoporosis is often under-diagnosed and usually only diagnosed when a fracture occurs (232). In 2017 to 2018, an estimated 924 000 Australians had osteoporosis; 20% of whom were aged 75 years and older (232). Osteoporosis is more common in older, postmenopausal women, affecting over one in four women aged 75 years and over (232). Treatment of hip fractures often includes hospitalisation, which can lead to a reduced quality of life and incurs significant economic and social costs (231, 233). Maintaining bone density and preventing fractures is therefore the primary goal in the management of osteoporosis (231). Adequate dietary calcium and vitamin D that meets the age-appropriate Australian recommended daily intake as well as regular weight-bearing and resistance exercise is encouraged, particularly for postmenopausal women (231, 235).

4.14.2 Description of studies

Five citations (236-240) corresponding to one RCT (Oksuz 2014) and two quasi RCTs (Angin 2015, Kucukcakir 2015) were identified in the literature search. There were no ongoing studies and one study awaiting classification (Patru 2017) (241). No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D5.5.1.

All three studies were conducted in Turkey. Angin 2015 was carried out in a single centre setting and Kucukcakir 2013 and Oksuz 2014 did not specify the study setting. The sample sizes ranged from 41 to 70 participants (total 158). All three studies included postmenopausal women who were diagnosed with osteoporosis and did not have a history of fracture (mean age ranged between 56-61 years).

Two studies (Angin 2015, Oksuz 2014) compared Pilates exercises with no intervention and one study (Kucukcakir 2013) compared Pilates exercises with an unbalanced support surface exercise practised at home. In all studies the Pilates sessions were one hour in duration, but the treatment program ranged in intensity from three times per week for 6 weeks (Kucukcakir 2013) or 24 weeks (Angin 2015) through to three times per week for one year (Oksuz 2014).

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings tables (see 4.14.4.1) (and Appendix F2)..

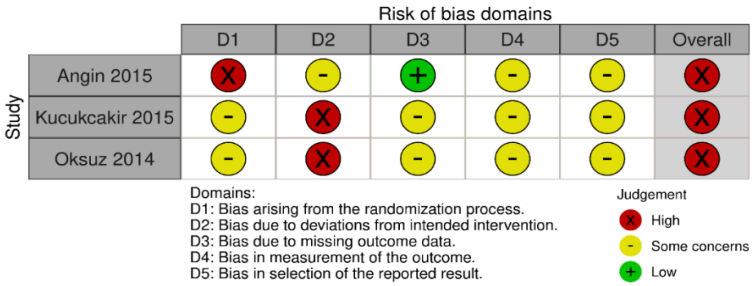
Results of the study (Kucukcakir 2015) comparing Pilates with an active comparator are presented in Appendix F2.

4.14.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 44. Details are provided in Appendix D5.5.2.

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

Figure 44 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Osteoporosis



4.14.4 Main comparison (vs control)

Two studies (Oksuz 2014, Angin 2015) were eligible for this comparison and contributed data to five outcomes. There were no studies awaiting classification or ongoing that compared Pilates with no intervention in people with osteoporosis that could have contributed data to these outcomes (see Appendix C6).

4.14.4.1 Summary of findings

Pilates compared to Control (no intervention, waitlist or usual care) for Osteoporosis

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

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with Control	Risk with Pilates				
Functional mobility assessed with: Six-minute walk test (higher is better) follow-up: 24 weeks	The mean distance was **400.42** metres	MD **53.4 metres more** (110.61 more to 3.81 less)	-	41 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on functional mobility in people with osteoporosis.**
Pain (while active) assessed with: Visual analogue scale (higher is worse) Scale from: 0 to 10 follow-up: 6 to 24 weeks	The mean change from baseline in pain score was **0.55 to 1.42** points	MD **3.25 points lower** (6.26 points lower to 0.23 points lower)	-	81 (2 RCTs)	⊕◯◯◯ VERY LOW c,d,e,f,g	The evidence is very uncertain about the effect of Pilates on pain (while active) in people with osteoporosis.***
Quality of life assessed with: QUALEFFO41 -total score (higher is better) Scale from: 0 to 100 follow-up: 6 weeks	The mean change from baseline in quality of life was **0.69 points**	MD **6.21 higher** (4.45 higher to 7.97 higher)	-	40 (1 RCT)^	⊕⊕◯◯ LOW a,b,c,e	The evidence suggests Pilates results in a slight improvement in quality of life in people with osteoporosis.****

Pilates compared to Control (no intervention, waitlist or usual care) for Osteoporosis

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

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with Control	Risk with Pilates				
Bone mineral density assessed with: DXA T-score (higher is better) follow-up: 6 weeks	The mean T-score was **–2.81**	MD **0.32 higher** (0.11 higher to 0.53 higher)	-	41 (1 RCT)	⨁◯◯◯ VERY LOW [a,b,c,d,e]	The evidence is very uncertain about the effect of Pilates on bone mineral density in people with osteoporosis.*****
Balance (static) assessed with: Berg Balance Scale (higher is better) Scale from: 0 to 56 follow-up: 24 weeks	The mean change from baseline in balance score was **0.05** points	MD **1.7 higher** (1.14 higher to 2.26 higher)	-	40 (1 RCT)	⨁⨁◯◯ LOW [a,b,c,e]	The evidence suggests of Pilates results in little to no difference in static balance in people with osteoporosis.******
Falls – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on preventing falls in people with osteoporosis is unknown.
Global disease assessment – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on global disease in people with osteoporosis is unknown

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
** The MCID for improvement in mobility ranges between 14.0 to 30.
*** The MCID for improvement pain is 2 points (187).
**** The MCID is unknown.[#]
***** A T-score less than –2.5 is diagnostic of osteoporosis (242).
****** The MCID for improvement in balance stability in older women is 6.5 points.

In the absence of an MCID, effect estimates were considered on three levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).
^ Data from one study (41 participants) not included as the study does not report a total score

CI: confidence interval; **MD:** mean difference; **QUALEFFO41**: Quality of Life Questionnaire of the European Foundation for Osteoporosis

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. One study (100% weight) at high risk of bias for the outcome. Certainty of evidence downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is directly generalisable to the Australian population with few caveats. Certainty of evidence not downgraded.
d. Serious imprecision. Wide confidence intervals (lower bounds overlap with no important difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.
f. Two studies (100% weight) at high risk of bias for the outcome. Certainty of evidence downgraded.
g. Serious inconsistency. No overlap of confidence intervals. Substantial heterogeneity (I^2 = 97%). Certainty of evidence downgraded.

4.14.4.2 Forest plots

Outcome results related to functional mobility in people with osteoporosis are shown in Figure 45.

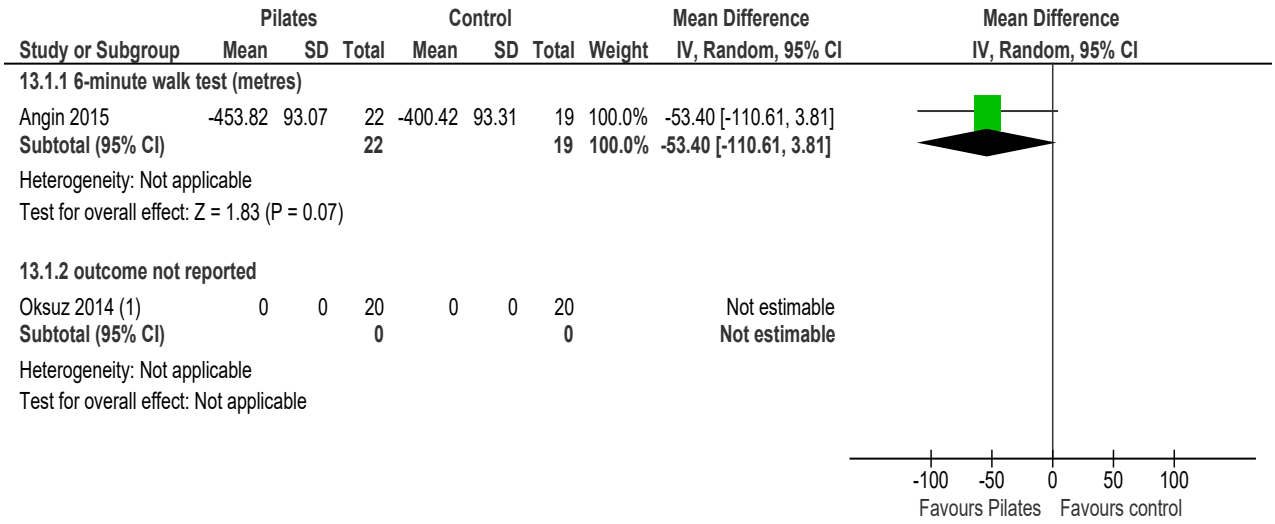
Outcome results related to pain for people with osteoporosis are shown in Figure 46.

Outcome results related to quality of life for people with osteoporosis are shown in Figure 47.

Outcome results related to BMD for people with osteoporosis are shown in Figure 48.

Outcome results related to balance in people with osteoporosis are shown in Figure 49.

Figure 45 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Osteoporosis – functional mobility



Footnotes

(1) Study does not report this outcome. Outcome of mobilty measured with the Timed Up and Go (s).

Figure 46 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Osteoporosis – pain (change from baseline)

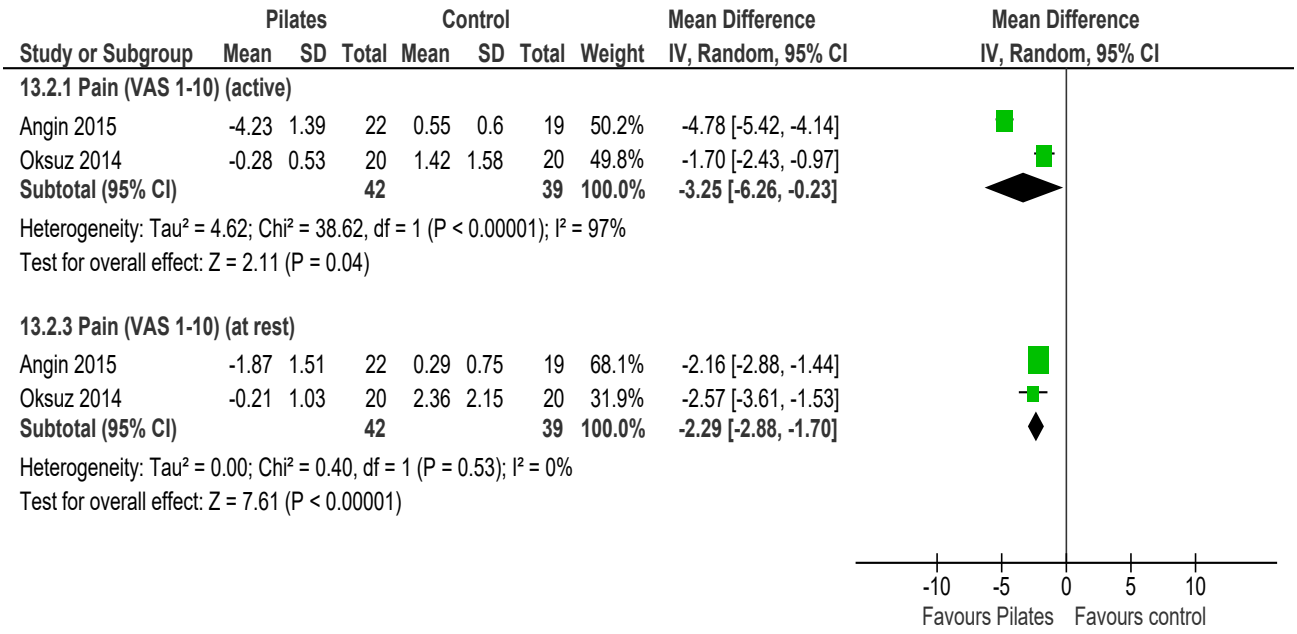
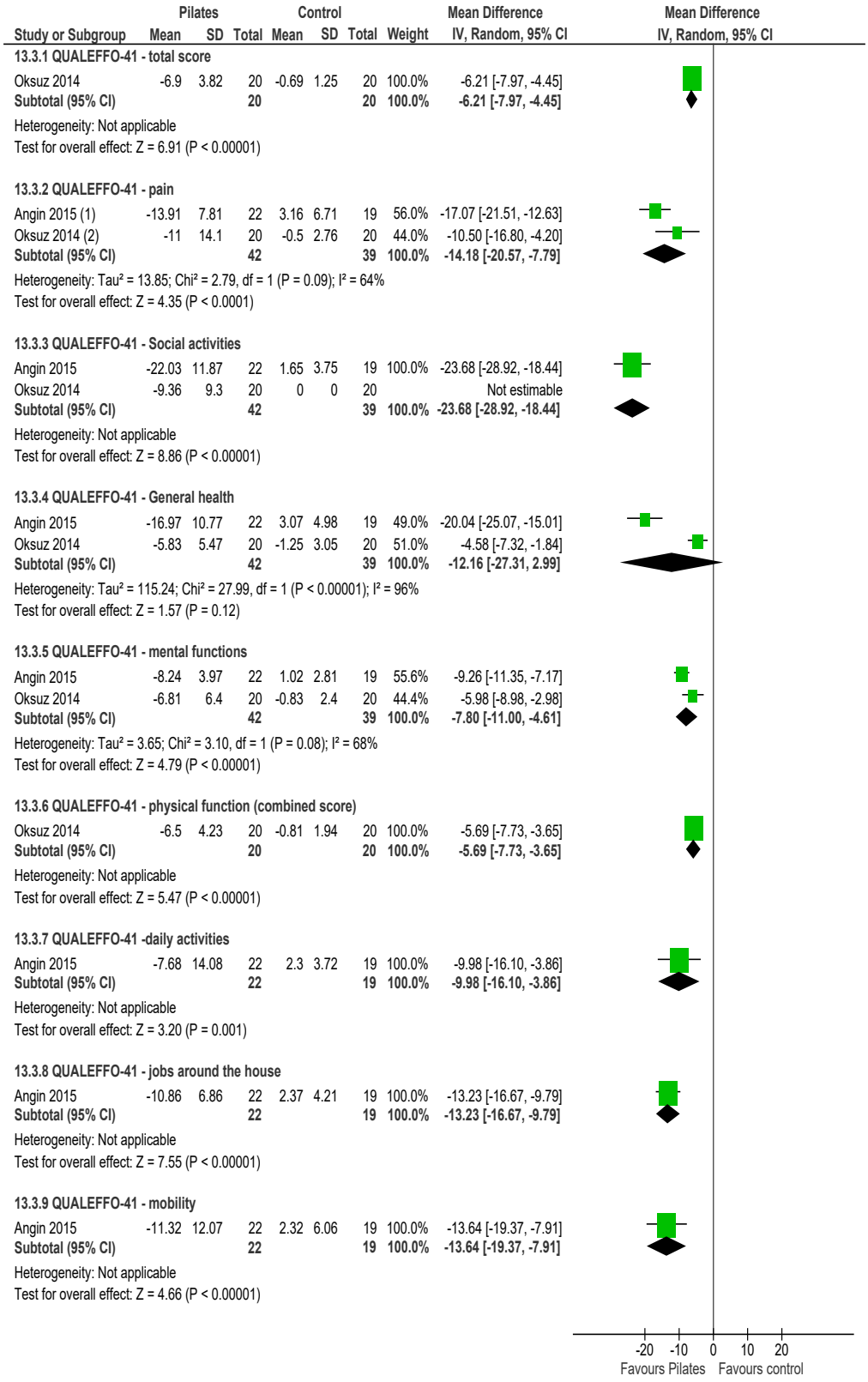
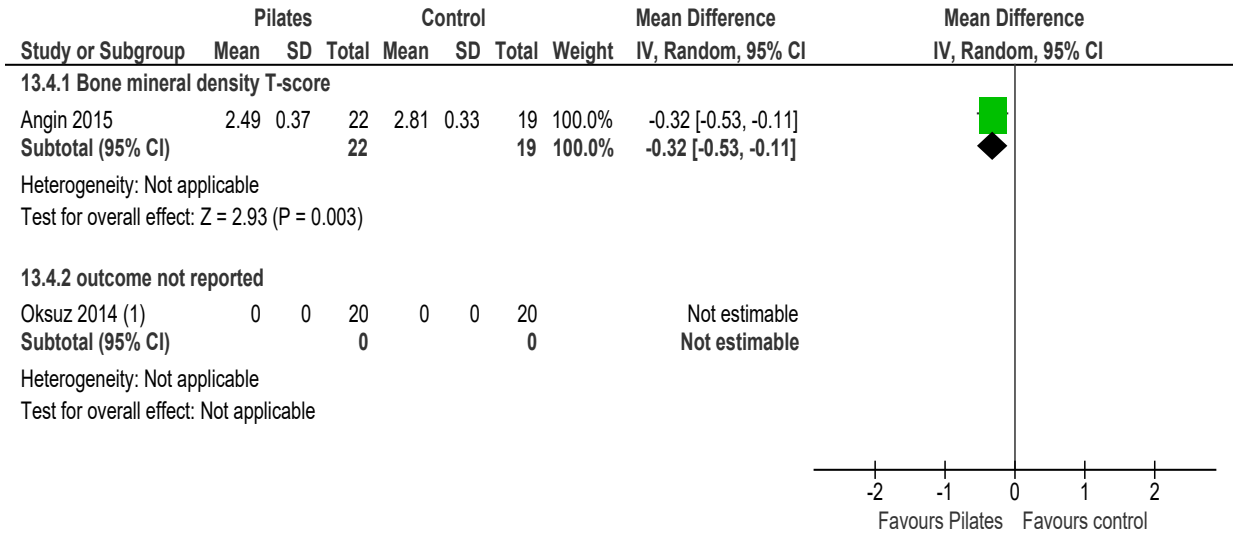


Figure 47 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Osteoporosis – quality of life (change from baseline)



Footnotes
(1) 24-weeks
(2) 6-weeks

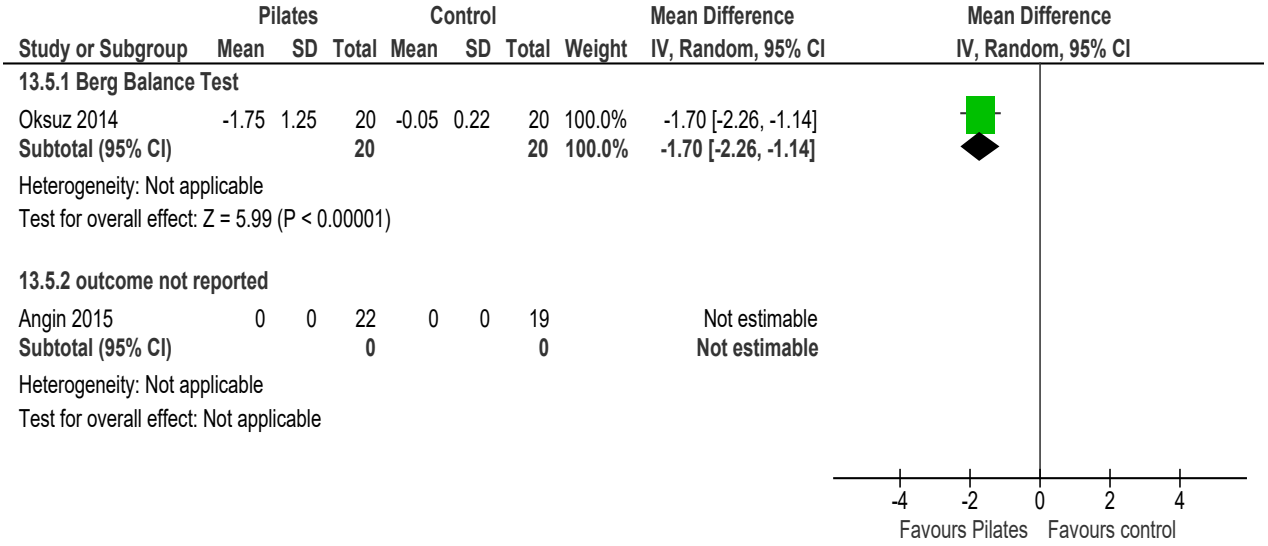
Figure 48 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Osteoporosis – bone mineral density



Footnotes

(1) Study does not report this outcome, probably because the outcome was not assessed.

Figure 49 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Osteoporosis – balance (change from baseline)



4.15 Chronic widespread pain (fibromyalgia)

4.15.1 Description of the condition

Chronic widespread pain is a multifactorial pain syndrome that may be influenced by biological, psychological and social factors (243, 244). It is characterised as a diffuse pain that occurs in at least four of five body regions lasting for a minimum of three months, and is associated with significant emotional distress (anxiety, anger/frustration or depressed mood) or functional disability (interference in daily life activities and reduced participation in social roles) (243, 245).

One condition characteristically associated with chronic widespread pain is fibromyalgia, which is defined by the American College of Rheumatology[d] (246) as a widespread and prolonged pain persisting for more than three months with pain on at least 11 of 18 specified tender points on the body when palpated. People diagnosed with fibromyalgia not only experience widespread pain but also experience poor sleep quality, fatigue, extreme sensitivity, irritable bowel (diarrhoea, stomach pain) as well headaches (247). Fibromyalgia can be difficult to diagnose as there is no single diagnostic test, symptoms may fluctuate from day to day, and it often coexists with other chronic illnesses such as arthritis, depression or sleep apnoea (248). In a North American survey, approximately half the participants surveyed had consulted three to six health care professionals before receiving their diagnosis (249).

Fibromyalgia is a chronic and disabling condition that can affect all aspects of life, including work, family and leisure (250). In developed countries, fibromyalgia is estimated to affect approximately 2 to 5% of the population, predominantly young to middle-aged women (248). For those who are successfully diagnosed, management of symptoms is the mainstay of treatment, with various drug and nondrug treatments playing a supportive role in managing pain, promoting sleep and reducing stress. Sedentary lifestyles for people diagnosed with fibromyalgia can increase their risk for several chronic diseases (251). International guidelines therefore encourage physical therapy and exercise, including yoga, Pilates and Tai chi to optimise overall health and quality of life (252-254). Regular exercise is important to manage fibromyalgia as it can improve range of motion, flexibility, bone and muscle strength as well as balance (253).

4.15.2 Description of studies

Five citations (255-259) corresponding to three RCTs (Altan 2009, de Medeiros 2020, Ekici 2014) and one quasi RCT (Ekici 2014) were identified in the literature search. There were four ongoing studies and three studies awaiting classification (Ekici 2008, Mendes Tozim 2014, Palekar 2014) (260, 261), two of which were published in a language other than English. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D5.6.1.

Three studies were carried out in outpatient settings in either Brazil (de Medeiros 2020) or Turkey (Altan 2009, Ekici 2014) with the sample size ranging from 36 to 50 participants (total 150). All three studies enrolled women who were diagnosed with fibromyalgia according to the American College of Rheumatology classification criteria. Two studies only included participants if they scored between three and eight (de Medeiros 2020) or more than five (Ekici 2014) on the Visual Analogue Scale for pain. There was no prespecified pain threshold required for inclusion in Altan 2009.

All three studies compared Pilates exercises with an active comparator, being either home relaxation and stretching exercises (Altan 2009), aqua aerobics (de Medeiros 2020), or connective tissue massage (Ekici 2014). Each Pilates session was typically one hour in duration, but the treatment programs ranged in intensity from three times a week for four weeks (Ekici 2014), to two (de Medeiros 2020) or three times a

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

week (Altan 2009) for 12 weeks. Post-treatment evaluation at 24 weeks was carried out in one study (Altan 2009).

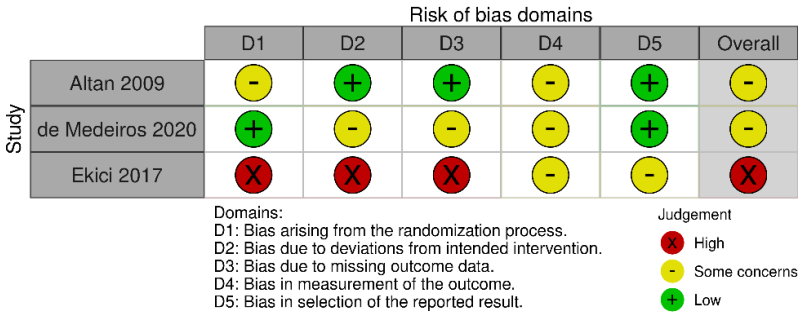
There were no studies identified comparing Pilates with no intervention in people with chronic widespread pain (fibromyalgia). Results of the three studies (Altan 2009, de Medeiros 2020, Ekici 2014) comparing Pilates with an active comparator are presented in Appendix F2.

4.15.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 50. Details are provided in Appendix D5.6.2.

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

Figure 50 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Chronic widespread pain (fibromyalgia)



4.15.4 Main comparison (vs control)

4.15.4.1 Summary of findings

There were no studies found for outcomes selected *a priori* as critical or important, thus the effect of Pilates compared with control on these outcomes in people with chronic widespread pain is unknown.

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

- pain
- functional capacity
- quality of life
- fatigue
- tenderness
- stiffness
- sleep quality

4.16 Low back pain

4.16.1 Description of the condition

Low back pain (LBP) is the most encountered musculoskeletal problem in general practice in Australia and the leading cause of disability globally (262-264). National data reports approximately 16% of Australians experienced back pain in 2017-18 (265). While LBP is generally benign and self-limiting, approximately 10-40% with acute LBP develop persistent and debilitating chronic LBP that continues for more than 3 months (263). Direct and indirect costs of LBP are reportedly $1 billion and $8 billion, respectively (266). LBP is defined by the location of pain, typically between the lower rib margins and the buttock creases and is commonly accompanied by pain in one or both legs. Some may also experience associated neurological symptoms in the lower limbs (264). In most cases there is no specific cause of LBP and is subsequently labelled nonspecific LBP[e]. Individuals with other general physical and mental health conditions are more likely to experience LBP and pain in other body sites. While the cause of LBP remains unclear, risk factors include genetics, previous episode of LBP, poor posture, physically demanding tasks and lack of physical activity (264).

International guidelines consistently recommend excluding serious and/or specific causes of LBP but spinal imaging should not be routinely requested (262, 263). Advice to stay active and return to normal activities as soon as possible is a core recommendation and if the problem continues, the international guidelines recommend various forms of exercise as therapy, but no one approach appears superior to another (262). However, evidence-based guidelines are not consistently translated into clinical practice and medications including opioids are overprescribed (267). Help seeking behaviours are primarily driven by characteristic factors of pain, impaired daily activities, diminished ability to work, and reduced enjoyment of life (268). Providers commonly sought include general practitioners, physiotherapists, chiropractors, massage therapists and acupuncturists and as per guidelines, exercise is commonly prescribed for people experiencing LBP (268). Various nonpharmacological therapies that may be beneficial for LBP include rehabilitation, spinal manipulation, exercise therapy and mind-body interventions (269).

4.16.2 Description of studies

Forty-two citations (270-311) corresponding to 19 RCTs (Albert Anand 2014, Bhadauria 2017, Brooks 2012, Cruz-Diaz 2015, Cruz-Diaz 2016, Cruz-Diaz 2017, Cruz-Diaz 2018, Devasahayam 2016, Dsa 2014, Kofotolis 2016, Lopes 2014, Miyamoto 2011, Miyamoto 2016, Mostagi 2015, Natour 2011, Patti 2016, Quinn 2011, Valenza 2017, Wajswelner 2011), 11 quasi RCTs (Avila Ribeiro 2015, Da Fonseca 2009, Donzelli 2006, Gladwell 2006, Gonzalez-Galvez 2019, Hasanpour-Dehkordi 2017, Mazloum 2016, Rajpal 2008, Rydeard 2006, Silva 2018, Zeada 2012) and three NRSIs (Kliziene 2017, Notarnicola 2014, Pappas 2013) were identified in the literature search.

There were nineteen ongoing studies and ten studies awaiting classification (312-321), two of which were published in a language other than English. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D5.7.1.

The studies were predominantly carried out in single care settings in a variety of countries including Brazil (Avila Ribeiro 2015, da Fonseca 2009, Miyamoto 2011, Natour 2011, Silva 2018), Egypt (Zeada 2012), Greece (Kofotolis 2016), India (Albert Anand 2014, Bhaduria 2017, Dsa 2014, Rajpal 2008), Iran (Hasanpour-Dehkordi 2017, Mazloum 2016), Italy (Donzelli 2006, Patti 2016), Lithuania (Kliziene 2017), Portugal (Lopes 2017),

[e] Mechanical causes of LBP related to spondylolisthesis and other arthropathies are discussed elsewhere

Singapore (Devasahayam 2016), Spain (Cruz-Diaz 2015, Cruz-Diaz 2018, Gonzalez-Galvez 2019, Valenza 2017) and the UK (Quinn 2011). Ten studies recruited participants from the local community or multiple care settings in Australia (Brooks 2012, Wajswelner 2011), Brazil (Miyamoto 2016, Mostagi 2015), Hong Kong (Rydeard 2006), Greece (Pappas 2013) Italy (Notarnicola 2014) and Spain (Cruz-Diaz 2016, Cruz-Diaz 2017,) and the UK (Gladwell 2006).

Twenty-nine studies included participants with chronic LBP defined as pain lasting for at least 3 months; with another two studies (Notarnicola 2014, Da Fonseca 2009) enrolling participants with chronic LBP defined as constant pain lasting for 6 months or longer. In two studies (Pappas 2013, Rydeard 2006) LBP had been persistent for at least six weeks or there had been at least two episodes of recurrent pain in the previous year. Participant ages ranged from 18 to 80 years in all studies except one (Gonzalez-Galvez 2019) that enrolled adolescents aged between 14-16 years. Sample sizes ranges from 5 to 296 participants (total 1946).

There were 21 studies that compared Pilates exercises (either mat or equipment based) with an inactive control being either: no intervention (Cruz-Diaz 2015, Cruz-Diaz 2016, Cruz-Diaz 2017, Hasanpour-Dehkordi 2017, Kliziene 2017, Kofotolis 2016, Lopes 2014, Miyamoto 2011, Miyamoto 2016, Natour 2011, Pappas 2013, Quinn 2011), usual activities or usual care (da Fonseca 2009, Gladwell 2006, Mazloum 2016, Notarnicola 2014, Patti 2016, Rydeard 2006, Zeada 2012) or an educational booklet providing advice about back care (Cruz-Diaz 2018, Valenza 2017). In one study (Natour 2011), Pilates was delivered as an adjunct to usual care that included the use of nonsteroidal anti-inflammatory drugs. Each Pilates session was typically one hour in duration, but the treatment programs ranged in intensity from a single session (Lopes 2014) to being practised between two and five times per week for four, six, eight, 12 or 24 weeks (Notarnicola 2014).

Fifteen studies compared Pilates with an active comparator or included an active comparator arm in the study. The interventions involved Classical kinesiotherapy (AvilaRibeiro 2015), McKenzie training (Hasanpour-Dehkordi 2017, Rajpal 2008), 'Back School' (Donzelli 2006), or conventional therapeutic exercises or physical therapy (Albert Anand 2014, Bhadauria 2017, Brooks 2012, Devasahayam 2016, Dsa 2014, Gonzalez-Galvez 2019, Kofotolis 2016, Mazloum 2016, Mostagi 2015, Silva 2018, Wajswelner 201).

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings table (see 4.16.4.1) (and Appendix F2).

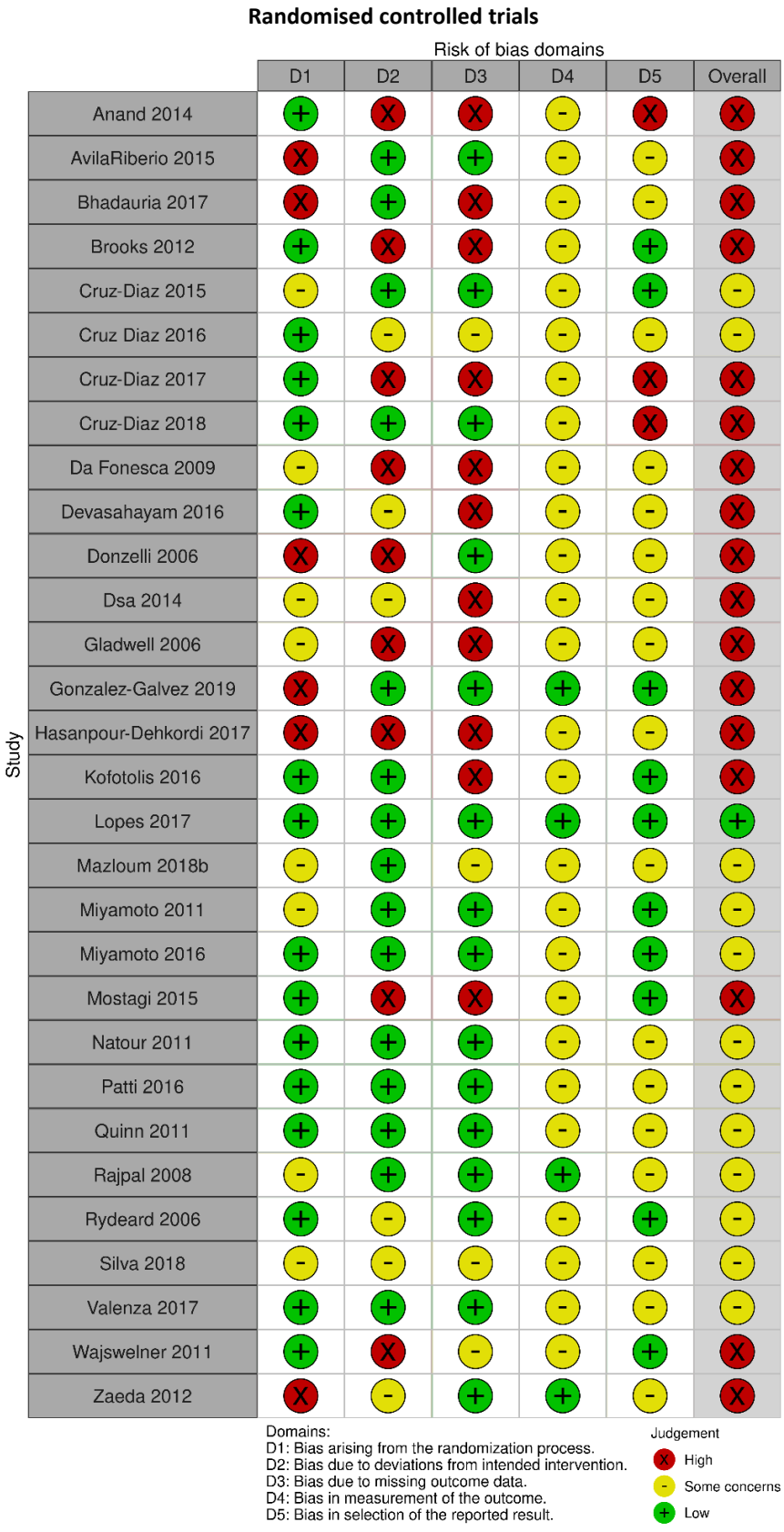
Results of the RCTs (Albert Anand 2014, Avila Ribeiro 2015, Bhaduria 2017, Brooks 2012, Devasahayam 2016, Donzelli 2006, Dsa 2014, Hasanpour-Dehkordi 2017, Kofotolis 2016, Mazloum 2016, Mostagi 2015, Rajpal 2008, Silva 2018, Wajswelner 2011) comparing Pilates with an active comparator are presented in Appendix F2. One study (Gonzalez-Galvez 2019) did not measure or report any outcomes considered critical or important to this review.

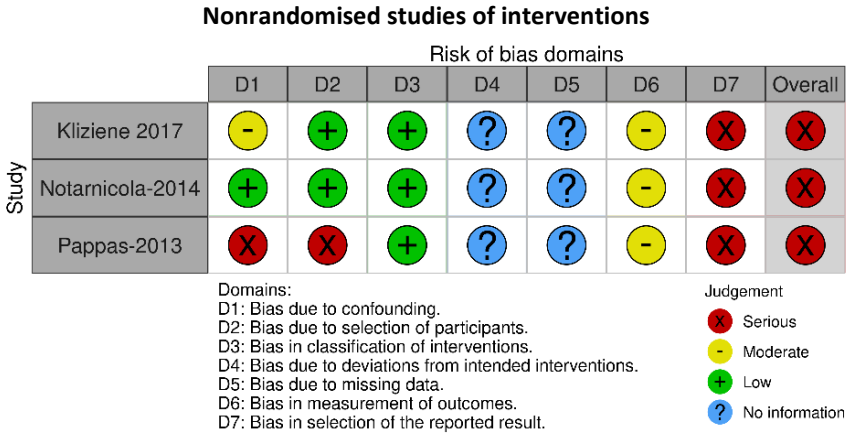
4.16.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 51. Details are provided in Appendix D5.7.2.

One study (Lopes 2017) was judged to be at overall low risk of bias.

Figure 51 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Low back pain





4.16.4 Main comparison (vs control)

Eighteen studies were eligible for this comparison and contributed data relevant to five of the six outcomes. (Cruz-Diaz 2015, Cruz Diaz 2016, Cruz-Diaz 2017, Cruz-Diaz 2018, da Fonesca 2009, Gladwell 2006, Hasanpour-Dehkordi 2017, Kofotolis 2016, Lopes 2014, Mazloum 2016, Miyamoto 2011, Miyamoto 2016, Natour 2011, Patti 2016, Quinn 2011, Rydeard 2006, Valenza 2017, Zeada 2012).

The three NRSIs (Kliziene 2017, Notarnicola 2014, Pappas 2013) were judged to be at serious risk of bias and were therefore not considered in the reporting of results, evidence synthesis or conclusions.

There were five additional studies awaiting classification (one published in language other than English) and one ongoing study (complete but results not available) that compared Pilates with no intervention in people with low back pain (total 230 participants) that could have contributed data to three outcomes (pain, disability and quality of life) (see Appendix C6).

4.16.4.1 Summary of findings

Pilates compared to control (no intervention, wait list or usual care) for Low back pain

Patient or population: Low back pain
Setting: Community
Intervention: Pilates
Comparison: control (no intervention, wait list or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Pain assessed with: NPRS (0-10) or McGill Pain Questionnaire (0-78) (Higher is worse) or SF-36 Bodily Pain (0-100) (higher is best) follow-up: range 1 day to 12 weeks	-	SMD **1.18 SD lower^** (1.62 lower to 0.75 lower)	-	966 (13 RCTs) missing data from 3 RCTs (194 participants)	⨁⨁◯◯ LOW [a,b,c,d,e]	The evidence suggests Pilates results in a large reduction in pain in people with low back pain.**

Pilates compared to control (no intervention, wait list or usual care) for Low back pain

Patient or population: Low back pain
Setting: Community
Intervention: Pilates
Comparison: control (no intervention, wait list or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Disability assessed with: ODI (0-100) or RMDQ (0-24) (Higher is worse) follow-up: range 6 weeks to 14 weeks	-	SMD **0.82 points lower^** (1.05 lower to 0.59 lower)	-	937 (12 RCTs) missing data from 2 RCTs (91 participants)	⊕⊕⊕◯ MODERATE c,d,e,f,g	Pilates probably results in a moderate reduction in disability in people with low back pain.***
Functional capacity assessed with: Patient Specific Functional Scale (3-items) (Higher is best) Scale from: 0 to 10 follow-up: 6 weeks	The mean functional capacity ranged from **5.0 to 6.4** points	MD **1.47 lower** (2.04 lower to 0.9 lower)	-	381 (2 RCTs)	⊕⊕⊕◯ MODERATE c,d,h,i,j	Pilates probably results in little to no difference in functional capacity in people with low back pain. ****
Quality of life assessed with: SF-6D Scale from: 0 to 1	The mean score was **0.78 points**	MD **0.04 higher** (0.06 higher to 0.02 higher)	-	295 (1 study)	⊕⊕⊕◯ MODERATE c,d,h,k,l	Pilates probably results in a slight improvement in quality of life in people with low back pain.*****
Physical performance - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on physical performance in people with low back pain is unknown.
Work status - not reported assessed with: Time to return to work	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on work status in people with low back pain is unknown.
Analgesic use (nonnarcotic) assessed with: Self-reported (higher is worse) follow-up: 90 days	The mean analgesic use (nonnarcotic) was **12.36**	MD **5.66 fewer** (13.73 fewer to 2.41 more)	-	60 (1 RCT)	⊕⊕◯◯ LOW c,h,k,l,m	The evidence suggests that Pilates results in little to no difference in nonnarcotic analgesic use in people with low back pain.
Analgesic use (narcotic) - not reported assessed with: Self-reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on narcotic analgesic use in people with low back pain is unknown.

Pilates compared to control (no intervention, wait list or usual care) for Low back pain

Patient or population: Low back pain
Setting: Community
Intervention: Pilates
Comparison: control (no intervention, wait list or usual care)

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

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
** The minimal detectable change for NPRS is 2 points (187) (not reached).
*** The MCID for ODI is 12.88 points (322) and for RMDQ is 5 points (171, 172) (not reached).
**** The minimal detectable change is 2 points (323) (not reached).
*****The MCID for the SF-6D in chronic low back pain is 0.031 (322).#

^ As a rule of thumb, an SMD of 0.2 represents a small difference, 0.5 is moderate, and 0.8 is a large difference (59).
# Effect estimates were considered on three levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).

CI: confidence interval; **MD:** mean difference; **NPRS:** Numeric Pain Rating Scale; **ODI:** Oswestry Disability Index; **RMDQ:** Roland Morris Disability Questionnaire

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. Five RCTs (35.7% weight) at high risk of bias that influence the results. Certainty of evidence downgraded.
b. Serious inconsistency. Confidence intervals do not overlap (I^2 = 87%). Certainty of evidence downgraded.
c. No serious indirectness. The available evidence is generalisable to the Australian population with few caveats. The studies are in people with chronic low back pain lasting longer than 3 months. Certainty of evidence not downgraded.
d. No serious imprecision. Certainty of evidence not downgraded.
e. Publication bias not suspected. Certainty of evidence not downgraded.
f. Three RCTs (22.8% weight) at high risk of bias that influence the results. Certainty of evidence downgraded.
g. Some inconsistency. Confidence intervals for most (but not all) studies overlap. Certainty of evidence not downgraded.
h. No serious risk of bias. Certainty of evidence not downgraded.
i. No serious inconsistency. Certainty of evidence not downgraded.
j. Publication bias suspected. Evidence limited to two studies from same research group. Certainty of evidence downgraded.
k. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
l. Publication bias suspected. Evidence limited to a small number of small trials. Certainty of evidence downgraded.
m. Serious imprecision. Single study (60 participants). Wide confidence interval (lower bound overlaps with no important difference). Certainty of evidence downgraded.

4.16.4.2 Forest plots

Outcome results related to pain in people with low back pain are presented in Figure 52.

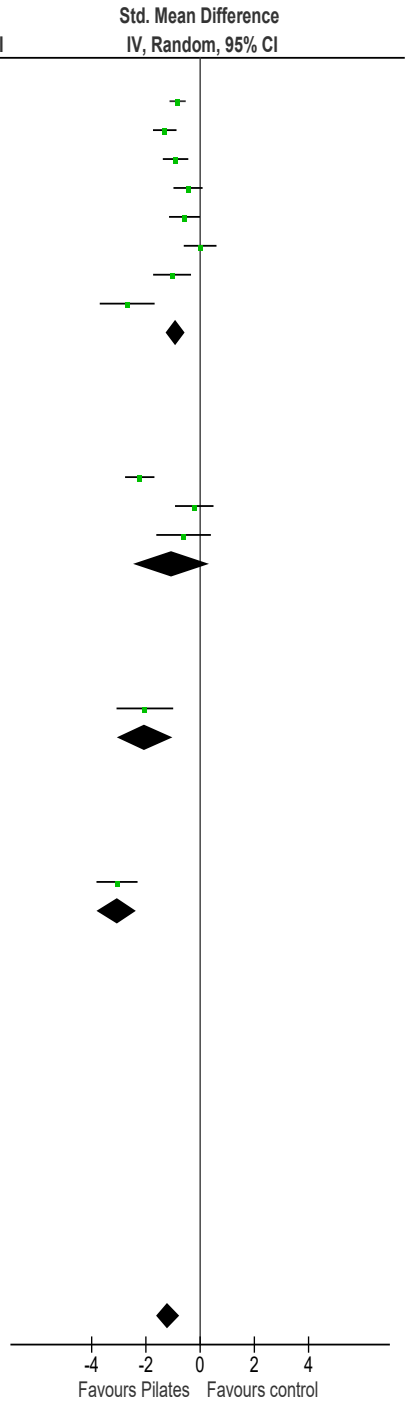
Outcome results related to disability in people with low back pain are presented in Figure 53.

Outcome results related to functional capacity in people with low back pain are presented in Figure 54.

Outcome results related to quality of life in people with low back pain are presented in Figure 55

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

Figure 52 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Low back pain – Pain



Footnotes

(1) Data reported as mean change from baseline (SD)

(2) measured immediately after one session.

(3) Reported by study authors as mean (SEM). SD calculated posthoc.

(4) Mat and Equipment Pilates groups combined as per Cochrane Chapter 6.

(5) Study does not report this outcome, probably because the outcome was not assessed.

(6) Results reported in graphs and not extracted. Authors note a signficant between group difference at end of treatment t(95) = 6.91, p < .000.

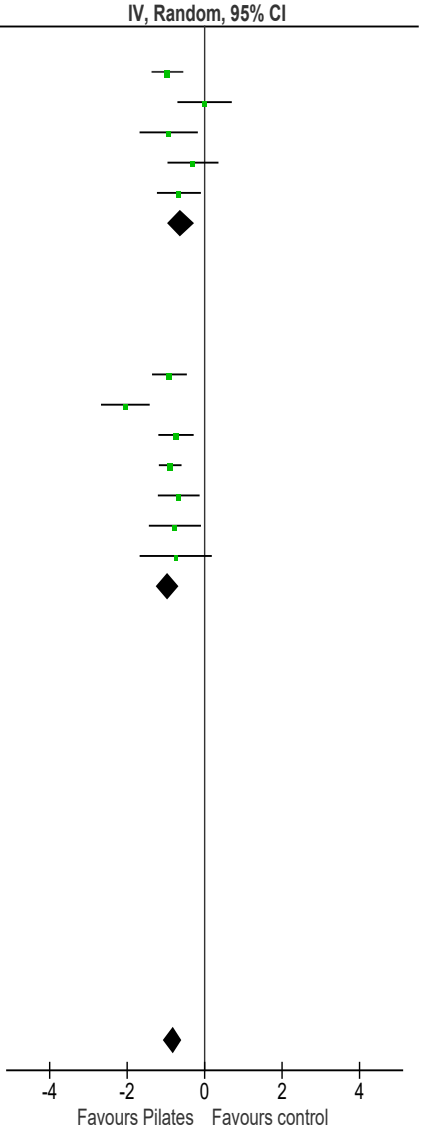
(7) Results are expressed as median and 95% CI (non-normal distributed data) and not included here.

(8) Results reported as mean change from baseline (range) and not included here. Authors report an effect favouring Pilates (p = 0.047).

(9) Study does not report this outcome, possibly because the P value, magnitude or direction of the results generated were considered unfavourable by the study...

Figure 53 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Low back pain – Disability

Study or Subgroup	Pilates Mean	Pilates SD	Pilates Total	Control Mean	Control SD	Control Total	Weight	Std. Mean Difference IV, Random, 95% CI
14.2.1 Oswestry Disability Index (0-100) (RCTs)								
Cruz-Diaz 2016	16.55	2.24	57	19.29	3.34	55	10.9%	-0.96 [-1.35, -0.57]
Gladwell 2006 (1)	18.1	11.2	20	18.1	13	14	6.6%	0.00 [-0.68, 0.68]
Mazloum 2018	22.7	3.1	16	26.6	4.9	16	6.1%	-0.93 [-1.66, -0.19]
Patti 2016	6.5	4	19	8.4	7.8	19	7.1%	-0.30 [-0.94, 0.34]
Valenza 2017 (2)	-16.35	14.07	27	-4.5	20.52	27	8.3%	-0.66 [-1.21, -0.11]
Subtotal (95% CI)			**139**			**131**	**39.0%**	**-0.61 [-0.97, -0.25]**
Heterogeneity: Tau² = 0.08; Chi² = 7.56, df = 4 (P = 0.11); I² = 47%								
Test for overall effect: Z = 3.36 (P = 0.0008)								
14.2.2 Roland Morris Disability Questionnaire (0-24)								
Cruz-Diaz 2017 (3)	5.57	5.13	68	10.41	5.6	34	10.2%	-0.91 [-1.34, -0.48]
Kofotolis 2016	3.32	1.78	37	10.09	4.55	28	7.5%	-2.05 [-2.66, -1.44]
Miyamoto 2011	3.6	3.4	43	7.1	5.7	43	10.1%	-0.74 [-1.18, -0.30]
Miyamoto 2016	6.7	4.82	222	11.3	6.1	73	13.0%	-0.89 [-1.16, -0.61]
Natour 2011	6.79	5.34	30	10.59	5.88	30	8.8%	-0.67 [-1.19, -0.15]
Rydeard 2006 (4)	2	1.3748	21	3.2	1.6971	18	6.9%	-0.77 [-1.42, -0.11]
Zeada 2012	4.65	2.8	10	6.35	1.3	10	4.5%	-0.75 [-1.66, 0.17]
Subtotal (95% CI)			**431**			**236**	**61.0%**	**-0.95 [-1.25, -0.66]**
Heterogeneity: Tau² = 0.09; Chi² = 15.04, df = 6 (P = 0.02); I² = 60%								
Test for overall effect: Z = 6.27 (P < 0.00001)								
14.2.3 outcome not reported								
Cruz-Diaz 2018 (5)	5	0	32	9	0	30		Not estimable
da Fonseca 2009 (6)	0	0	8	0	0	9		Not estimable
Hasanpour-Dehkordi 2017 (7)	0	0	12	0	0	12		Not estimable
Lopes 2014 (8)	0	0	23	0	0	23		Not estimable
Quinn 2011 (9)	-4.5	0	15	-7.5	0	14		Not estimable
Valenza 2017 (10)	-5.31	3.37	27	-2.4	6.78	27	0.0%	-2.91 [-5.77, -0.05]
Subtotal (95% CI)			**0**			**0**		**Not estimable**
Heterogeneity: Not applicable								
Test for overall effect: Not applicable								
Total (95% CI)			**570**			**367**	**100.0%**	**-0.82 [-1.05, -0.59]**
Heterogeneity: Tau² = 0.09; Chi² = 25.29, df = 11 (P = 0.008); I² = 56%								
Test for overall effect: Z = 7.01 (P < 0.00001)								
Test for subgroup differences: Chi² = 2.08, df = 1 (P = 0.15), I² = 52.0%								



Footnotes

(1) RCT at high risk of bias

(2) Data reported as mean change from baseline (SD)

(3) Mat and Equipment Pilates groups combined as per Cochrane Chapter 6.

(4) Reported by study authors as mean (SEM). SD calculated posthoc.

(5) Values are expressed as median and 95% CI (non-normal distributed data) and not included here.

(6) Study does not report this outcome, and it is unclear if the outcome was assessed.

(7) Study does not report this outcome, and it is unclear if the outcome was assessed.

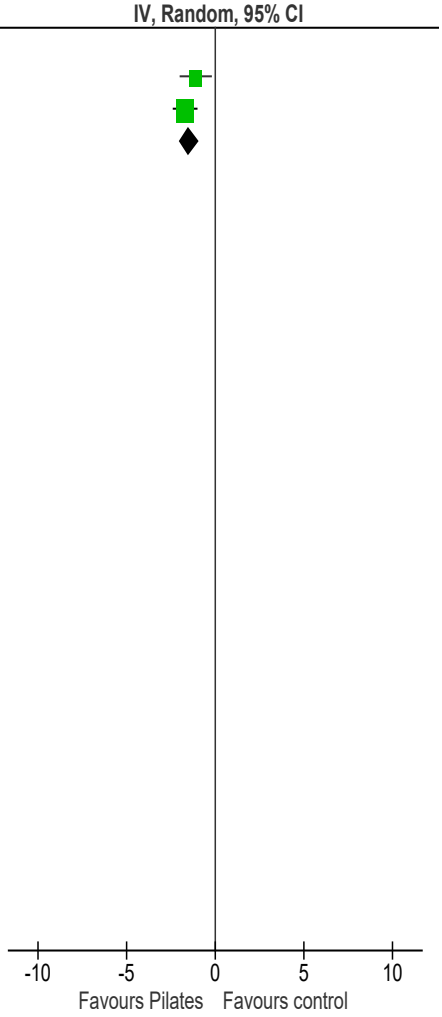
(8) Study does not report this outcome, and it is unclear if the outcome was assessed.

(9) Authors only report mean change.

(10) Study measures and reports both RMDQ and ODI. Only the ODI results included here.

Figure 54 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Low back pain – Functional capacity

Study or Subgroup	Pilates Mean	Pilates SD	Pilates Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
14.3.3 Patient Specific Functional Scale (3-items)								
Miyamoto 2011	-7.5	2.1	43	-6.4	2	43	38.5%	-1.10 [-1.97, -0.23]
Miyamoto 2016 (1)	-6.7	2.1	222	-5	2.6	73	61.5%	-1.70 [-2.36, -1.04]
Subtotal (95% CI)			**265**			**116**	**100.0%**	**-1.47 [-2.04, -0.90]**
Heterogeneity: Tau² = 0.03; Chi² = 1.17, df = 1 (P = 0.28); I² = 14%								
Test for overall effect: Z = 5.03 (P < 0.00001)								
14.3.4 outcome not reported, probably not assessed								
Cruz-Diaz 2015	0	0	51	0	0	52		Not estimable
Cruz-Diaz 2016	0	0	57	0	0	55		Not estimable
Cruz-Diaz 2017	0	0	68	0	0	34		Not estimable
Cruz-Diaz 2018	0	0	32	9	0	30		Not estimable
da Fonseca 2009	0	0	8	0	0	9		Not estimable
Gladwell 2006	0	0	20	0	0	14		Not estimable
Hasanpour-Dehkordi 2017	0	0	12	0	0	12		Not estimable
Kofotolis 2016	0	0	37	0	0	28		Not estimable
Lopes 2014	0	0	23	0	0	23		Not estimable
Mazloum 2018	0	1	16	0	0	16		Not estimable
Natour 2011	0	0	30	0	0	30		Not estimable
Patti 2016	0	0	19	0	0	19		Not estimable
Quinn 2011	0	0	15	0	0	14		Not estimable
Rydeard 2006	0	0	21	0	0	18		Not estimable
Valenza 2017	0	0	27	0	0	27		Not estimable
Zeada 2012	0	0	0	0	0	0		Not estimable
Subtotal (95% CI)			**0**			**0**		**Not estimable**
Heterogeneity: Not applicable								
Test for overall effect: Not applicable								

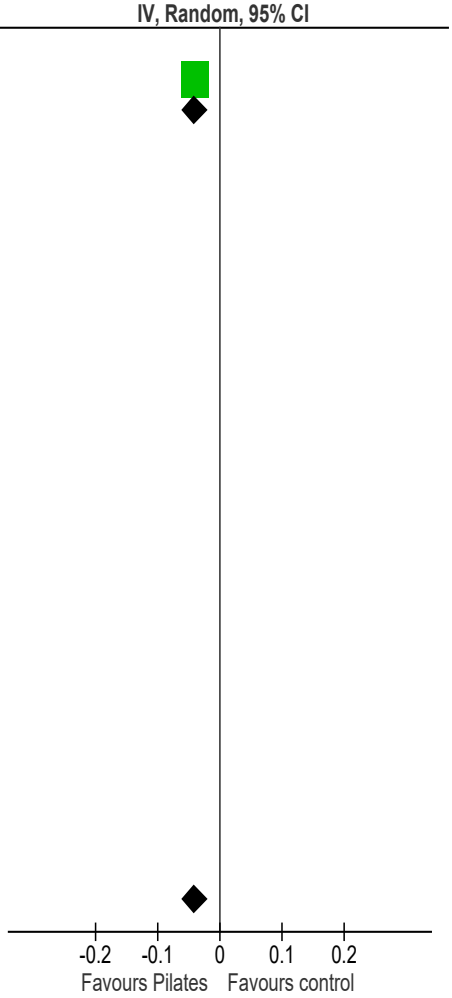


Footnotes

(1) The summary statistics across the three intervention arms (different number of sessions of Pilates per week) were combined as per Cochrane...

Figure 55 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Low back pain – Quality of life

Study or Subgroup	Pilates Mean	Pilates SD	Pilates Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
14.4.9 Overall Quality of Life (SF-6D)								
Miyamoto 2016 (1)	-0.82	0.08	222	-0.78	0.08	73	100.0%	-0.04 [-0.06, -0.02]
Subtotal (95% CI)			**222**			**73**	**100.0%**	**-0.04 [-0.06, -0.02]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 3.71 (P = 0.0002)								
14.4.10 outcome not reported, probably not assessed								
Cruz-Diaz 2015	0	0	51	0	0	52		Not estimable
Cruz-Diaz 2016	0	0	57	0	0	55		Not estimable
Cruz-Diaz 2017	0	0	68	0	0	34		Not estimable
Cruz-Diaz 2018	0	0	32	9	0	30		Not estimable
da Fonseca 2009	0	0	8	0	0	9		Not estimable
Gladwell 2006 (2)	0	0	20	0	0	14		Not estimable
Hasanpour-Dehkordi 2017	0	0	12	0	0	12		Not estimable
Kofotolis 2016	0	0	37	0	0	28		Not estimable
Lopes 2014	0	0	23	0	0	23		Not estimable
Mazloum 2018	0	0	16	0	0	16		Not estimable
Patti 2016	0	0	19	0	0	19		Not estimable
Quinn 2011	0	0	15	0	0	14		Not estimable
Rydeard 2006	0	0	21	0	0	18		Not estimable
Valenza 2017	0	0	27	0	0	27		Not estimable
Zeada 2012	0	0	10	0	0	10		Not estimable
Subtotal (95% CI)			**416**			**361**		**Not estimable**
Heterogeneity: Not applicable								
Test for overall effect: Not applicable								
Total (95% CI)			**638**			**434**	**100.0%**	**-0.04 [-0.06, -0.02]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 3.71 (P = 0.0002)								
Test for subgroup differences: Not applicable								



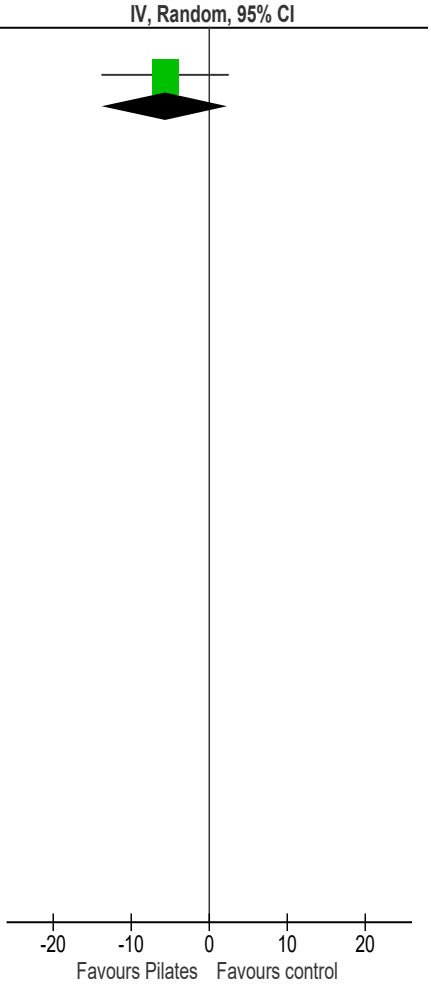
Footnotes

(1) The summary statistics across the three intervention arms (different number of sessions of Pilates per week) were combined as per Cochrane...

(2) Data not able to be interpreted. Scores don't correlate with expected values.

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

Study or Subgroup	Pilates Mean	Pilates SD	Pilates Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
14.6.1 Non-narcotic								
Natour 2011	6.7	12.77	30	12.36	18.59	30	100.0%	-5.66 [-13.73, 2.41]
Subtotal (95% CI)			**30**			**30**	**100.0%**	**-5.66 [-13.73, 2.41]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.37 (P = 0.17)								
14.6.10 outcome not reported, probably not assessed								
Cruz-Diaz 2015	0	0	51	0	0	52		Not estimable
Cruz-Diaz 2016	0	0	57	0	0	55		Not estimable
Cruz-Diaz 2017	0	0	68	0	0	34		Not estimable
Cruz-Diaz 2018	0	0	32	9	0	30		Not estimable
da Fonseca 2009	0	0	8	0	0	9		Not estimable
Gladwell 2006 (1)	0	0	20	0	0	14		Not estimable
Hasanpour-Dehkordi 2017	0	0	12	0	0	12		Not estimable
Kofotolis 2016	0	0	37	0	0	28		Not estimable
Lopes 2014	0	0	23	0	0	23		Not estimable
Mazloum 2018	0	0	16	0	0	16		Not estimable
Miyamoto 2011	0	0	43	0	0	43		Not estimable
Miyamoto 2016 (2)	0	0	222	0	0	73		Not estimable
Patti 2016	0	0	19	0	0	19		Not estimable
Quinn 2011	0	0	15	0	0	14		Not estimable
Rydeard 2006	0	0	21	0	0	18		Not estimable
Valenza 2017	0	0	27	0	0	27		Not estimable
Zeada 2012	0	0	10	0	0	10		Not estimable
Subtotal (95% CI)			**681**			**477**		**Not estimable**
Heterogeneity: Not applicable								
Test for overall effect: Not applicable								



Test for subgroup differences: Not applicable

Footnotes

(1) Data not able to be interpreted. Scores don't correlate with expected values.

(2) The summary statistics across the three intervention arms (different number of sessions of Pilates per week) were combined as per Cochrane Chapter...

4.17 Neck and shoulder pain

4.17.1 Description of the condition

Neck and shoulder pain are common complaints that can impact a person's ability to carry out normal daily activities (324) and lead to considerable disability and economic burden (325). Neck and shoulder pain often prompt a person to consider seeking action. There are multiple origins of neck and shoulder pain. Pain can arise from musculoskeletal conditions including cervical spondylitis and subacromial bursitis (324), shoulder disorders such as rotator cuff tendonitis, acromio-clavicular bursitis and frozen shoulder (326). However, in many cases the pathophysiological mechanisms underlying pain are unclear (324). Risk factors for neck and shoulder pain include individual factors (gender, mental distress, low physical capacity, history of neck or back pain) and workplace factors (physical workload, organisational structure and psychosocial factors) and person's general physical health and wellbeing is thought to be associated with neck and shoulder pain (327).

Prevalence of neck and shoulder pain is high. In Australia, the number of incident cases of neck pain were reportedly 190 000 in 2017 (325). Shoulder pain, the third most frequent musculoskeletal presentation in general practice in Australia, has a reported prevalence of 7 to 34% in the general population (328). In some situations, neck and shoulder pain may occur concurrently and therefore treated as a single diagnostic entity. It may also be accompanied by pain in other anatomical sites. Other times pain isolated to the neck or shoulder may be reflective of local pathology (324).

Nonpharmacologic therapies such as mind-body therapies (Pilates, yoga, tai chi) are thought to improve outcomes for people with neck and shoulder pain. Studies investigating the benefits of mind-body exercises on neck and shoulder pain are limited. Exercises that may reduce pain, improve movement and increase function include strengthening exercises, stretching and breathing techniques (329-331).

4.17.2 Description of studies

Six citations (332-337) corresponding to three RCTs (Atilgan 2017, Cazotti 2015, Ulug 2018) and one quasi RCT (Dunleavy 2016) were identified in the literature search. There were two ongoing studies , two studies awaiting classification (Cheng 2011, Rajalaxmi 2018) (338, 339). No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D5.8.1.

Two studies were carried out in outpatient settings in Brazil (Cazotti 2015) and Turkey (Atilgan 2017). One study (Dunleavy 2016) carried out in the USA included home-based exercises. One study carried out in Turkey did not provide details of the setting (Ulug 2018). Sample sizes range from 30 to 64 (total 171 participants. Three studies included adult participants with non-radiating neck pain lasting for more than 3 months (Cazotti 2013, Dunleavy 2016, Ulug 2018). Cazotti 2015 included participants with mechanical neck pain and an intensity between 3 and 8 on a 10-cm Numerical Pain Scale (NPS) and Dunleavy 2016 included participants who reported average NPS scores of more than three. One study (Atilgan 2017) included 30 participants with persistent shoulder pain lasting for at least four weeks. No details of pain rating or other inclusion criteria were described.

Two studies (Cazotti 2015, Dunleavy 2016) compared Pilates exercises with an inactive control (no intervention). In one study (Cazotti 2015) participants in the control group received only pharmacological treatment throughout the study and were not allowed the use of any adjuvant treatment for neck pain. In both studies, the Pilates sessions lasted 60-minutes and were delivered over 12 weeks, with the exercise intensity progressing over the course of treatment. In one study (Dunleavy 2016) participants attended one session per week and participants in the other study (Cazotti 2015) attended two sessions per week.

Three studies compared Pilates exercises with an active intervention, being either yoga (Dunleavy 2016, Ulug 2018), conventional exercises (Atilgan 2017) or isometric exercises (Ulug 2018). In two studies (Atilgan 2017, Ulug 2018) all participants also received the same pain-relieving therapy consisting of hot pack application and conventional transcutaneous electrical nerve stimulation (TENS) followed by continuous ultrasound for on the shoulder area before the exercises. Exercise sessions were typically 60 minutes in duration, but the intensity ranged from five days a week for two (Atilgan 2017) or six weeks (Ulug 2018) to once a week over a period of 12 weeks (Dunleavy 2016). In one study (Ulug 2018) exercises were supervised for the first three weeks and were home-based thereafter. Prior to exercise training, participant in Ulug 2018 were also provided with information about chronic neck pain, the anatomy of the spine and postural alignment.

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings tables (see 4.17.4.1) (and Appendix F2).

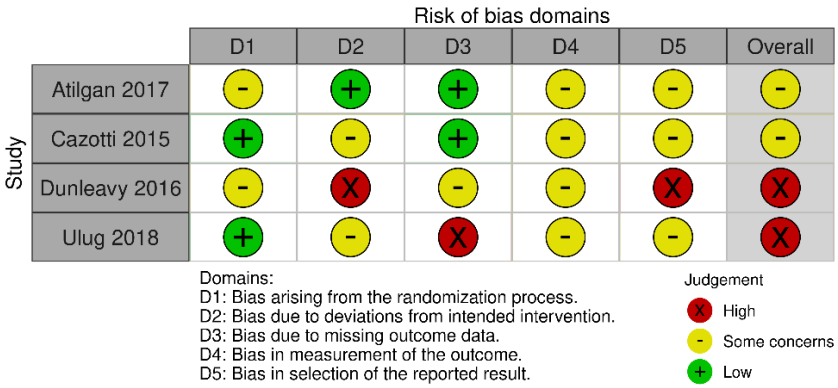
Results of the three studies (Dunleavy 2016, Atiligan 2017, Ulug 2018) that compared Pilates with an active comparator are presented in Appendix F2.

4.17.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 57. Details are provided in Appendix D5.8.2.

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

Figure 57 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Neck and shoulder pain



4.17.4 Main comparison (vs control)

Two studies (Cazotti 2015, Dunleavy 2016) were eligible for this comparison and contributed data to two outcomes. There were two additional studies awaiting classification (available as abstracts only) that compared Pilates with no intervention in people with neck pain (total 97 participants) that could have contributed data to the outcomes of pain and disability (see Appendix C6).

4.17.4.1 Summary of findings

Neck pain

Pilates compared to control (no intervention, wait list or usual care) for Neck Pain

Patient or population: Neck pain
Setting: Community or Outpatient
Intervention: Pilates
Comparison: control (no intervention, waitlist or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Pain assessed with: Numeric Pain Scale (Higher is worse) Scale from: 0 to 10 follow-up: 12 weeks	The mean pain - score ranged from **3.9 to 5.47** points	MD **3.10 lower** (5.22 lower to 0.97 lower)	-	101 (2 RCTs)	⊕◯◯◯ VERY LOW [a,b,c,d,e]	The evidence is very uncertain about the effect of Pilates on pain in people with chronic neck pain.**
Disability assessed with: Neck disability index (Higher is worse) Scale range: 0 to 50 follow-up: 12 weeks	The mean disability score ranged from **10.59 to 12.5** points	MD **6.55 points lower** (8.80 lower to 4.30 lower)	-	101 (2 RCTs)	⊕⊕◯◯ LOW [c,d,e,f,g]	The evidence suggests Pilates reduces neck-related disability in people with chronic neck pain.***
Quality of life assessed with: SF-36 (Higher is best) Scale range: 0 to 100 follow-up: 12 weeks	An effect favouring Pilates found for three of four domains associated with physical wellbeing and three of four domains associated with mental wellbeing. No difference between groups found for two domains.		-	64 (1 RCT)	⊕⊕◯◯ LOW [c,e,h,l,j]	The evidence suggests that Pilates improves some (but not all) aspects of health-related quality of life in people with chronic neck pain.****
Flexibility/Range of motion – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on flexibility/range of motion in people with chronic neck pain is unknown.
Fatigue – not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on fatigue in people with chronic neck pain is unknown.
Return to work - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on the ability of people with chronic neck pain to return to work is unknown.
Psychosocial wellbeing - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on psychosocial wellbeing in people with chronic neck pain is unknown.

Pilates compared to control (no intervention, wait list or usual care) for Neck Pain

Patient or population: Neck pain
Setting: Community or Outpatient
Intervention: Pilates
Comparison: control (no intervention, waitlist or usual care)

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

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
** The MCID for improvement in pain is 2 points (187).
*** The MCID for a reduction in disability is between 4.7 and 5.0 points (340).#
**** The MCID for SF-36-bodily pain is 15.5 points in people with chronic non-specific neck pain (341). For all other domains, the MCID is unknown#. Across each domain, the clinical importance of the effect is variable; being either not different (general health perceptions, role-emotional); not important (bodily pain); moderate (physical function, vitality, role-social, mental health); or large (role-physical).

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

CI: confidence interval; **MD:** mean difference; **SF-36**: 36-item short-form; **SMD:** standardised mean difference

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. One study at high risk of bias (49.4% weight) that does not seriously change the result. Certainty of evidence not downgraded.
b. Serious inconsistency. Minimal overall in confidence intervals. Substantial statistical heterogeneity (I^2 = 89%). Certainty of evidence downgraded.
c. No serious indirectness. The evidence is directly generalisable to the Australian population with few caveats. The studies are in adults with chronic neck pain. Certainty of evidence not downgraded.
d. Serious imprecision. Wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.
f. One study at high risk of bias (36% weight) that does not seriously change the result. Certainty of evidence not downgraded.
g. No serious inconsistency. Certainty of evidence not downgraded.
h. No serious risk of bias. Certainty of evidence not downgraded.
i. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
J. Serious imprecision. Single study. Wide confidence intervals (upper and lower bounds overlap with large to small or no important difference). Certainty of evidence downgraded.

Shoulder pain

There were no studies found for outcomes selected *a priori* as critical or important, thus the effect of Pilates compared with control on these outcomes in people with shoulder pain is unknown.

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

- pain
- function/disability
- quality of life
- flexibility/Range of motion
- global perceived effect
- work status

4.17.4.2 Forest plots

Outcome results related to pain in people with chronic neck pain are presented in Figure 58.

Outcome results related to disability in people with chronic neck pain are presented in Figure 59.

Outcome results related to quality of life in people with chronic neck pain are presented in Figure 60.

Figure 58 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Chronic neck pain – pain

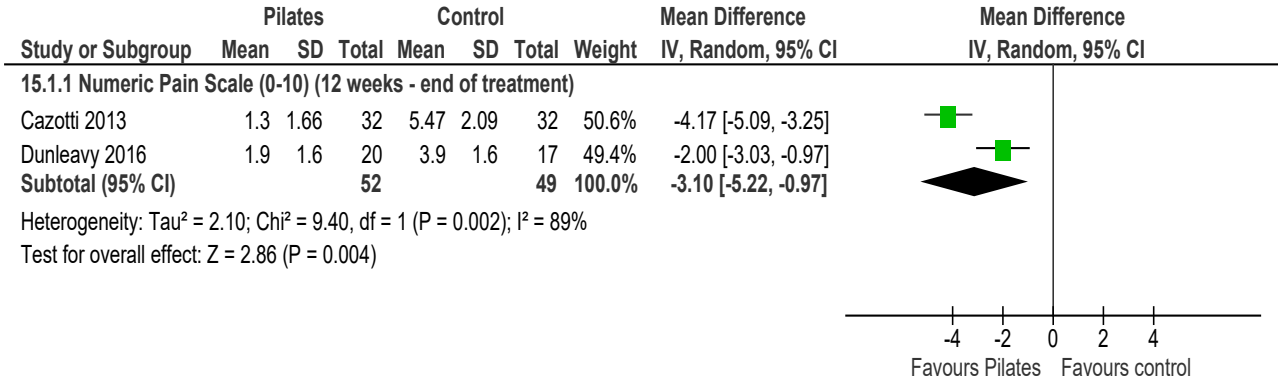


Figure 59 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Chronic neck pain – function/disability

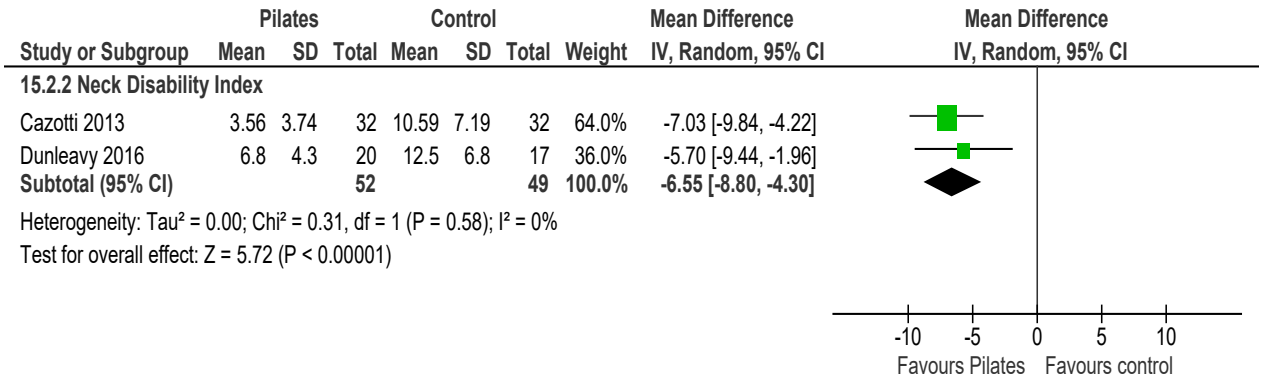
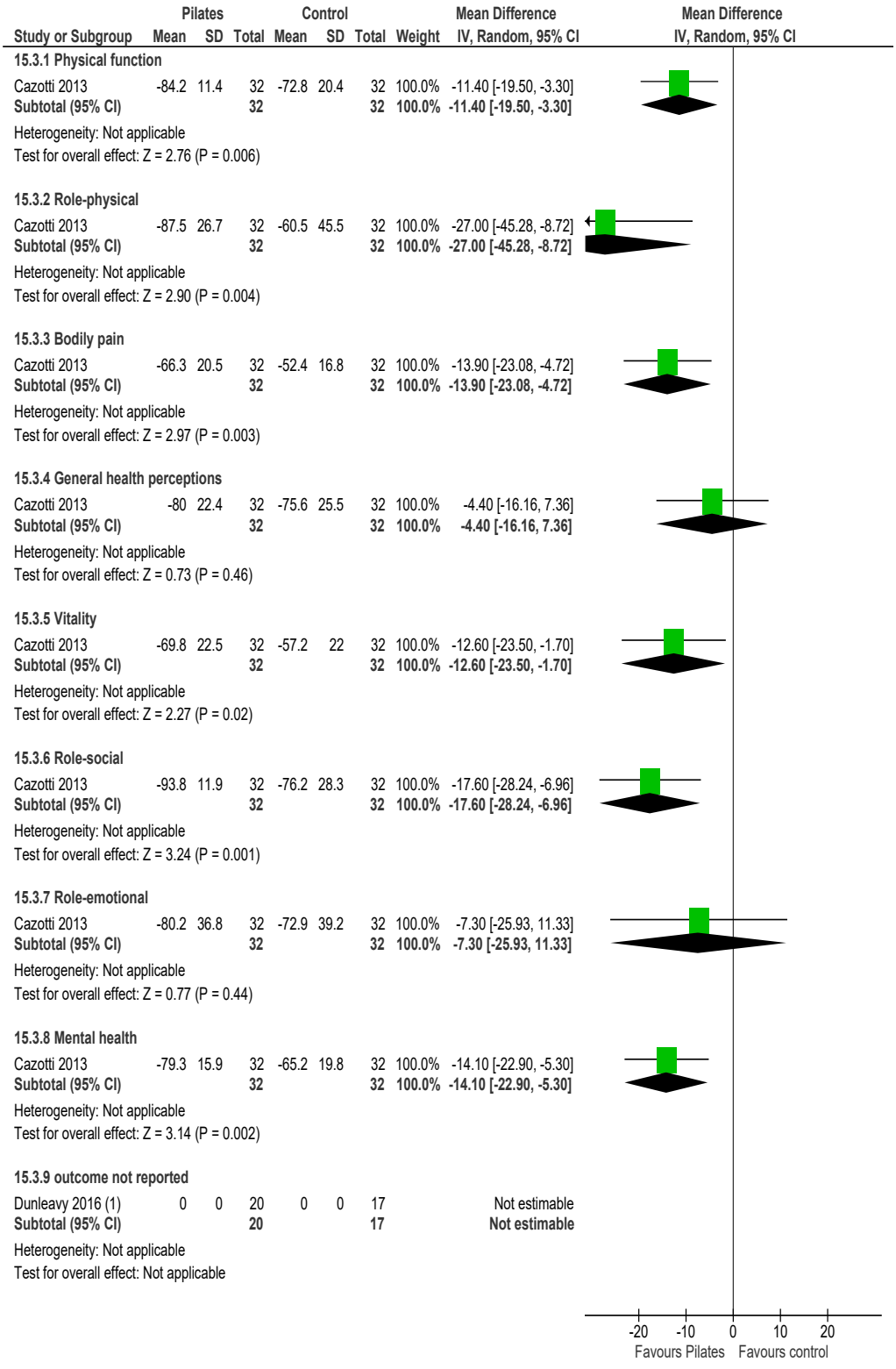


Figure 60 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Neck pain – Quality of life



Footnotes

(1) Study does not report this outcome, probably because the outcome was not assessed.

4.18 Menopausal symptom or complaint

4.18.1 Description of the condition

Natural menopause is defined as the permanent cessation of menses and is a normal process of ageing that is typically confirmed after menstrual periods have been absent for 12 months (342-346). Symptoms of menopause are characterised by the pathological changes that occur during the transition period (perimenopause) and are related to the gradual loss of ovarian follicular function and decline in circulating blood oestrogen levels (345, 347). Perimenopause is estimated to last around four years and is the period when bothersome symptoms such as hot flushes, headache, sleep disturbance, lack of concentration, depressed mood, atrophic genital changes and bone loss can begin, with women who experience a longer transition period more likely to seek help (342, 343). Women with artificial menopause, induced after the surgical removal of ovaries, or through interventions such as chemotherapy or radiation therapy, are also more likely to experience bothersome or disabling symptoms of menopause (344); as are women who experience premature (before 40 years of age) or early menopause (aged between 40 and 45 years) (346).

Natural menopause is estimated to occur between the ages of 47 and 53 years, with education, lifestyle factors (such as smoking, high physical activity), and ethnicity reported to play a role (346, 348, 349). Globally, between 2% and 3.7% of women are estimated to experience premature menopause and between 7.6% and 12.2% of women are estimated to undergo early menopause (349, 350), which places them at increased risk of chronic conditions later in life. In Australia, natural menopause is estimated to occur at a mean age of 52 years (348), with about 1.2% of women undergoing premature menopause and 5.8% experiencing early menopause (349).

Treatment and management of troublesome and disruptive symptoms associated with menopause centre on minimising the effects of declining oestrogen levels through hormone replacement therapy (345, 351-353). Other treatments may focus on managing or preventing specific symptoms such as localised oestrogen cream for vaginal atrophy, blood pressure medications for hot flushes, antidepressants for mood changes, or calcium and Vitamin D for bone loss (351, 353-355). Given the risks associated with long-term hormone replacement therapy (e.g., thromboembolic or coronary events, breast cancer) (344, 351-353), and the variability of symptom severity, many women experiencing mild or moderate symptoms of menopause seek lifestyle and behavioural therapies as an alternative. These include acupuncture (356), herbal medicines (357), relaxation therapies (358) and exercise therapies (359). The Australasian Menopause Society notes that the evidence for the effectiveness of lifestyle or behavioural changes is mixed and limited (351), but note that some may improve general wellbeing and help women manage their symptoms.

4.18.2 Description of studies

Six citations (360-365) corresponding to two RCTs (Ahmadinezhad 2017, Campos de Oliveira 2018) and one quasi RCT (Lee 2016a) were identified in the literature search. There were two ongoing studies (366, 367) and no studies awaiting classification. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D6.1.1.

Two studies were conducted in the community setting in Brazil (Campos de Oliveira 2018) or South Korea (Lee 2016a) and one study was carried out in women referred to a medical clinical in Iran (Ahmadinezhad 2017). The sample size ranged from 51 to 108 participants (total 233). All three studies enrolled women who had confirmed natural menopause (cessation of menses for one or more years), with the mean age of participants being around 50 to 55 years. Participants in Ahmadinezhad 2017 were required to have symptoms of poor sleep quality at enrolment (i.e., a score of 5 or more on the Pittsburgh Sleep Quality Index [PSQI]); whereas participants in Campos de Oliveira 2018 and Lee 2016a had not practised any physical

exercise for 6 months prior to enrolment. Approximately 61% of women in Campos de Oliveira 2018 were assessed to be osteopenic at baseline (T-score between –1 and –2.5), with a further 20% assessed as osteoporotic (T-score less than –2.5).

All three studies compared Pilates exercises with control (no intervention), with the program delivered in one study (Campos de Oliveira 2018) being equipment based (i.e., Cadillac, Reformer, Ladder Barrel, Wall Unit, Chair, Spine Corrector and Small Barrel). In each study, the Pilates sessions were typically one hour in duration and were offered three times a week, but the program ranged from six or eight weeks (Ahmadinezhad 2017, Lee 2016a) to six months (Campos de Oliveira 2018). Two studies also included a second intervention group, with the effect of acupressure examined in one study (Ahmadinezhad 2017) and the effect of whole-body vibration assessed in the other (Campos de Oliveira 2018).

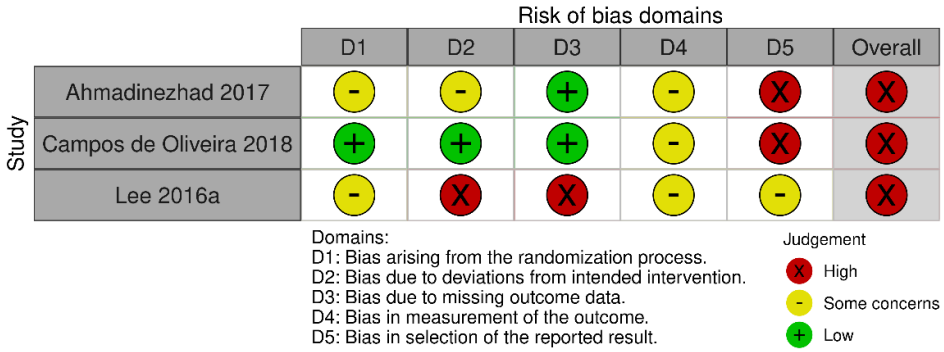
Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings tables (see 4.18.4.1) (and Appendix F2). Results of the two studies (Ahmadinezhad 2017, Campos de Oliveira 2018) that compared Pilates with an active comparator are presented in Appendix F2.

4.18.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 61. Details are provided in Appendix D6.1.2.

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

Figure 61 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Menopausal symptom or complaint



4.18.4 Main comparison (vs control)

Three studies (Ahmadinezhad 2017, Campos de Oliveira 2018, Lee 2016a) were eligible for this comparison and contributed data to six outcomes. There were no studies awaiting classification or ongoing that compared Pilates with no intervention in otherwise healthy menopausal or postmenopausal women that could have contributed data to these outcomes (see Appendix C6).

4.18.4.1 Summary of findings

Pilates compared to Control (no intervention, waitlist, usual care) for menopausal symptoms or complaints

Patient or population: Menopausal symptoms or complaints
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Quality of life, global assessed with: SF-36 (higher is best) follow-up: 26 weeks	Between group differences reported in four domains (role-physical, bodily pain, role-social and role-emotional) but no between group differences reported for (physical function, general health perceptions, vitality or mental health)			34 (1 RCT)	⊕◯◯◯ VERY LOW [a,b,c,d,e]	The evidence is very uncertain about the effect of Pilates on overall quality of life in menopausal and postmenopausal women.
Sleep quality assessed with: Pittsburgh Sleep Quality Index (higher is worse) Scale from: 0 to 21 follow-up: 6 weeks	The mean sleep quality was **14.58** points	MD **9.83 points lower** (11.11 lower to 8.55 lower)	-	72 (1 RCT)	⊕⊕◯◯ LOW [a,b,e,f]	The evidence suggests Pilates results in a large improvement in sleep quality in menopausal and postmenopausal women.**
Vasomotor symptoms assessed with: Menopause Symptoms Questionnaire (higher is worse) Scale from: 0 to 42 follow-up: 8 weeks	The mean vasomotor symptoms score was **17.74**	MD **8.88 points lower** (13.4 lower to 4.36 lower)	-	74 (1 RCT)	⊕⊕◯◯ LOW [a,b,e,g]	The evidence suggests Pilates reduces vasomotor symptoms in menopausal and postmenopausal women.***
Physical symptoms assessed with: Menopause Symptoms Questionnaire (higher is worse) Scale from: 0 to 66 follow-up: 8 weeks	The mean physical symptoms was **33.21** points	MD **14.44 points lower** (20.19 lower to 8.69 lower)	-	74 (1 RCT)	⊕⊕◯◯ LOW [a,b,e,g]	The evidence suggests Pilates improves global physical symptoms in menopausal and postmenopausal women.***
Isokinetic muscle strength (peak torque - knee extensors) assessed with: Dynamometer (60 degrees/s) (higher is better) follow-up: 26 weeks	The mean isokinetic muscle strength (knee extensors) was **95.4 Nm**	MD **14.6 Nm higher** (0.54 higher to 28.66 higher)	-	34 (1 RCT)	⊕◯◯◯ VERY LOW [a,b,c,e,h]	The evidence is very uncertain about the effect of Pilates on muscle strength in menopausal and postmenopausal women.

Pilates compared to Control (no intervention, waitlist, usual care) for menopausal symptoms or complaints

Patient or population: Menopausal symptoms or complaints
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Isokinetic muscle strength (peak torque - knee flexors) assessed with: Dynamometer (60 degrees/s) (higher is better) follow-up: 26 weeks	The mean isokinetic muscle strength (knee flexors) was **50.7 Nm**	MD **6.8 Nm higher** (1.21 lower to 14.81 higher)	-	34 (1 RCT)	⊕◯◯◯ VERY LOW [a,b,c,e,h]	The evidence is very uncertain about the effect of Pilates on muscle strength in menopausal and postmenopausal women.
Bone mineral density assessed with: Dual energy X-ray Absorption follow-up: 26 weeks	No difference between groups observed at the end of treatment for six different bone regions including lumbar spine (L1-L4), femoral neck, total hip, trochanter, intertrochanter and Ward's area.			34 (1 RCT)	⊕◯◯◯ VERY LOW [a,b,c,d,e]	The evidence is very uncertain about the effect of Pilates on bone mineral density in menopausal and postmenopausal women.
Depression - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on depression in menopausal and postmenopausal women is unknown.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
** MCID unknown#. A score of five or more is associated with poor sleep quality.
*** MCID unknown.#

In the absence of an MCID, effect estimates were considered based on the following thresholds: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale), or large (MD more than 20% of the scale).
CI: confidence interval; **MD:** mean difference; **SF-36**: 36-item short-form

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. One study (100% weight) at high risk of bias for the outcome. Certainty of evidence downgraded.
b. Single study. Heterogeneity not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is directly generalisable to the Australian population with some caveats. The available evidence is in postmenopausal women aged between 40 and 70 years. Approximately 61% of women were assessed to be osteopenic at baseline, with an additional 20% assessed as osteoporotic.
d. Serious imprecision. Small study (fewer than 35 participants). Certainty of evidence downgraded.

e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.

f. No serious indirectness. The evidence is generalisable to the Australian population with some caveats. The study is in postmenopausal women aged between 40 and 60 years with poor sleep quality at study entry (score five or more on the PSQI). Certainty of evidence not downgraded.

g. No serious indirectness. The evidence is directly generalisable to the Australian population with few caveats. The study is in menopausal women aged between 45 and 60 years. Certainty of evidence not downgraded.

4.18.4.2 Forest plots

Outcome results related to quality of life in healthy menopausal or postmenopausal women are presented in Figure 62.

Outcome results related to sleep quality in healthy menopausal or postmenopausal women is presented in Figure 63.

Outcome results related to vasomotor symptoms in healthy menopausal or postmenopausal women are presented in Figure 64.

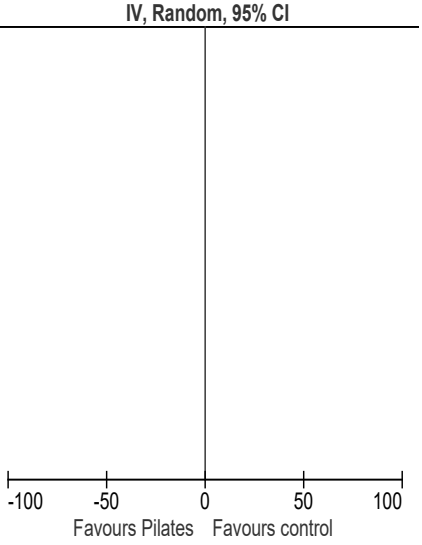
Outcome results related to physical functioning in healthy menopausal or postmenopausal women are presented in Figure 64.

Outcome results related to physical performance in healthy menopausal or postmenopausal women are presented in Figure 65.

Outcome results related to BMD in healthy menopausal or postmenopausal women are presented in Figure 66.

Figure 62 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Menopausal symptom or complaint – quality of life

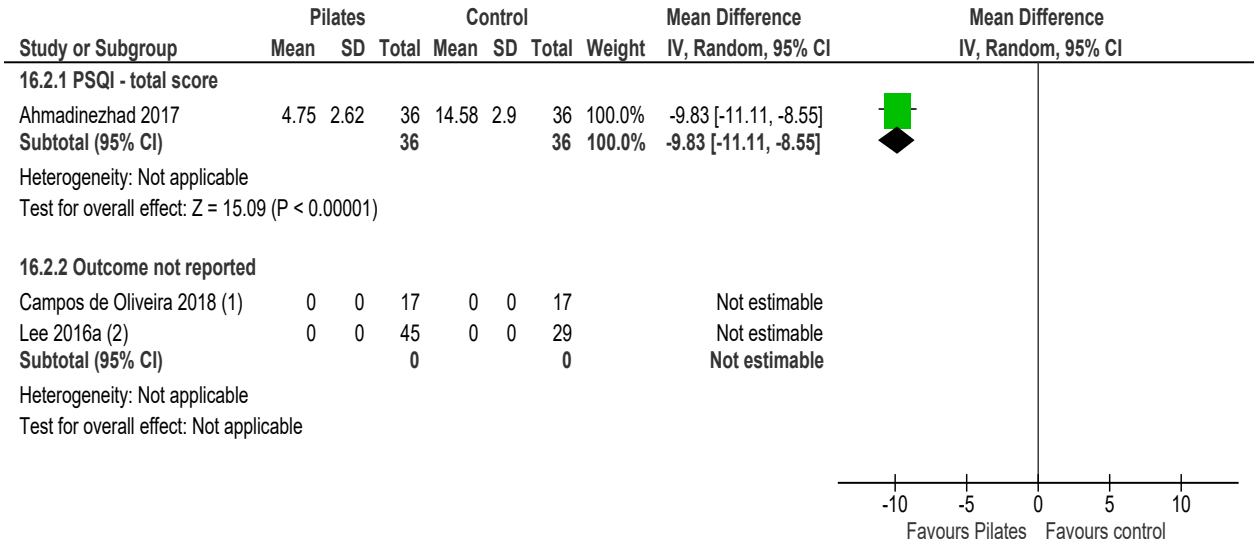
Study or Subgroup	Pilates Mean	Pilates SD	Pilates Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
16.1.1 SF-36 total score								
Campos de Oliveira 2018 (1)	0	0	17	0	0	17		Not estimable
Subtotal (95% CI)			**17**			**17**		**Not estimable**
Heterogeneity: Not applicable								
Test for overall effect: Not applicable								
16.1.2 Outcome not measured								
Ahmadinezhad 2017	0	0	36	0	0	36		Not estimable
Lee 2016a	0	0	45	0	0	29		Not estimable
Subtotal (95% CI)			**0**			**0**		**Not estimable**
Heterogeneity: Not applicable								
Test for overall effect: Not applicable								
Total (95% CI)			**17**			**17**		**Not estimable**
Heterogeneity: Not applicable								
Test for overall effect: Not applicable								
Test for subgroup differences: Not applicable								



Footnotes

(1) Skewed data. Total score not reported by the study authors.

Figure 63 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Menopausal symptom or complaint – sleep quality

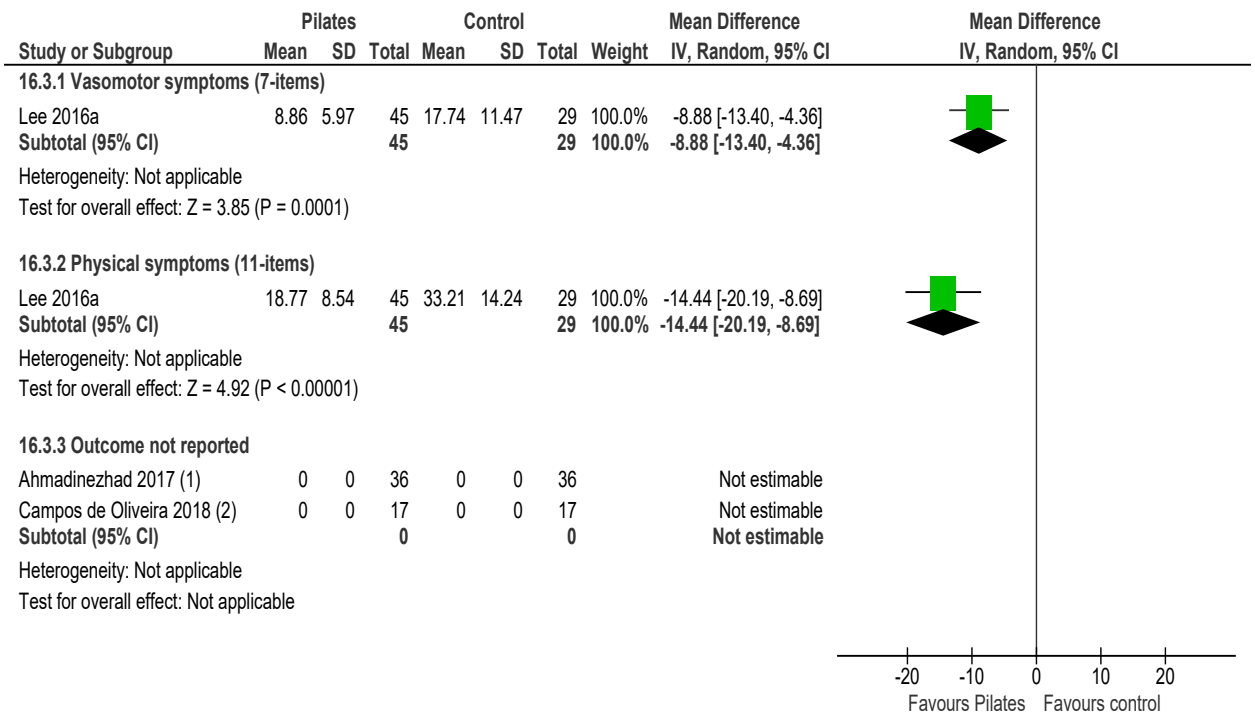


Footnotes

(1) Study does not report this outcome, probably because the outcome was not assessed.

(2) Study does not report this outcome, probably because the outcome was not assessed.

Figure 64 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Menopausal symptom or complaint – menopause symptoms questionnaire

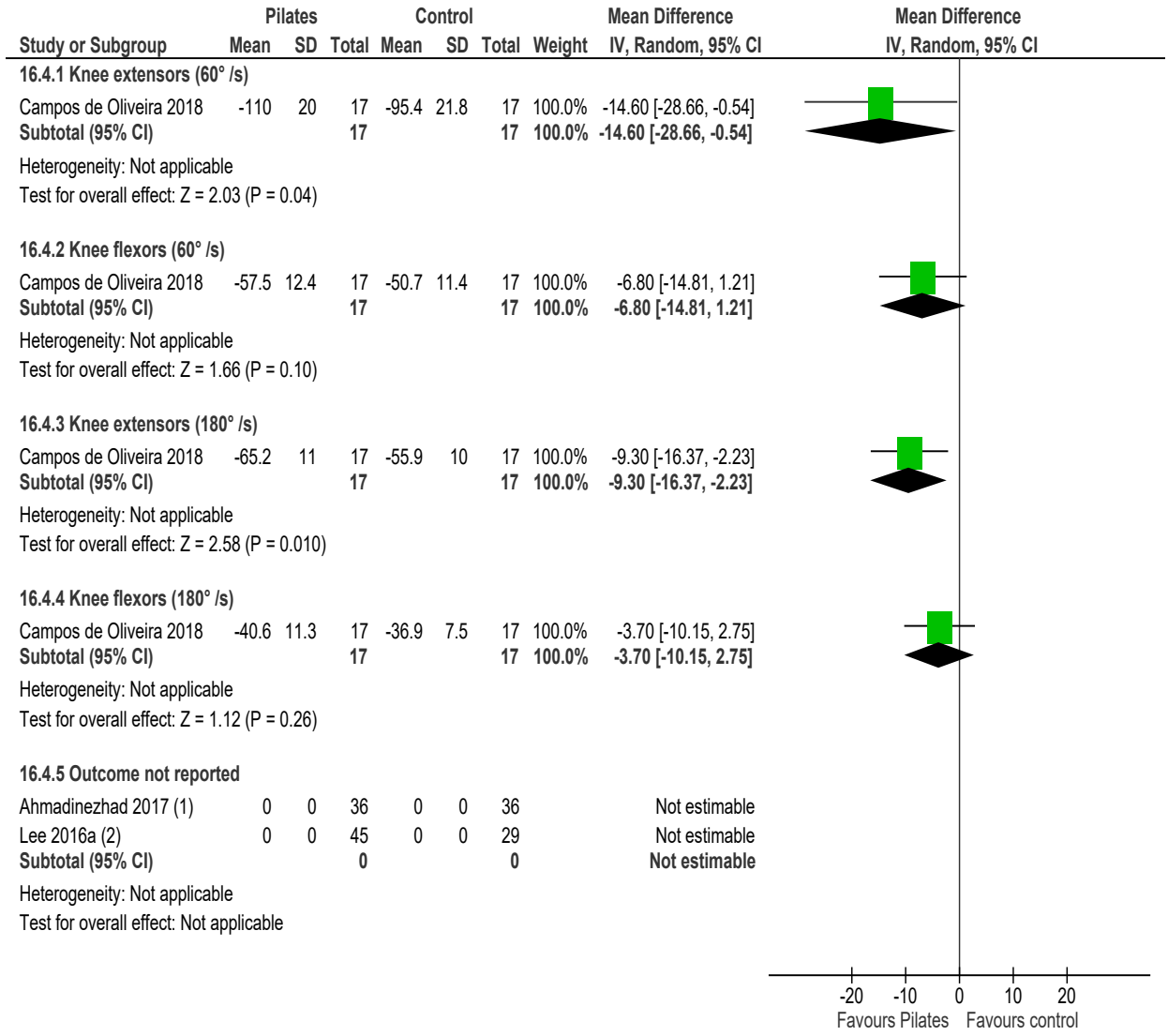


Footnotes

(1) Study does not report this outcome, probably because the outcome was not assessed.

(2) Study does not report this outcome, probably because the outcome was not assessed.

Figure 65 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Menopausal symptom or complaint – isokinetic muscle strength (Nm)

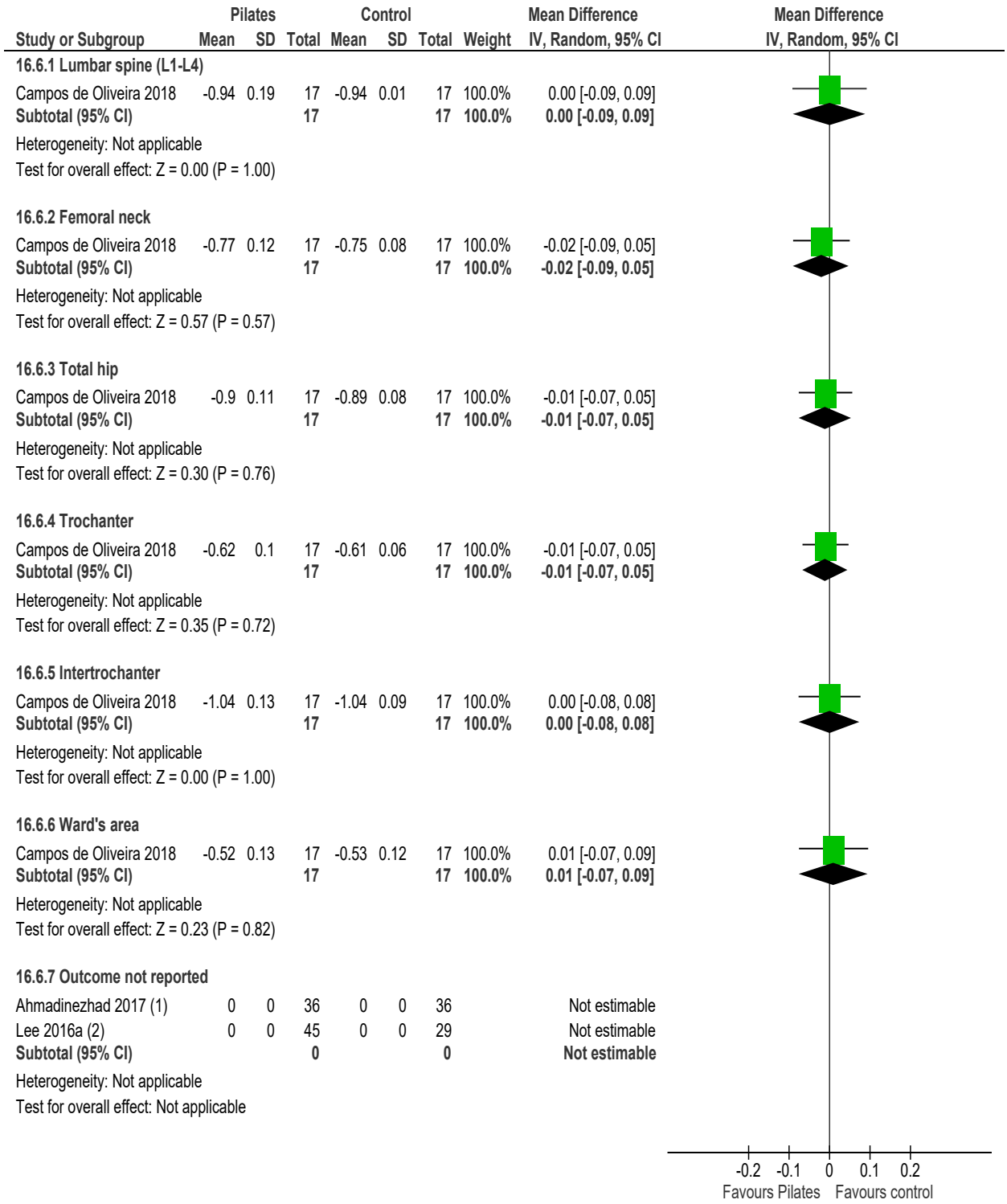


Footnotes

(1) Study does not report this outcome, probably because the outcome was not assessed.

(2) Study does not report this outcome, probably because the outcome was not assessed.

Figure 66 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Menopausal symptom or complaint – bone mineral density (g/cm²)



Footnotes

(1) Study does not report this outcome, probably because the outcome was not assessed.

(2) Study does not report this outcome, probably because the outcome was not assessed.

4.19 Postpartum recovery

4.19.1 Description of the condition

Maternity care relates to the provision of care to women in the antenatal, intrapartum and postnatal period (up to six weeks after birth) to manage conditions associated with the fetus, or to issues associated with labour and birth (368). In 2018 there were 303 029 babies born to 298 630 mothers in Australia. The health of both mother and baby can have significant short and long-term implications (369). Medical conditions and lifestyle factors such as diabetes and obesity can increase the risk of adverse outcomes for both mother and baby. Fetal adverse outcomes include congenital anomalies, premature birth and neonatal mortality (370, 371). Other consequences include increased risk of high birth weight, fat mass and fetal overgrowth which may increase the risk of metabolic complications later in life (372). Adverse outcomes for mothers may include pre-eclampsia, the need for induction or caesarean, pregnancy induced hypertension and maternal mortality (370, 372).

The notable physiological changes that occur during pregnancy often result in more than 60% of women experiencing lower back pain (373). Further, pregnancy and childbirth, particularly the mechanical stress on the body, have long been considered risk factors for the development of pelvic floor injury and dysfunction, such as stress urinary incontinence (374). Health promoting behaviours before and during pregnancy, as well as following birth, may reduce the likelihood of negative outcomes for both mothers and babies, improving positive outcomes and experiences. Such behaviours include regular physical activity (375), nutrition (376), support networks (377) and stress management (378).

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists and other guidelines recommend regular physical activity in pregnancy, noting resistance and stretching exercises as safe and beneficial for mother and baby (368, 373, 379). Antenatal exercises, including mind-body interventions such as Pilates, are thought to increase the likelihood of vaginal birth and are associated with less bodily pain. In addition, perinatal exercises are believed to decrease postpartum recovery time and thought to prevent depressive disorders during the postpartum period (380, 381).

4.19.2 Description of studies

Four citations (382-385) corresponding to one RCT (Mirmohammadali 2012) were identified in the literature search. There were no ongoing studies and no studies awaiting classification. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D7.1.1.

Mirmohammadali 2012 was conducted across seven health care centres in Iran and comprised 80 primiparous women aged between 18 to 35 years who had experienced a full-term vaginal birth of a healthy baby (singleton). Individuals who attended four randomly selected centres were assigned to a home-based Pilates exercise program, with individuals who attended the remaining three centres assigned to the control group. The Pilates home exercises (aided by a video, training booklet, and audio CD) were practised 72 hours to one week after childbirth and continued five day per week for 8 weeks. Sessions were 30 minutes in duration with the intensity of each exercise and number of repetitions gradually increased throughout the duration of the intervention. The participants were required to keep a daily exercise diary and were visited by the researcher every two weeks to review progress.

Participants in the control group attended one educational session on postnatal care, kept an exercise dairy and were followed up with weekly phone calls.

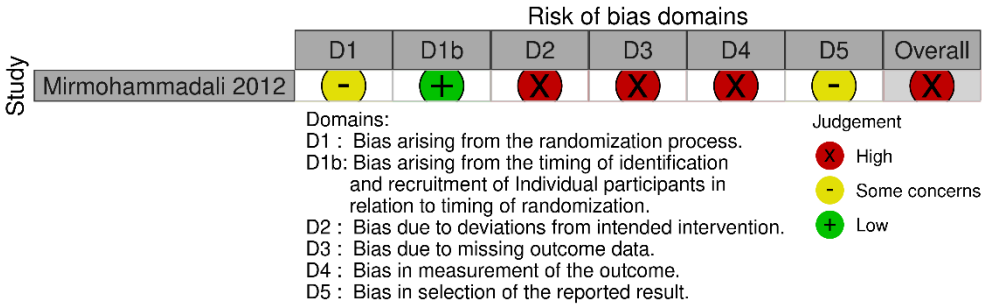
Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings tables (see 4.19.4.1) (and Appendix F2). There were no studies that compared Pilates with an active comparator.

4.19.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 67. Details are provided in Appendix D7.1.2.

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

Figure 67 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Postpartum recovery



4.19.4 Main comparison (vs control)

One study (Mirmohammadali 2012) was eligible for this comparison and contributed data to one outcome. There were no additional studies awaiting classification or ongoing that compared Pilates with no intervention in postpartum mothers that could have contributed data to the outcomes considered critical or important to this review (see Appendix C6).

4.19.4.1 Summary of findings

Pilates compared to Control (no intervention, waitlist or usual care) for postpartum recovery

Patient or population: Postpartum recovery
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence Statement
	Risk with Control	Risk with Pilates				
Pelvic pain and dysfunction - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on pelvic pain and dysfunction in postpartum women is unknown.
Quality of life - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on quality of life in postpartum women is unknown.

Pilates compared to Control (no intervention, waitlist or usual care) for postpartum recovery

Patient or population: Postpartum recovery
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence Statement
	Risk with Control	Risk with Pilates				
Fatigue (general) assessed with: Multidimensional Fatigue Inventory (higher is worse) Scale from: 4 to 20 follow-up: 8 weeks	The mean fatigue (general) score was **12.72** points	MD **4.92 points lower** (5.77 lower to 4.07 lower)	-	80 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on general fatigue in postpartum women.**
Pelvic floor muscle function - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on pelvic floor muscle function in postpartum women is unknown.
Body composition - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on body composition in postpartum women is unknown.
Mental health - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on mental health in postpartum women is unknown.
Exercise capacity - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on exercise capacity in postpartum women is unknown.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
** The MCID in postpartum women in unknown; in cancer patients change scores range from 1.36 to 2.39.

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

CI: Confidence interval; **MD:** Mean difference

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

a. One study (100% weight) at high risk of bias for this outcome. Certainty of evidence downgraded.

b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.

c. Serious indirectness. Evidence is not directly generalisable to the Australian population and it is difficult to judge if it could be sensibly applied. The study is conducted in Iran in young women (mean age 25 years) with first time singleton pregnancy, after noncomplicated vaginal birth. The intervention was practised at home, guided by video and audio CD, with follow-up visits every two weeks. Certainty of evidence downgraded.

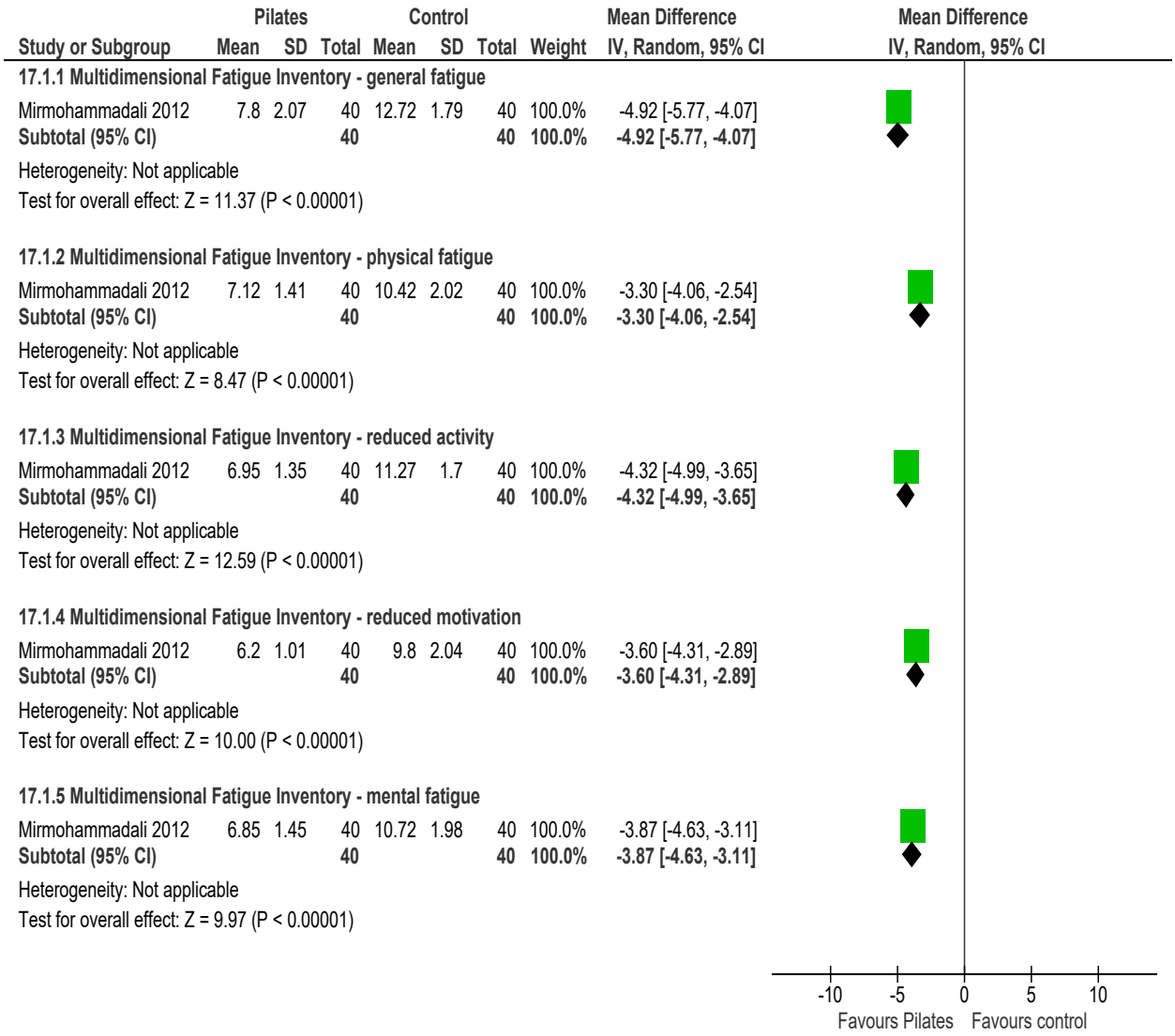
d. No imprecision. Certainty of evidence not downgraded.

e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.

4.19.4.2 Forest plots

Outcome results related to fatigue in postpartum women are presented in Figure 68.

Figure 68 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Postpartum recovery – fatigue



4.20 Rehabilitation of the knee after injury

4.20.1 Description of the condition

The knee is the largest joint in the body and consists of four main tissue types – bone, ligaments, cartilage and tendons – that can easily be injured (386). Common types of knee injury include sprain, torn ligament, strain, damage to cartilage, and torn meniscus (386). Injuries commonly occur during sport, or activities that involve awkward movements, falls, sudden twists, excessive force, or overuse (387). Often, knee injuries can be treated with rest, ice, compression and elevation, with medical management aimed at managing pain, minimising knee swelling, maintaining range of movement and quadriceps activation (388). Medial collateral ligament, posterior cruciate ligament and some small meniscal injuries can usually be managed conservatively (388), however, some more serious forms of knee injury can require surgery or rehabilitation (386, 388, 389).

In 2016-2017, almost 60 000 people in Australia were hospitalised due to a sports-related injury, with around 16 000 (28%) of these involving the hip and lower limb (excluding ankle and foot) (390). This is considered to represent fewer than 3% of total sports injuries (390). The incidence of knee injuries in Australian is increasing, with annual incidence of primary ACL reconstruction surgery increasing by 43% from 2000 to 2015, and by 74% among those under 25 years of age (391).

After injury, regardless of whether surgery will take place or not, management of serious knee injury such as rupture of the anterior cruciate ligament (ACL), typically focuses on regaining range of movement, strength, proprioception and stability (389). This is to restore knee function, prevent further injury, and avoid longer-term effects that include osteoarthritis and functional disability (389, 391).

4.20.2 Description of the studies

One citation (392) corresponding to one RCT (Celik 2017) was identified in the literature search. There were no ongoing studies and no studies awaiting classification. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D8.1.1.

One study (Celik 2017) was carried out in an orthopaedics department in Turkey and included 61 participants with a mean age of 25 years who had experienced an isolated ACL injury that did not require surgery. Of the 50 participants analysed, the majority (96%) had sustained their injury while playing sport; only four participants (8%) were male.

The study examined the effects of Pilates exercise compared to a waitlist control group, with the Pilate exercises practised over a period of 12 weeks. For the first six weeks, participants were supervised in a group setting, with classes being 60 minutes in duration and delivered three times per week. The participants then practised the prescribed Pilates exercises at home for an additional six weeks, with the intensity of training adjusted every two weeks (increased number of repetitions).

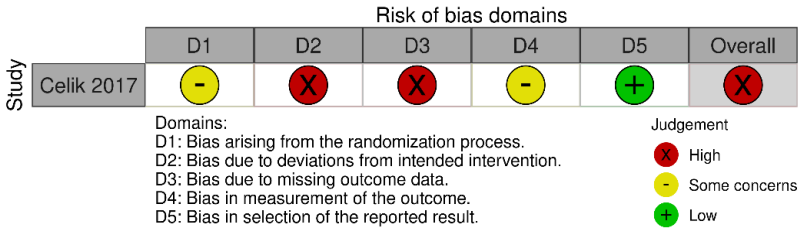
Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings tables (see 4.20.4.1) (and Appendix F2). There were no studies that compared Pilates with an active comparator.

4.20.3 Risk of bias – per item

The risk of bias for each item in the included RCTs is summarised in Figure 69. Details are provided in Appendix D8.1.2.

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

Figure 69 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Rehabilitation of the knee after injury



4.20.4 Main comparison (vs control)

One study (Celik 2017) was eligible for this comparison and contributed data to three outcomes. There were no additional studies awaiting classification or ongoing that compared Pilates with no intervention in people undergoing knee rehabilitation after injury that could have contributed data to the outcomes considered critical or important to this review (see Appendix C6).

4.20.4.1 Summary of findings

Pilates compared to control (no intervention, wait list or usual care) for rehabilitation of the knee after injury

Patient or population: Rehabilitation of the knee after injury
Setting: Community
Setting: Orthopaedics department
Intervention: Pilates
Comparison: Control (no intervention, wait list or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Knee function assessed with: Cincinnati knee rating scale (higher is best) Scale from: 120 to 420 follow-up: 12 weeks	The mean knee function was **83 points**	MD **4.1 points lower** (10.1 lower to 1.9 higher)	-	50 (1 RCT)	⨁◯◯◯ VERY LOW [a,b,c,d,e]	The evidence is very uncertain about the effect of Pilates on knee function in people rehabilitating after knee injury.**
Quality of life - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates of quality of life in people rehabilitating after knee injury is unknown.
Return to activities/sport - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on return to activities in people rehabilitating after knee injury is unknown.
Knee stability assessed with: Global Rating of Change Scale follow-up: 12 weeks	**231** per 1000	**939 per 1000** (480 to 1000)	**RR 4.07** (2.08 to 7.97)	50 (1 RCT)	⨁⨁◯◯ LOW [a,b,c,e]	The evidence suggests Pilates results in a large improvement in knee stability in people rehabilitating after knee injury.***

Pilates compared to control (no intervention, wait list or usual care) for rehabilitation of the knee after injury

Patient or population: Rehabilitation of the knee after injury
Setting: Community
Setting: Orthopaedics department
Intervention: Pilates
Comparison: Control (no intervention, wait list or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Physical function - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on physical function in people rehabilitating after knee injury is unknown.
Isokinetic muscle strength (peak torque) assessed with: Dynamometer (180 degrees/s) follow-up: 12 weeks	No difference in peak strength for flexion (hamstring) (MD 9.10; 95% CI 23.16, –4.69; *p* = 0.20) An effect favouring Pilates for extension (quadriceps) (MD 23.90; 95% CI 39.59, 8.21; *p* = 0.003).		-	50 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on isokinetic muscle strength in people rehabilitating after knee injury.**
Requirement for surgery - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on the need for surgery in people rehabilitating after knee injury is unknown.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
** MCID unknown.[A]
*** A 25% relative improvement was considered important (i.e. RR > 1.25).

Effect estimates were considered on three levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).
^ In the absence of an MCID, effect estimates were considered based on the SMD: where an SMD of 0.2 represents a small difference, 0.5 is moderate, and 0.8 is a large difference.
CI: confidence interval; **MD:** mean difference; **RR:** risk ratio

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. One RCT (100% weight) at high risk of bias for the outcome. Certainty of evidence downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is generalisable to the Australian population with some caveats. The study population consisted of mostly women aged between of 20 and 45 with isolated ACL injury, who were sedentary or had low activity level, and low pain score. Certainty of evidence not downgraded.

d. Serious imprecision. Single study (50 participants). Wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded.

e. Publication bias. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.

4.20.4.2 Forest plots

Outcome results related to knee function in people undergoing knee rehabilitation are presented in Figure 70.

Outcome results related to knee stability in people undergoing knee rehabilitation after injury are presented in Figure 71.

Outcome results related to isokinetic muscle strength in people undergoing knee rehabilitation are presented in Figure 72.

Figure 70 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): rehabilitation of the knee after injury - knee function

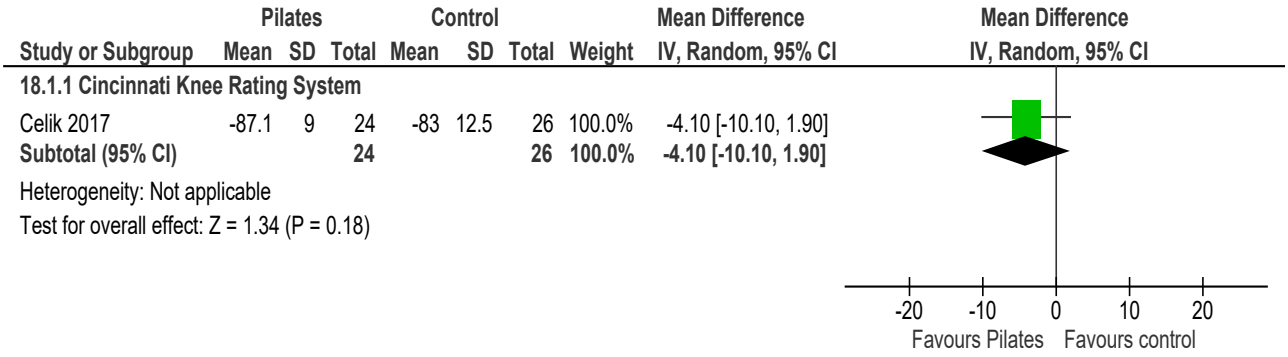


Figure 71 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): rehabilitation of the knee after injury - improvement in stability

Note that this is a dichotomous outcome, so Pilates is shown on the opposite side to other outcomes.

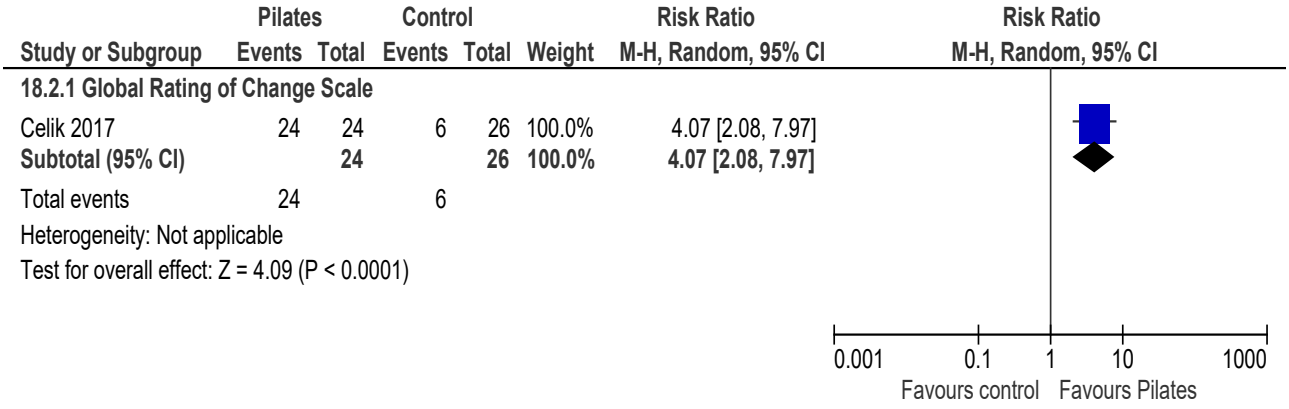
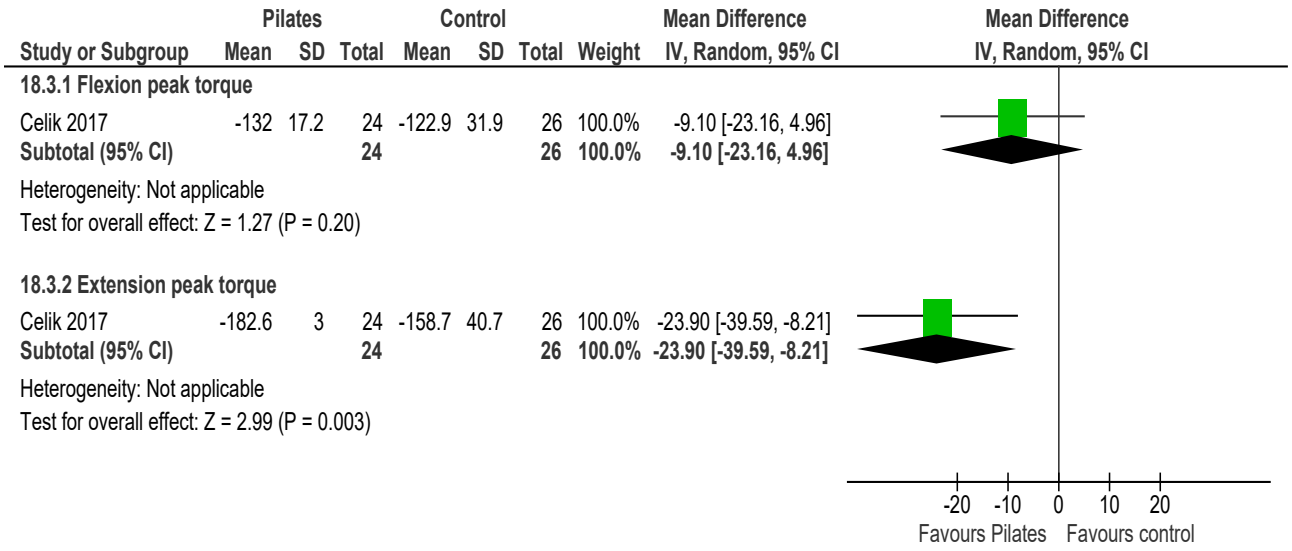


Figure 72 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): rehabilitation of the knee after injury - strength



4.21 Rehabilitation of the knee after arthroplasty

4.21.1 Description of the condition

Knee arthroplasty (also known as knee replacement) is a procedure that involves cutting away damaged bone and cartilage from the thigh bone, shin bone and kneecap, and replacing it with an artificial joint (393). The most common reason for the procedure is to relieve severe pain and loss of mobility cause by osteoarthritis. This occurs because the normal surface of the joint wears away, leading to stiffness and swelling. For most people, knee replacement restores near normal function, provides pain relief and improves quality of life (394).

In Australia, there were 54 102 knee replacements (a rate of 218 per 100 000 population) performed in 2017-2018, with a principal diagnosis of osteoarthritis (166). The rate of knee replacements was greatest in those aged 75-79. By 2030 the number of total knee replacement surgeries is expected to substantially increase by more than 250% (395).

After surgery, patients are typically advised to follow rapid recovery protocols that include early mobilisation and exercise therapy (396-398). Early post-operative exercises focus on increasing mobility and flexion of the joint, with the aim of improving range of motion and strength in the knee (398). After hospital discharge, both supervised and home-based exercise programs (such as traditional physiotherapy, hydrotherapy, ergometer cycling, balance exercises) have been shown to provide some benefit in improving physical function and reducing pain (399), but optimal exercises and evidence of long-term benefits are not known (398, 399). Activities of daily living such as gardening, bowls, and golf can usually resume after about 3 months (400).

4.21.2 Description of studies

One citation (401) corresponding to one quasi RCT (Karaman 2017) was identified in the literature search. There were no studies awaiting classification and no ongoing studies. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D9.1.1.

One study (Karaman 2017) was carried out in a community setting in Turkey and included 46 participants aged between 55 and 85 years who underwent primary unilateral total knee arthroplasty. The same surgeon using the same technique carried out the knee arthroplasties, and all participants received a standard exercise program during their hospital stay.

Karaman 2017 examined the effectiveness of a Pilates-based exercise program delivered as an adjunct to standard home-based post-operative exercises after discharge. All participants began the intervention after discharge from hospital (mean 5.5 to 6.0 days) and were monitored by a physiotherapist over the six-week period. The intensity and type Pilates exercises were increased every two weeks (time and number of repetitions not provided), whereas the standard exercise program progressed based on weekly observations.

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings tables (see 4.21.4.1) (and Appendix F2).

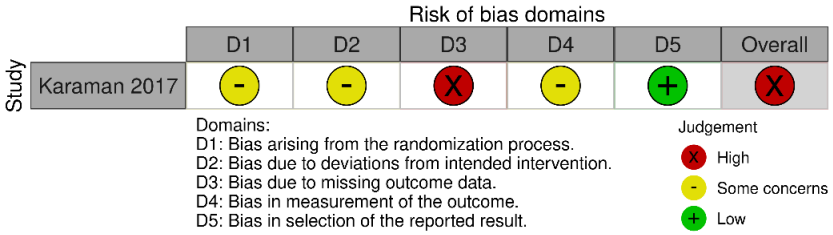
There were no studies that compared Pilates with an active comparator.

4.21.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 73. Details are provided in Appendix D9.1.2.

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

Figure 73 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Rehabilitation of the knee after arthroplasty



4.21.4 Main comparison (vs control)

One study (Karaman 2017) was eligible for this comparison and contributed data to three outcomes. There were no additional studies awaiting classification or ongoing that compared Pilates with no intervention in people after TKA that could have contributed data to the outcomes considered critical or important to this review (see Appendix C6).

4.21.4.1 Summary of findings

Pilates compared to Control (no intervention, waitlist or usual care) for rehabilitation after knee arthroplasty

Patient or population: Rehabilitation after knee arthroplasty
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence Statement
	Risk with Control	Risk with Pilates				
Quality of life - physical assessed with: SF-36 (higher is best) Scale from: 0 to 100 follow-up: 6 weeks	The mean quality of life - physical was **37.5** points	mean **6.7 points higher** (11.24 higher to 2.16 higher)	-	34 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on physical wellbeing in people rehabilitating after total knee arthroplasty.**
Quality of life - mental assessed with: SF-36 (higher is best) Scale from: 0 to 100 follow-up: 6 weeks	The mean quality of life - mental was **41.1** points	mean **12.5 points higher** (20.3 higher to 4.7 higher)	-	34 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on mental wellbeing in people after total knee arthroplasty.**
Balance (static) assessed with: Berg Balance Scale (higher is best) Scale from: 0 to 56 follow-up: 6 weeks	The mean balance was **41.1** points	mean **9.5 points higher** (12.55 higher to 6.45 higher)	-	34 (1 RCT)	⨁◯◯◯ VERY LOW a,b,c,e	The evidence is very uncertain about the effect of Pilates on static balance in people after total knee arthroplasty.**

Pilates compared to Control (no intervention, waitlist or usual care) for rehabilitation after knee arthroplasty

Patient or population: Rehabilitation after knee arthroplasty
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist or usual care)

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

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

In the absence of an MCID, effect estimates were considered based on the following thresholds: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale), or large (MD more than 20% of the scale).

CI: confidence interval; **SF-36**: 36-item short-form

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. One study (100% weight) at high risk of bias for the outcome. Certainty of evidence downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The evidence is applicable to the Australian population with some caveats. The study is in people aged over 55 years undergoing primary unilateral total knee arthroplasty, with Pilates delivered as an adjunct to standard post-operative exercises. It may not be applicable to people aged under 55 years or rehabilitation after other types of surgery. Certainty of evidence not downgraded.
d. Serious imprecision. Small study (fewer than 40 participants). Wide confidence intervals (upper and lower bounds overlap with large and small important difference). Certainty of evidence downgraded..
d. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.

4.21.4.2 Forest plots

Outcome results related to quality of life in people after total knee arthroscopy are presented in Figure 74.

Outcome results related to balance in people after total knee arthroscopy are presented in Figure 75.

Figure 74 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Rehabilitation of the knee after arthroplasty – quality of life

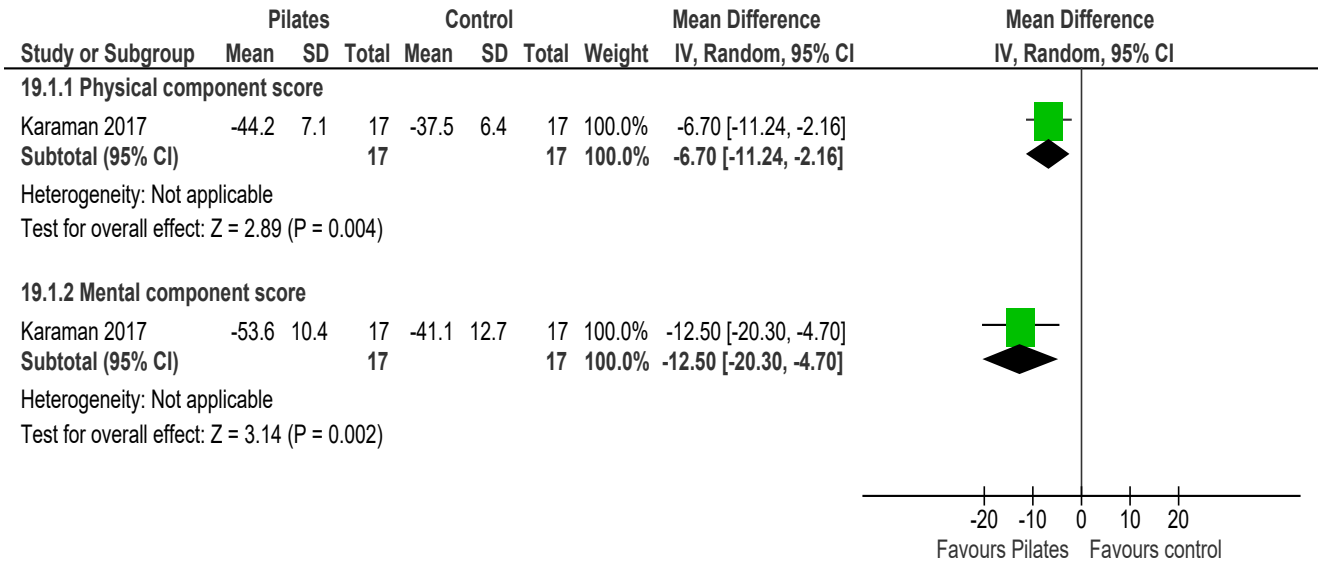
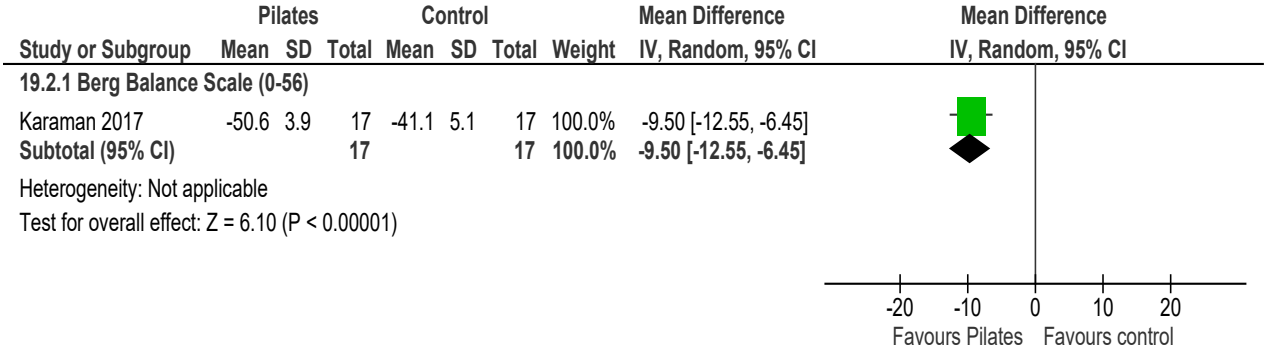


Figure 75 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Rehabilitation of the knee after arthroplasty – balance



4.22 Prevention of mental health conditions

4.22.1 Description of the condition

Mental health plays a vital role in overall health and wellbeing. An estimated 1 in 5 Australians aged between 16 and 85 years' experience a common mental health condition each year. Among children and adolescents (aged between 4 and 17 years), approximately 1 in 7 meet the clinical criteria for one or more mental health conditions each year (402). Anxiety disorders are the most common mental health conditions experienced by Australian adults followed by affective disorders such as depression, with women experiencing a higher prevalence than men (402). In children and adolescents, attention deficit hyperactive disorder is the most common, followed by anxiety and major depressive disorder.

Several factors can impact a person's developmental, emotional or behavioural wellbeing, increasing the risk of developing a mental health condition (or problem, symptom or disorder) that can be temporary or persistent. Adverse workplace environments may lead to substantial stress and burnout which can result in negative mental health outcomes such as depression (403). Families and other informal caregivers providing long-term care to older adults or persons with chronic illness and disabilities face additional stressors that can be associated with poorer mental health (404). Social inequalities such as poverty and access to education and health care have a clear relationship with poor mental health, particularly in children and adolescents (405).

Mental health conditions are a significant burden in Australia and globally, ranked the fourth highest group of diseases behind cancer, cardiovascular disease and musculoskeletal conditions (402). Strengthening factors that improve resistance to mental health is a key part of preventing poor mental health outcomes (406). Nonpharmacological interventions such as physical activity and mindfulness have few negative side effects and are thought to have several positive benefits to physical, emotional and mental wellbeing (406-408). Physical activity releases endorphins and may influence neurotransmitters, hormones and the hypothalamic-pituitary gland that impact mood and adaptive responses to stressful situations (409, 410). Physical activity and deep breathing exercises may reduce symptoms of anxiety and depression while increasing self-esteem.

4.22.2 Description of studies

Two citations (411, 412) corresponding to one quasi RCT (Abavisani 2019) was identified in the literature search. There were two ongoing studies (413, 414) and no studies awaiting classification. No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D10.1.1.

Abavisani 2019 was carried out in a community setting in Iran. The study enrolled 62 people aged between 19 and 40 years who were at risk of increased anxiety associated with their employment (medical emergency department). Participants were excluded if they had previous or current history of various disorders including physical and mental illness, had engaged in regular physical activity in the last month, or had a stressful event in the past six weeks (e.g., marriage, divorce, death). Baseline anxiety scores indicated all enrolled participants had probable anxiety (state anxiety greater than 40).

Abavisani 2019 compared Pilates with no intervention (usual activities). Participants in the Pilates group performed two one-hour sessions for eight weeks. Each session consisted of an eleven-minute warm up followed by various movements including standing, breathing and reaching the floor with two hands. The authors do not report if each Pilates session was delivered by a certified instructor or undertaken individually or in a group.

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings tables (see 4.22.4.1) (and Appendix F2).

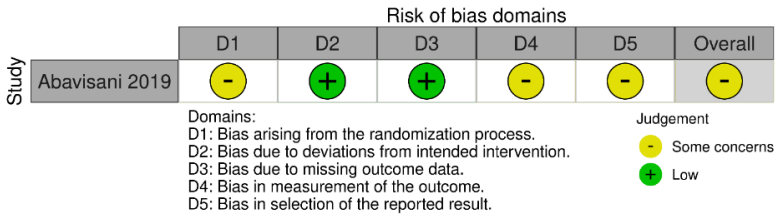
There were no studies that compared Pilates with an active comparator.

4.22.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 76. Details are provided in Appendix D10.1.2.

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

Figure 76 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Prevention of mental health conditions



4.22.4 Main comparison (vs control)

One study (Abavisani 2019) was eligible for this comparison and contributed data to one outcome. There were no additional studies awaiting classification or ongoing that compared Pilates with no intervention in people at risk of mental health conditions that could have contributed data to the outcomes considered critical or important to this review (see Appendix C6).

4.22.4.1 Summary of findings

Pilates compared to control (no intervention, usual activities) for Prevention of mental health conditions

Patient or population: Prevention of mental health conditions
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, usual activities)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Quality of life - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on persons at risk of developing a mental health condition is unknown.
Anxiety (state) assessed with: Spielberger anxiety questionnaire Scale from: 20 to 80 (higher score is worse) follow-up: 8 weeks	The mean state anxiety score was **51.81**.	MD **5.46 points lower** (1.84 lower to 9.08 lower)	-	62 (1 RCT)	⨁⨁◯◯ LOW [a,b,c,d,e]	The evidence suggests that Pilates results in an slight improvement in state anxiety in persons at risk of developing a mental health condition.**

Pilates compared to control (no intervention, usual activities) for Prevention of mental health conditions

Patient or population: Prevention of mental health conditions
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, usual activities)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Anxiety (trait) assessed with: Spielberger anxiety questionnaire Scale from: 20 to 80 (higher is worse) follow-up: 8 weeks	The mean trait anxiety score was **53.29**.	MD **10.52 points lower** (6.75 lower to 14.29 lower)	-	62 (1 RCT)	⨁⨁◯◯ LOW [a,b,c,e,f]	The evidence suggests that Pilates results in an improvement in trait anxiety in persons at risk of developing a mental health condition.**
Depression - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on persons at risk of developing a mental health condition is unknown.
Active coping - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on persons at risk of developing a mental health condition is unknown.
Physical stress symptoms - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on persons at risk of developing a mental health condition is unknown.
Fatigue - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on persons at risk of developing a mental health condition is unknown.
Stress / stress perception / burnout - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on persons at risk of developing a mental health condition is unknown.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
** MCID is unknown#. Noting a mean score above 39-40 (state anxiety) in the intervention group suggests clinically important symptoms remain.

In the absence of an MCID, effect estimates were considered based on the following thresholds: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale), or large (MD more than 20% of the scale).

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

Pilates compared to control (no intervention, usual activities) for Prevention of mental health conditions

Patient or population: Prevention of mental health conditions
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, usual activities)

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

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

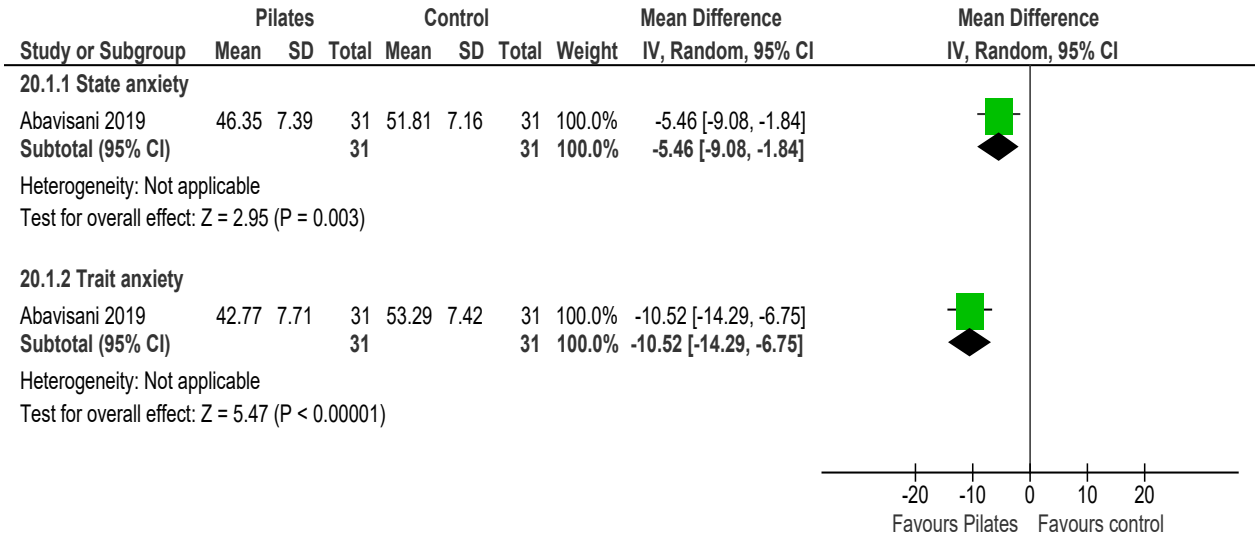
Explanations

a. One study (100% weight) with some concerns of bias that were not considered to raise serious doubts about the results. Certainty of evidence not downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. Evidence is directly generalisable to the Australian population with some caveats. The study includes emergency department medical students and may not be reflective of the general population at risk of mental health conditions. Certainty of evidence not downgraded.
d. Serious imprecision. Single study. Wide confidence intervals (upper and lower bounds overlap with a moderate and small important difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.
f. Serious imprecision. Single study. Wide confidence intervals (upper and lower bounds overlaps with a large and moderate important difference). Certainty of evidence downgraded.

4.22.4.2 Forest plots

Outcome results related to people at risk of mental health conditions are presented in Figure 77.

Figure 77 Forest plot of comparison: Pilates vs control (usual activities): Prevention of mental health conditions – anxiety



4.23 Prevention of metabolic or weight problems in sedentary populations

4.23.1 Description of the condition

Insufficient physical activity and sedentary behaviours are leading contributors to global mortality (415). Sedentary behaviours have detrimental associations including obesity, insulin resistance, type 2 diabetes and cardiovascular disease (415, 416). Australian physical activity guidelines recommend adults engage in activity most days, achieving 2.5-5 hours of moderate activity or 1.25-2.5 hours of vigorous activity each week (417). However, more than half of Australian adults and 70% of children aged 2 to 17 years do not meet these recommendations (418). The burden of physical inactivity and sedentary behaviours is significant, accounting for 2.5% of all Australian disease burden in 2015 (419).

Persons who are physically fit and active are more likely to have improved glucose and insulin metabolism and less likely to be overweight or obese compared to persons who are physically inactive (416). For overweight or obese persons, weight loss can be challenging to achieve through diet and exercise, therefore, prevention of weight gain is considered more effective at reducing obesity. Furthermore, exercise can substantially improve glycaemic control and blood lipid levels (416). It is suggested that Pilates can have positive impacts on weight management, blood glucose and lipid metabolism in persons presenting with metabolic and weight concerns (420, 421).

4.23.2 Description of studies

One citation (422) corresponding to one quasi RCT (Garcia-Soidan 2014) was identified in the literature search. There were no ongoing studies and no studies awaiting classification. One additional study (Sahinci Gokgul 2017) was identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D10.2.1.

Two studies were carried out in the community setting in Spain (Garcia-Soidan 2014) and Turkey (Sahinci Gokgul 2017). Sample sizes ranged from 22 to 99 participants (total 121), with both studies enrolling adults with confirmed sedentary behaviours. One study (Garcia-Soidan 2014) included male and female volunteers aged 40-60 years who had a medical attestation about their good health status and did not use any medications to sleep. One study (Sahinci Gokgul 2017) included female volunteers aged between 25 and 55 years.

One study (Garcia-Soidan 2014) compared Pilates with control (no intervention), with participants engaging in 60-minute Pilates exercises twice a week for 12 weeks. The study followed progressive loading, gradually increasing intensity from week six.

One study (Sahinci Gokgul 2017) compared Pilates with cyclic exercises, with participants engaging in the allocated exercises for 30 minutes, three times a week for eight weeks. A five-minute warmup immediately before Pilates exercises, and a five-minute cooldown immediately after Pilates exercises, was also provided.

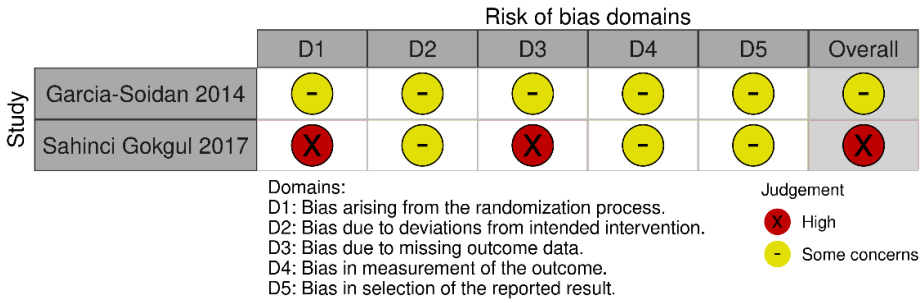
Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings tables (see 4.23.4.1) (and Appendix F2). Results of the study (Sahinci Gokgul 2017) that compared Pilates with an active comparator are presented in Appendix F2.

4.23.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 78. Details are provided in Appendix D10.2.2.

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

Figure 78 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Prevention of metabolic disorders or weight problems associated with sedentary behaviour



4.23.4 Main comparison (vs control)

One study (Garcia-Soidan 2014) was eligible for this comparison and contributed data to two outcomes. There were no additional studies awaiting classification or ongoing that compared Pilates with no intervention in people at risk of metabolic disorders or weight problems associated with sedentary behaviour that could have contributed data to the outcomes considered critical or important to this review (see Appendix C6).

4.23.4.1 Summary of findings

Pilates compared to control (no intervention) for Prevention of metabolic disorders or weight problems

Patient or population: Prevention of metabolic disorders or weight problems
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Functional/ physical performance assessed with: Accelerometery (higher is best) follow-up: mean 12 weeks	The mean activity count per minute was **12 673.8**	MD **422 count per minute more** (3770.23 more to 2926.23 fewer)	-	99 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on physical performance in sedentary adults at risk of metabolic disorder or weight problems.**
Quality of life assessed with: SF-36 – Physical wellbeing (higher is best) Range from: 0 to 100 follow-up: mean 12 weeks	An effect favouring Pilates across three of four domains associated with physical wellbeing (physical functioning, role-physical, general health perceptions) (MD range from **9.20** to **18.30 higher**). An effect favouring the control group reported for bodily pain (MD **12.00 lower**).		-	99 (1 RCT)	⊕⊕◯◯ LOW a,b,c,e,f	The evidence suggests of Pilates results in a slight improvement in physical functioning and role-physical, improves general health perceptions but increases bodily pain in sedentary adults at risk of metabolic disorders or weight problems.***

Pilates compared to control (no intervention) for Prevention of metabolic disorders or weight problems

Patient or population: Prevention of metabolic disorders or weight problems
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Quality of life assessed with: SF-36 – Mental wellbeing (higher is best) Range from: 0 to 100 follow-up: mean 12 weeks	An effect favouring Pilates across four domains associated mental wellbeing (vitality, role-emotion, social function, mental health) (MD range from **12.40** to **31.20 higher**). The effect for mental health did not reach statistical.		-	99 (1 RCT)	⨁⨁◯◯ LOW [a,b,c,e,f]	The evidence suggests of Pilates improves vitality, social functioning and mental health and results in a large improvement in emotional aspects of life in sedentary adults at risk of metabolic disorders or weight problems.***
Sedentary behaviour - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on sedentary behaviour in people at risk of metabolic disorders or weight problems is unknown.
Physical functioning - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on physical functioning in people at risk of metabolic disorders or weight problems associated with sedentary behaviour is unknown.
Glycaemic control - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on glycaemic control in people at risk of metabolic disorders or weight problems associated with sedentary behaviour is unknown.
Cardiovascular disease risk - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on cardiovascular disease markers in people at risk of metabolic disorders or weight problems associated with sedentary behaviour is unknown.
Anthropometrics - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on hip or waist circumference in people at risk of metabolic disorders or weight problems associated with sedentary behaviour is unknown.

Pilates compared to control (no intervention) for Prevention of metabolic disorders or weight problems

Patient or population: Prevention of metabolic disorders or weight problems
Setting: Community
Intervention: Pilates
Comparison: Control (no intervention, waitlist or usual care)

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

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

In the absence of an MCID, effect estimates were considered based on the following thresholds: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale), or large (MD more than 20% of the scale).
^ In the absence of an MCID, effect estimates were considered based on the SMD: where an SMD of 0.2 represents a small difference, 0.5 is moderate, and 0.8 is a large difference.

CI: confidence interval; **SF-36**: 36-item short-form; **SMD:** standardised mean difference;

GRADE Working Group grades of evidence
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. No serious risk of bias. Certainty of evidence not downgraded
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No indirectness. Evidence is directly generalisable and applicable to the target population with some caveats. The study includes otherwise healthy people aged between 40 and 60 years who were sedentary or had less than 30 minutes of leisure physical activity per day. Certainty of evidence not downgraded.
d. Very serious imprecision. Single study. Wide confidence intervals (upper and lower bounds overlap with moderate and no important difference). Certainty of evidence downgraded by two levels.
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.
f. Serious imprecision. Single study. Wide confidence intervals (upper and lower bounds overlap with large, moderate or small important differences). Certainty of evidence downgraded.

4.23.4.2 Forest plots

Outcome results related to physical performance for people at risk of metabolic disorders or weight problems associated with sedentary behaviour are presented in Figure 79.

Outcome results related to quality of life for people at risk of metabolic disorders or weight problems associated with sedentary behaviour are presented in Figure 80.

Figure 79 Forest plot of comparison: Pilates vs control (usual activities): Prevention of metabolic disorders or weight problems associated with sedentary behaviours: Functional/physical performance

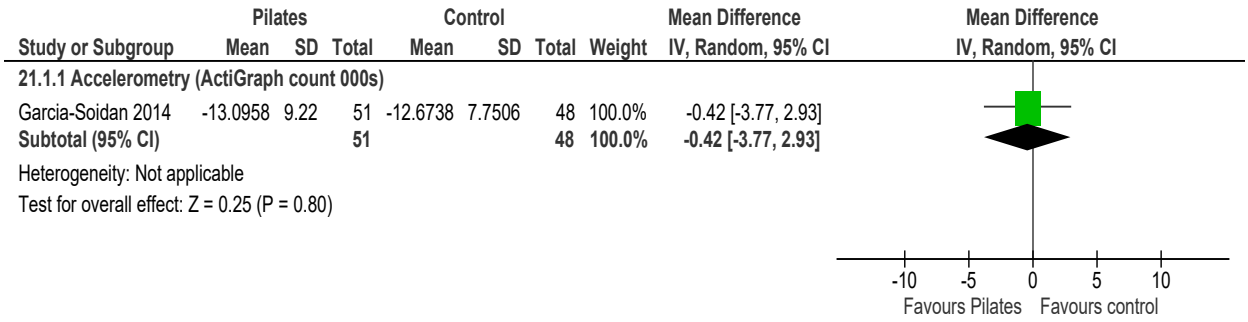
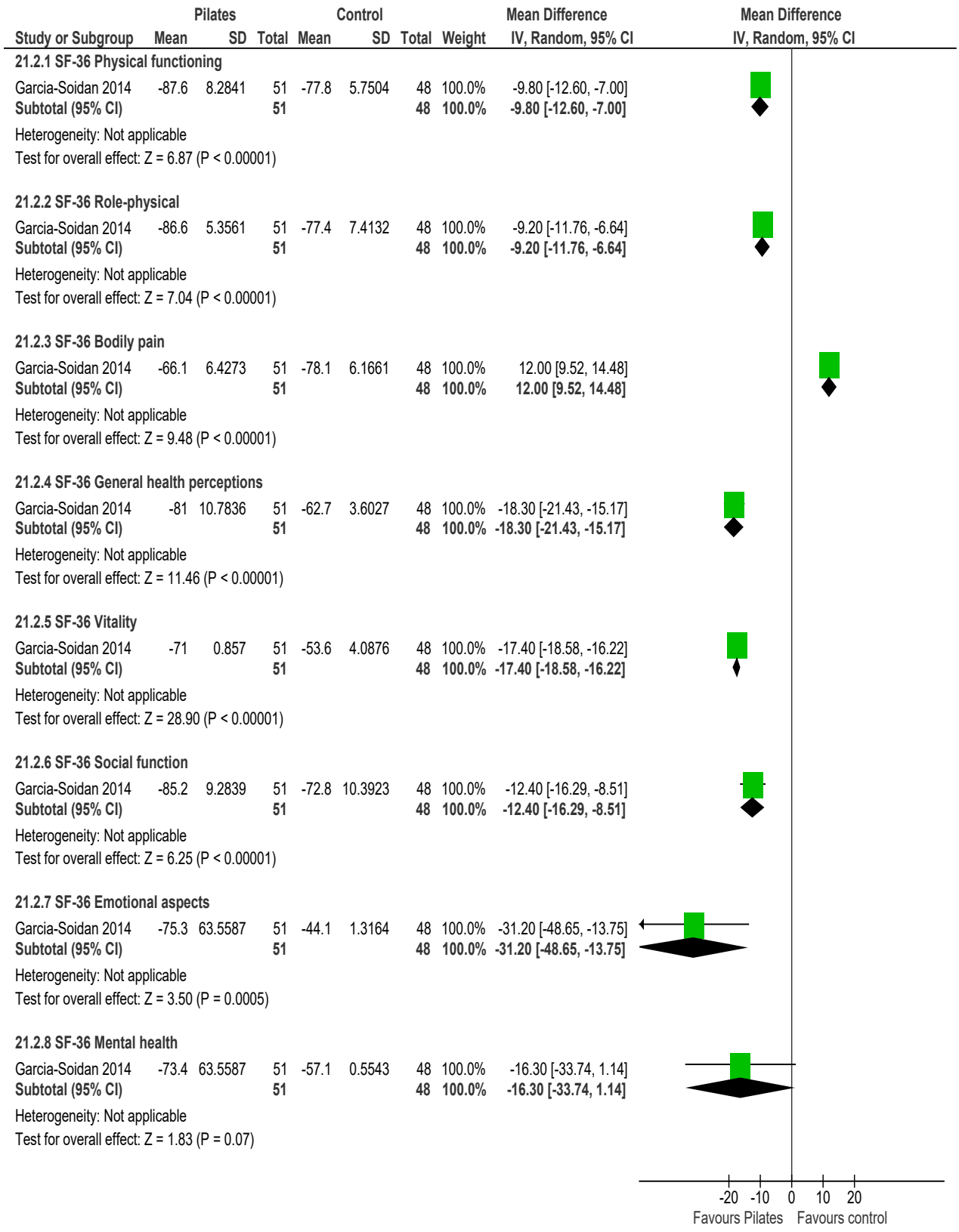


Figure 80 Forest plot of comparison: Pilates vs control (usual activities): Prevention of metabolic disorders or weight problems associated with sedentary behaviours: Quality of life



4.24 Prevention of age-related physical and cognitive decline

4.24.1 Description of the condition

Maintaining a healthy body and brain is critical to preserving independence and preventing a decline in quality of life in older adults (423, 424). This is because the physical and cognitive deterioration that occurs during the ageing process poses challenges to maintaining social, functional, and financial independence (423, 424). Age-related changes to the musculoskeletal system (e.g., bone loss, muscle shrinkage, reduced flexibility), cardiorespiratory system (e.g., stiffening of the blood vessel leading increase workload on the heart), digestive system (e.g., increased constipation or urination) and central nervous system (e.g., changes to memory and thinking skills) can result in wide-ranging limitations in the capacity to function in daily life, leading to cardiovascular disease, weight problems, mobility problems, an increased risk of falls, and mental health problems (424-426)

In Australia, older people are typically described as people who are aged 65 years or older, who are either living independently in the community or receiving some form of assisted living (residential or community care homes etc.) (427) Healthy ageing, defined as 'the process of developing and maintaining functional ability that enables wellbeing in older age' (428) focuses on promoting participation in functional and social activities prior to this age so as to maintain adequate physical and mental health status (423, 427). Many of the ideas focus on modifiable lifestyle factors such as increased physical activity, dietary modification to manage glucose and blood pressure, tobacco, alcohol and salt reduction, as well as promoting social or group activities to enhance cognitive functioning and promote resilience (424, 427, 428).

4.24.2 Description of studies

Twelve citations (429-436) corresponding to three RCTs (Aibar-Almazan 2019, Curi 2018, de Andrade Mesquita 2015), two quasi RCTs (Irez 2011, Liposcki 2019) and one NRSI (Gandolfi 2020) were identified in the literature search. There were four ongoing studies (437-440) and six studies awaiting classification (Aradmehr 2015, Cascales-Ruiz 2015, Dashti 2015, Filho 2016, Lopes Macedo 2016, Mokhtari 2013) (441-448). No additional studies were identified in the Department's public call for evidence. An overview of the PICO criteria of included studies is provided in Appendix D10.3.1.

Five studies were conducted in the community setting in Brazil (Curi 2018, de Andrade Mesquita 2015, Gandolfi 2020, Liposcki 2019) or Spain (Aibar-Almazan 2019) and one study was conducted in a residential care home setting in Turkey (Irez 2011). The sample sizes ranged from 24 to 110 participants (total 365). All six studies enrolled women who were aged over 60 (Aibar-Almazan 2019, Curi 2018, de Andrade Mesquita 2015, Gandolfi 2020, Irez 2011) or 65 years (Liposcki 2019) and considered inactive (not practise any physical exercise for 6 months prior to enrolment) or sedentary (according to the short version of the International Physical Activity Questionnaire)

Five studies compared Pilates exercises with control (no intervention or usual activities), with participants engaged in the Pilates sessions for 60-minutes, for anywhere between one session per week for 20 weeks (Gandolfi 2020), through to two sessions per week for 16 (Curi 2018) or 24 weeks (Liposki 2019), up to three sessions per week for 12 weeks (Irez 2011), or four sessions a week for four weeks (de Andrade Mesquita 2015). All studies included Pilates exercises that increased in intensity (hold time and number of repetitions) through the course of the intervention, many adding resistance bands and balls, with two studies (Gandolfi 2020, Liposki 2019) including equipment (Cadillac, Reformer and Chair) in the final phase.

Two studies compared Pilates with another intervention, with participants in one study (Aibar-Almazan2019) engaging in an education program and participants in the other study (de Andrade Mesquita 2015) receiving proprioceptive neuromuscular facilitation. In one study (Aibar-Almazan2019) the treatment sessions were

delivered twice-weekly for 12 weeks, for a total of 24 sessions. In de Andrade Mesquita 2015 the Pilates sessions were delivered three times a week for four weeks, for a total of 12 sessions.

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings tables (see 4.24.4.1) (and Appendix F2).

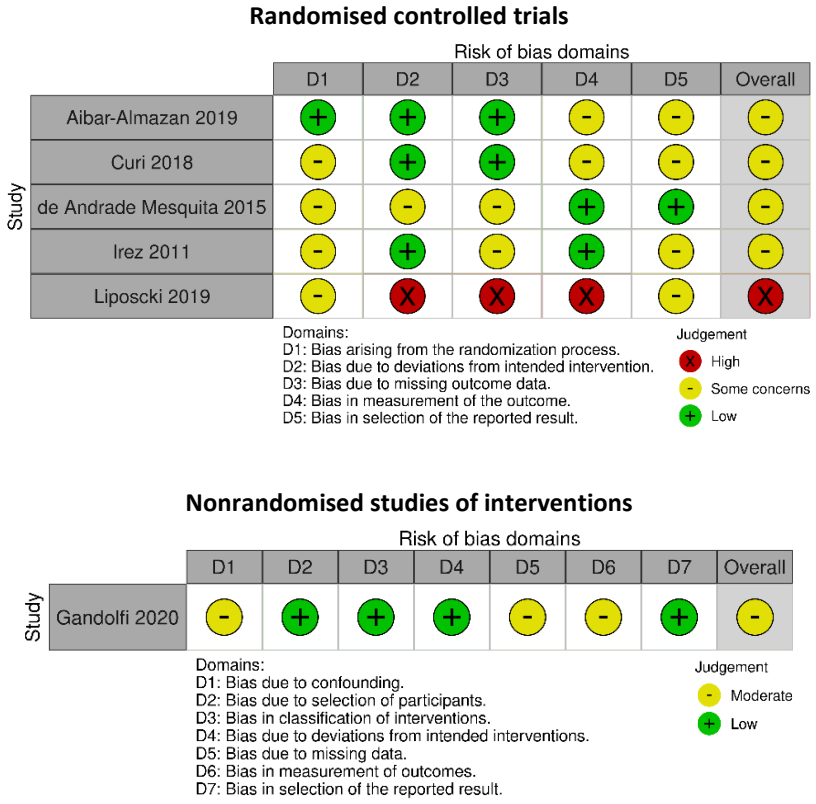
Results of the two studies (Aibar-Almazan 2019, de Andrade Mesquita 2015) that compared Pilates with an active comparator are presented in Appendix F2.

4.24.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 81. Details are provided in Appendix D10.3.2.

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

Figure 81 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Prevention of age-related physical and mental decline



4.24.4 Main comparison (vs control)

Five studies comparing Pilates with control (no intervention or usual activities) were eligible for this comparison. Three studies (Curi 2018, de Andrade Mesquita 2015, Liposcki 2019) and one NRSI (Gandolfi 2020) contributed data relevant to four outcomes relating to age-related physical decline. Two RCTs (Curi 2018, Liposcki 2019) and one NRSI (Gandolfi 2020) contributed data relevant to three outcomes relating to age-related mental decline. One study (Irez 2011) did not measure or assess any outcomes considered critical or important to this review and it is unclear if there is any missing data.

There were five additional studies published in a language other than English (awaiting classification) and two ongoing studies that compared Pilates with no intervention in people at risk of age-related physical or

mental decline (total 193 participants) that could have contributed data to some of the outcomes considered critical or important to this review (see Appendix C6).

4.24.4.1 Summary of findings

Age-related physical decline

Pilates compared to Control (no intervention, waitlist, usual activities) for prevention of age-related physical decline

Patient or population: prevention of age-related physical decline
Setting: Community or residential care home
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual activities)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with Control	Risk with Pilates				
Functional mobility assessed with: TUG test (higher is worse) follow-up: range 4 weeks to 16 weeks	The mean functional mobility ranged from **7.86 to 13.9** seconds	MD **3.75 seconds lower** (8.33 lower to 0.84 higher)	-	102 (2 RCTs)	⊕◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on functional mobility in older adults at risk of age-related physical decline.**
Physical functioning: SF-36 - Physical functioning (higher is best) Scale from: 0 to 100 follow-up: range 20 weeks to 26 weeks	The mean physical functioning ranged from **55.5 to 62.6** points	MD **30.3 points higher** (38.98 higher to 21.63 higher)	-	60 (1 RCT 1 NRSI^)	⊕⊕◯◯ LOW c,e,f,g,h	The evidence suggests Pilates results in a large improvement in physical functioning in older adults at risk of age-related physical decline.***
Quality of life assessed with: SF-36 - General health perceptions (higher is best) Scale from: 0 to 100 follow-up: range 20 weeks to 26 weeks	The mean quality of life was **71** points	MD **12.65 points higher** (23.34 higher to 1.97 higher)	-	60 (1 RCT 1 NRSI^)	⊕◯◯◯ VERY LOW c,d,e,g,i	The evidence is very uncertain about the effect of Pilates on general health perceptions in older adults at risk of age-related physical decline.***
Balance assessed with: Berg Balance Scale (higher is better) Scale from: 0 to 56 follow-up: 4 weeks	The mean balance was **51** points	MD **5 points higher** (6.62 higher to 3.38 higher)	-	38 (1 RCT)	⊕◯◯◯ VERY LOW a,c,e,j,k	The evidence is very uncertain about the effect of Pilates on balance in older adults at risk of age-related physical decline.****
Pain assessed with: SF-36 - bodily pain (higher is best) Scale from: 0 to 100 follow-up: range 20 weeks to 26 weeks	The mean pain ranged from **46.5 to 52.2** points	MD **23.36 points higher** (62.06 higher to 15.34 lower)	-	60 (1 RCT 1 NRSI^)	⊕◯◯◯ VERY LOW b,c,d,e,l	The evidence is very uncertain about the effect Pilates on bodily pain in older adults at risk of age-related physical decline.***

Pilates compared to Control (no intervention, waitlist, usual activities) for prevention of age-related physical decline

Patient or population: prevention of age-related physical decline
Setting: Community or residential care home
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual activities)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with Control	Risk with Pilates				
Aerobic endurance - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on aerobic endurance or fitness in older adults at risk of age-related physical decline is unknown.
Isokinetic muscle strength - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on isokinetic muscle strength in older adults at risk of age-related physical decline is unknown.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
** The MCID is assumed between 2.9 to 3.5 seconds based on MCID in people with chronic stroke (154) or Parkinson's disease (128). Participants in both groups are not at high risk of falling (TUG time is less than 13.5 seconds) therefore the clinically relevance is not clear.
*** MCID is unknown.#
**** The MCID in older adults is 6.5 points (449). It was not possible to measure a larger improvement because scores were so close to the maximum.

In the absence of an MCID, effect estimates were considered based on the following thresholds: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale), or large (MD more than 20% of the scale).
^ NRSI was asking sufficiently similar question to be combined in meta-analyses. The study was judged to be at moderate risk of bias. Exclusion from the evidence summary does not substantially change the result.

CI: confidence interval; **MD:** mean difference; **SF-36**: 36-item short-form; **TUG:** timed up and go

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. No serious risk of bias. Certainty of evidence not downgraded.
b. Serious inconsistency. No overlap confidence intervals. Substantial heterogeneity (I^2 > 90%). Certainty of evidence downgraded.
c. No serious indirectness. The evidence is generalisable to the Australian population with some caveats. The studies are in sedentary women aged over 60 years and may not be directly applicable to men. Certainty of evidence not downgraded.
d. Serious imprecision. Wide confidence intervals (upper and lower bounds overlap with large and no important difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence limited to a small number of small trials. Certainty of evidence downgraded.
f. One RCT (25% weight) at high risk of bias that raises serious doubts about the results. Certainty of evidence downgraded.
g. No serious inconsistency. Certainty of evidence not downgraded.

h. No serious imprecision. Certainty of evidence not downgraded.
i. One RCT (40% weight) at high risk of bias that raises serious doubts about the results. Certainty of evidence downgraded.
j. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
k. Very serious imprecision. Single study (fewer than 40 participants). Wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded by two levels.
l. One RCT (49% weight) at high risk of bias that raises serious doubts about the results. Certainty of evidence downgraded.

Age-related mental decline

Pilates compared to Control (no intervention, waitlist, usual activities) for Prevention of age-related mental decline

Patient or population: Prevention of age-related mental decline
Setting: Community or residential care home
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual activities)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with Control	Risk with Pilates				
Quality of life assessed with: SF-36 - mental component score (higher is better) follow-up: range 20 weeks to 26 weeks	Effect favouring Pilates for three out of four domains: vitality (MD –19.21; 95% CI –27.57, –10.84; p < 0.00001; I^2 = 0%), role-emotional (MD –46.51; 95% CI –64.73, –28.28; p < 0.00001; I^2 = 0%) and mental health (MD –14.62; 95% CI –23.51, –5.74; p = 0.001; I^2 = 0%). Variable effect of Pilates on role-social (MD –5.19; 95% CI –31.42, 21.03; p = 0.70; I^2 = 89%).			60 (1 RCT 1 NRSI^)	⨁◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on mental wellbeing in older adults at risk of age-related mental decline.
General health perceptions assessed with: General Health Questionnaire (higher is worse) Scale from: 0 to 36 follow-up: 16 weeks	The mean general health perceptions score was **12.4** points	MD **5 points lower** (2.43 lower to 7.73 lower)	-	64 (1 RCT)	⨁⨁◯◯ LOW a,c,d,e,f	The evidence suggests Pilates results in little to no difference in general health perceptions in older adults at risk of age-related mental decline.**
Emotional wellbeing - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on emotional wellbeing in older adults at risk of age-related mental decline is unknown.
Sleep quality assessed with: Pittsburgh Sleep Quality Index (higher is worse) Scale from: 0 to 21 follow-up: 16 weeks	The mean Sleep quality was **7.6** points	MD **1.99 points lower** (4.25 lower to 0.27 higher)	-	64 (1 RCT)	⨁◯◯◯ VERY LOW a,c,d,e,f	The evidence is very uncertain about the effect of Pilates on sleep quality in older adults at risk of age-related mental decline.***
Carer burden - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on carer burden in older adults at risk of age-related mental decline is unknown.

Pilates compared to Control (no intervention, waitlist, usual activities) for Prevention of age-related mental decline

Patient or population: Prevention of age-related mental decline
Setting: Community or residential care home
Intervention: Pilates
Comparison: Control (no intervention, waitlist, usual activities)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with Control	Risk with Pilates				
Loneliness / isolation - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on loneliness or isolation in older adults at risk of age-related mental decline is unknown.
Cognitive function - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on cognitive function in older adults at risk of age-related mental decline is unknown.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).
** MCID is unknown#. Scores > 15 suggesting evidence of distress. Participants in both groups are within the range considered typical, so the clinical relevance of the observed improvement is not important.
*** MCID is unknown#. A score ≥ 5 is associated with poor sleep quality. Participants in both groups continue to have poor sleep quality.

In the absence of an MCID, effect estimates were considered based on the following thresholds: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale), or large (MD more than 20% of the scale).
^ NRSI was judged to be at moderate risk of bias. Exclusion from the evidence summary does not substantially change the result.

CI: confidence interval; **MD**: mean difference; **SF-36**: 36-item short-form

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

a. No serious risk of bias. Certainty of evidence not downgraded.
b. Serious inconsistency for one domain. Confidence intervals do not overlap. Certainty of evidence downgraded.
c. No serious indirectness. The evidence is directly generalisable to the Australian population with some caveats. The studies are in sedentary women aged over 60 years and may not be directly applicable to men. Certainty of evidence not downgraded.
c. Serious imprecision. Wide confidence intervals (upper and lower bounds overlap with large, small or no important difference) Certainty of evidence downgraded.
d. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.
f. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.

4.24.4.2 Forest plots

Age-related physical decline

Outcome results related to functional mobility in older adults at risk of age-related physical decline are presented in Figure 82.

Outcome results related to physical functioning in older adults at risk of age-related physical decline are presented in Figure 83.

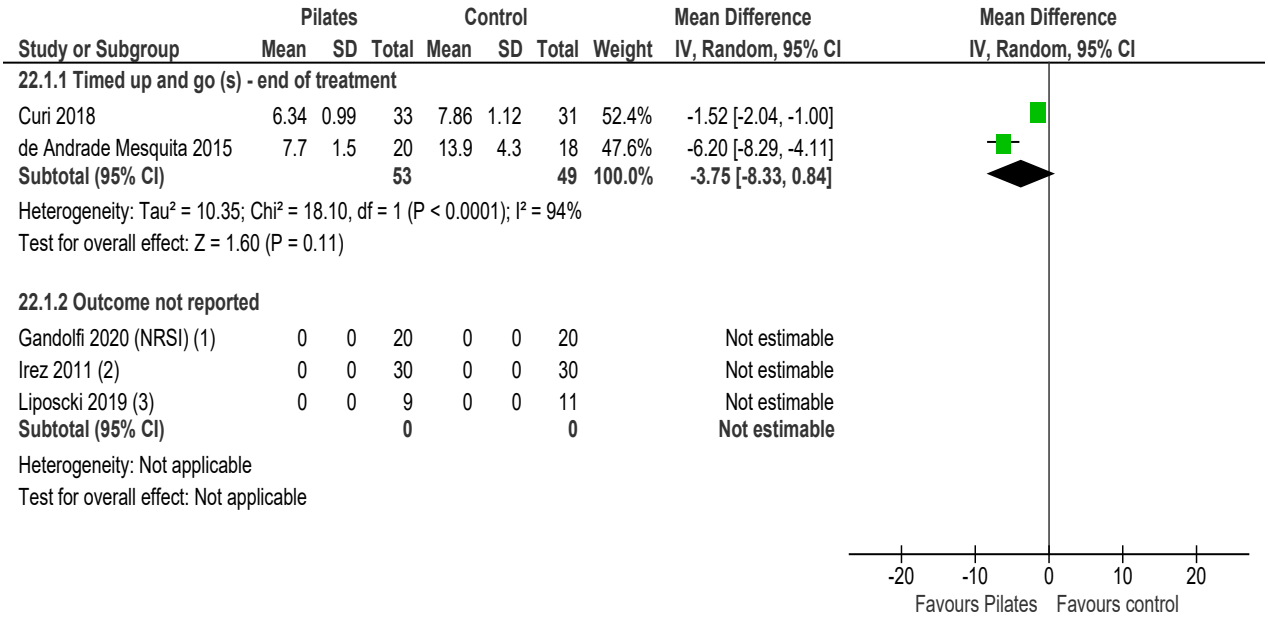
Outcome results related to general health perceptions in older adults at risk of age-related physical decline are presented in Figure 84

Outcome results related to balance in older adults at risk of age-related physical decline are presented in Figure 85.

Outcome results related to pain in older adults at risk of age-related physical decline are presented in Figure 86.

Outcome results related to aerobic capacity or fitness in older adults at risk of age-related physical decline are presented in Figure 87.

Figure 82 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): older adults at risk of age-related physical decline – functional mobility



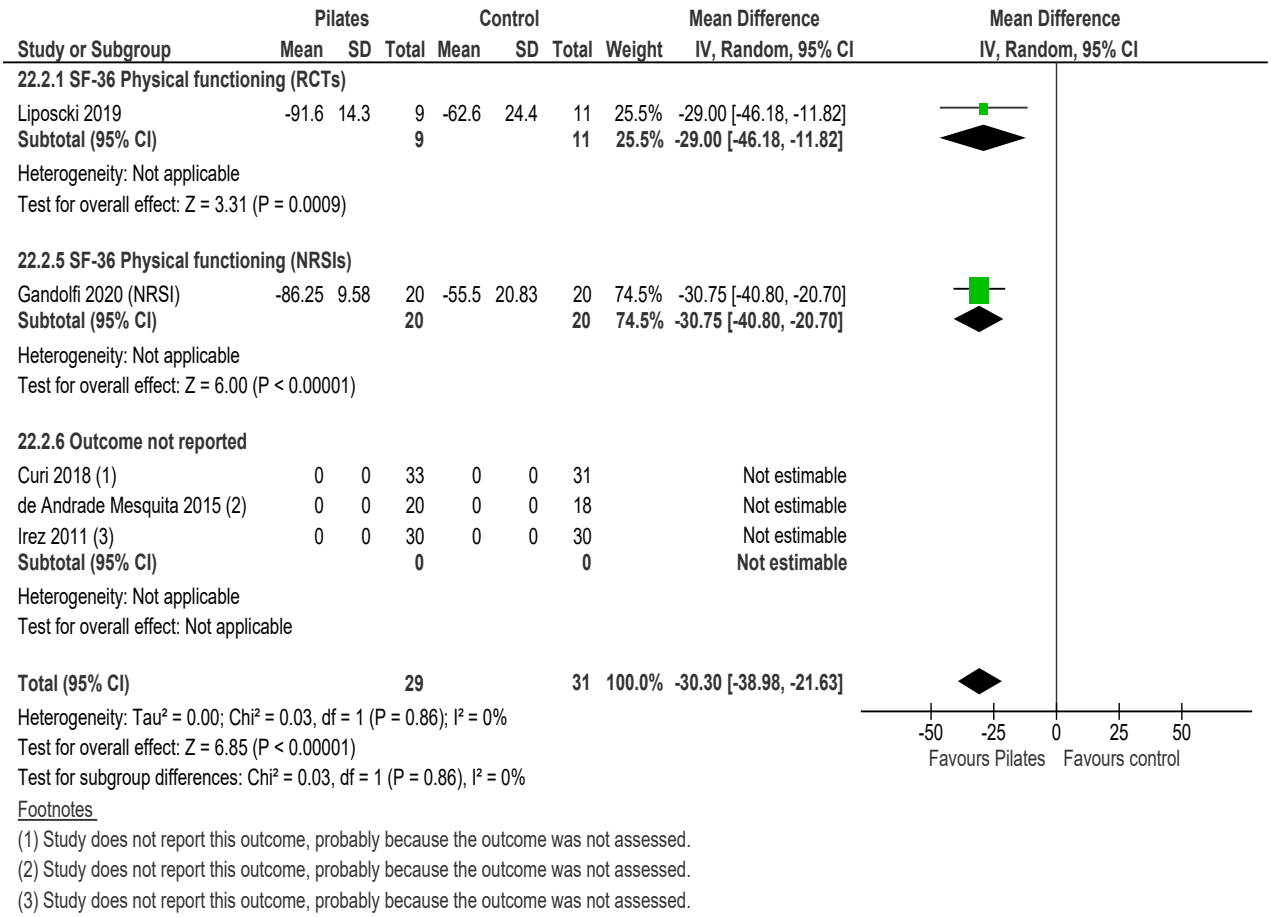
Footnotes

(1) Study does not report this outcome, probably because the outcome was not assessed.

(2) Study does not report this outcome, and it is unclear if the outcome was measured or assessed.

(3) Study does not report this outcome, probably because the outcome was not assessed.

Figure 83 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): older adults at risk of age-related physical decline – physical functioning



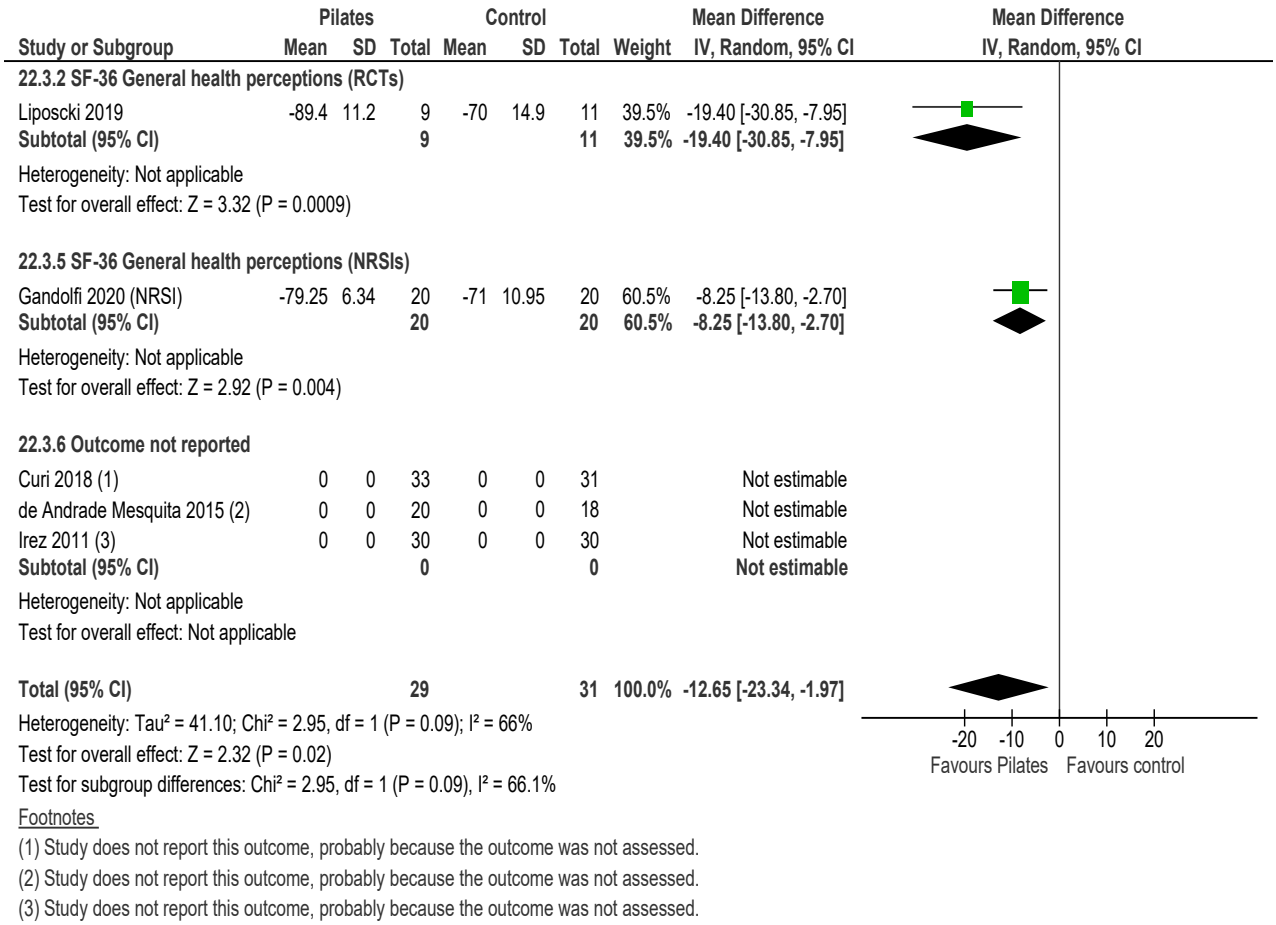
Footnotes

(1) Study does not report this outcome, probably because the outcome was not assessed.

(2) Study does not report this outcome, probably because the outcome was not assessed.

(3) Study does not report this outcome, probably because the outcome was not assessed.

Figure 84 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): older adults at risk of age-related physical decline – general health perceptions



Footnotes

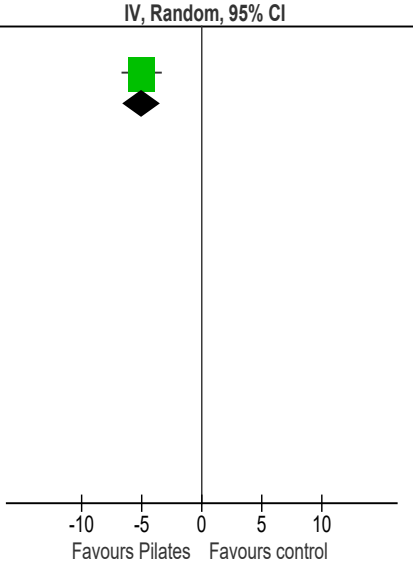
(1) Study does not report this outcome, probably because the outcome was not assessed.

(2) Study does not report this outcome, probably because the outcome was not assessed.

(3) Study does not report this outcome, probably because the outcome was not assessed.

Figure 85 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): older adults at risk of age-related physical decline – balance

Study or Subgroup	Pilates Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
22.4.1 Berg balance scale (0-56)								
de Andrade Mesquita 2015	-56	0.1	20	-51	3.5	18	100.0%	-5.00 [-6.62, -3.38]
Subtotal (95% CI)			**20**			**18**	**100.0%**	**-5.00 [-6.62, -3.38]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 6.06 (P < 0.00001)								
22.4.6 Outcome not reported								
Curi 2018 (1)	0	0	33	0	0	31		Not estimable
Gandolfi 2020 (NRSI) (2)	0	0	20	0	0	20		Not estimable
Irez 2011 (3)	0	0	30	0	0	30		Not estimable
Liposcki 2019 (4)	0	0	9	0	0	11		Not estimable
Subtotal (95% CI)			**0**			**0**		**Not estimable**
Heterogeneity: Not applicable								
Test for overall effect: Not applicable								



Footnotes

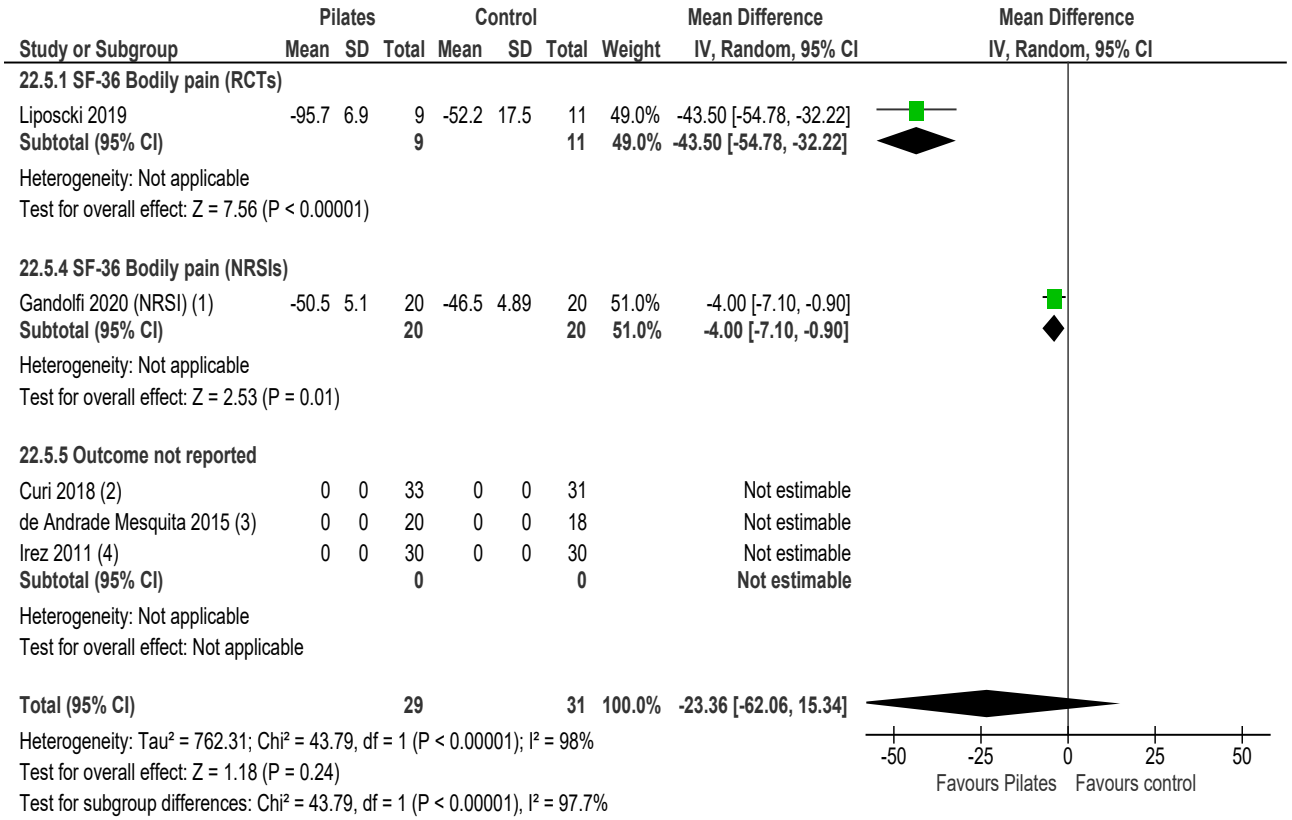
(1) Study does not report this outcome, probably because the outcome was not assessed.

(2) Study does not report this outcome, probably because the outcome was not assessed.

(3) Study does not report this outcome. Outcome measured with dynamic stability platform.

(4) Study does not report this outcome, probably because the outcome was not assessed.

Figure 86 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): older adults at risk of age-related physical decline – pain



Footnotes

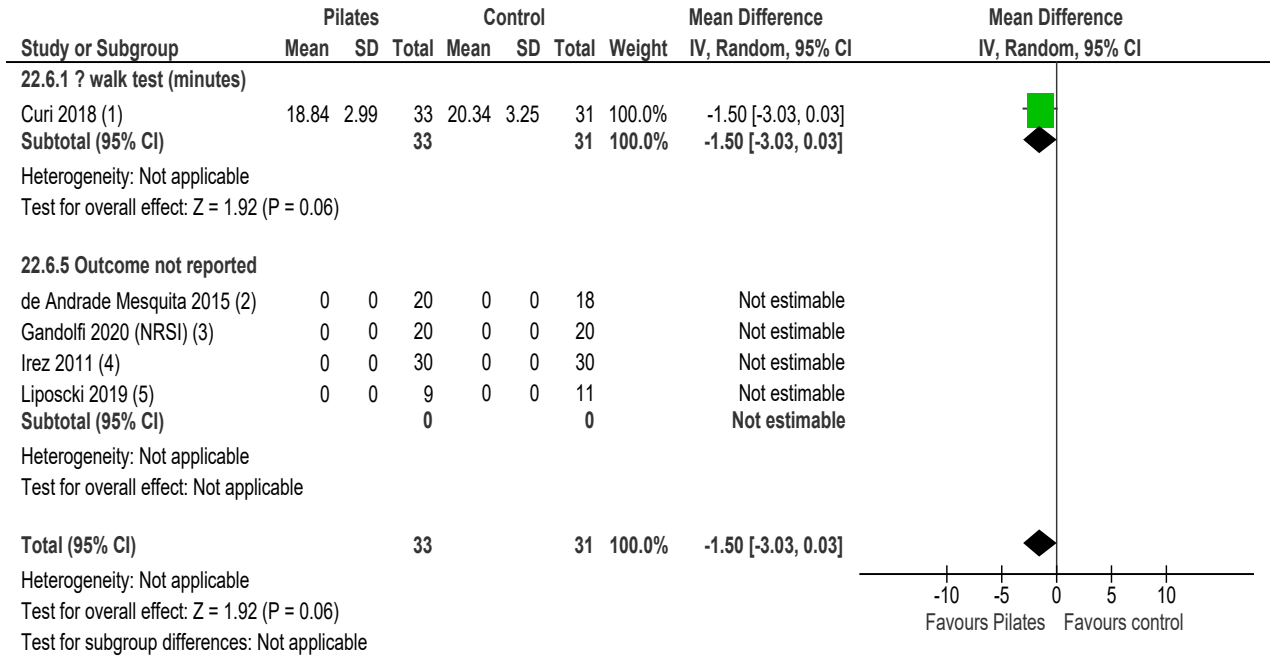
(1) Inclusion of NRSI reduced the size of the effect.

(2) Study does not report this outcome, probably because the outcome was not assessed.

(3) Study does not report this outcome, probably because the outcome was not assessed.

(4) Study does not report this outcome, probably because the outcome was not assessed.

Figure 87 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): older adults at risk of age-related physical decline – aerobic capacity or fitness



Footnotes

(1) Authors not clear what test is used. Assumed to be a distance-based (e.g. 10M or 50-foot walk test) (higher is worse).

(2) Study does not report this outcome, probably because the outcome was not assessed.

(3) Study does not report this outcome, probably because the outcome was not assessed.

(4) Study does not report this outcome, probably because the outcome was not assessed.

(5) Study does not report this outcome, probably because the outcome was not assessed.

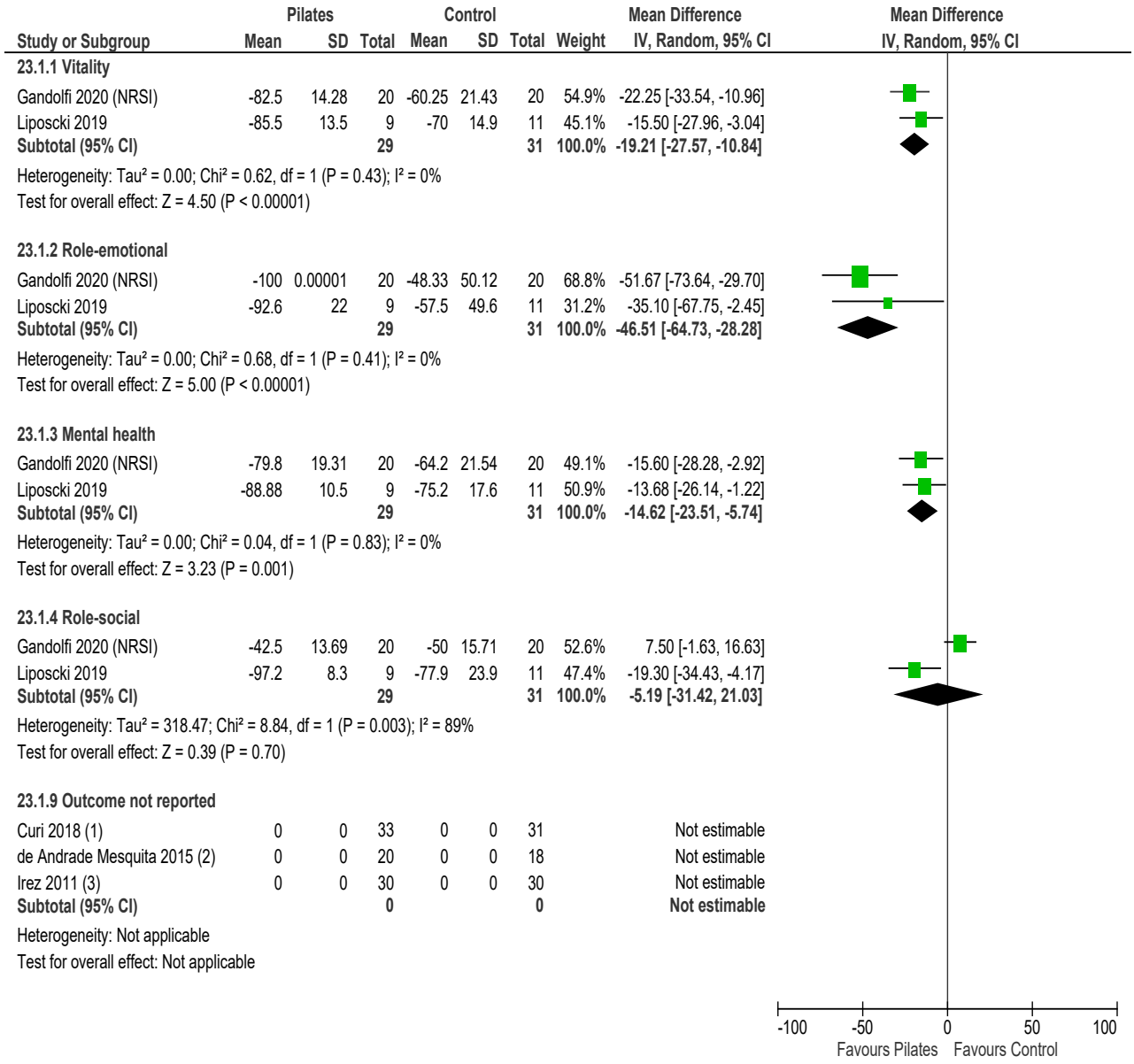
Age-related mental decline

Outcome results related to mental wellbeing in older adults at risk of age-related mental decline are presented in Figure 88.

Outcome results related to general health perceptions in older adults at risk of age-related mental decline are presented in Figure 89.

Outcome results related to sleep quality in older adults at risk of age-related mental decline are presented in Figure 90.

Figure 88 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): older adults at risk of age-related mental decline – mental wellbeing



Footnotes

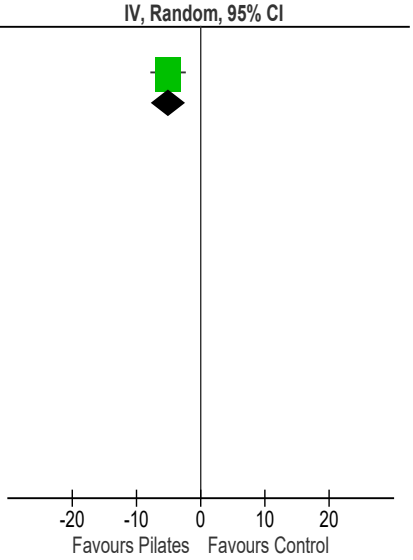
(1) Study does not report this outcome, probably because the outcome was not assessed.

(2) Study does not report this outcome, probably because the outcome was not assessed.

(3) Study does not report this outcome, probably because the outcome was not assessed.

Figure 89 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): older adults at risk of age-related mental decline – general health perceptions

Study or Subgroup	Pilates Mean	Pilates SD	Pilates Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
23.3.1 GHQ-12 (0-24)								
Curi 2018	7.32	4.36	33	12.4	6.23	31	100.0%	-5.08 [-7.73, -2.43]
Subtotal (95% CI)			**33**			**31**	**100.0%**	**-5.08 [-7.73, -2.43]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 3.76 (P = 0.0002)								
23.3.9 Outcome not reported								
de Andrade Mesquita 2015 (1)	0	0	20	0	0	18		Not estimable
Gandolfi 2020 (NRSI) (2)	0	0	20	0	0	20		Not estimable
Irez 2011 (3)	0	0	30	0	0	30		Not estimable
Liposcki 2019 (4)	0	0	9	0	0	11		Not estimable
Subtotal (95% CI)			**0**			**0**		**Not estimable**
Heterogeneity: Not applicable								
Test for overall effect: Not applicable								

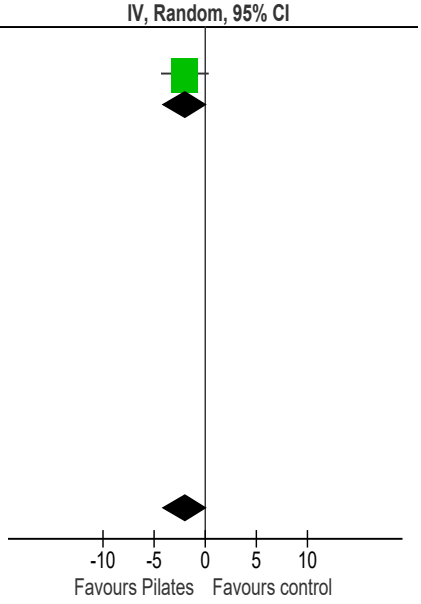


Footnotes

(1) Study does not report this outcome, probably because the outcome was not assessed.
(2) Study does not report this outcome, probably because the outcome was not assessed.
(3) Study does not report this outcome, probably because the outcome was not assessed.
(4) Study does not report this outcome, probably because the outcome was not assessed.

Figure 90 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): older adults at risk of age-related mental decline – sleep quality

Study or Subgroup	Pilates Mean	Pilates SD	Pilates Total	Control Mean	Control SD	Control Total	Weight	Mean Difference IV, Random, 95% CI
23.4.1 PSQI - total score								
Curi 2018	5.61	2.93	33	7.6	5.77	31	100.0%	-1.99 [-4.25, 0.27]
Subtotal (95% CI)			**33**			**31**	**100.0%**	**-1.99 [-4.25, 0.27]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.72 (P = 0.08)								
23.4.9 Outcome not reported								
de Andrade Mesquita 2015 (1)	0	0	20	0	0	18		Not estimable
Gandolfi 2020 (NRSI) (2)	0	0	20	0	0	20		Not estimable
Irez 2011 (3)	0	0	30	0	0	30		Not estimable
Liposcki 2019 (4)	0	0	9	0	0	11		Not estimable
Subtotal (95% CI)			**0**			**0**		**Not estimable**
Heterogeneity: Not applicable								
Test for overall effect: Not applicable								
Total (95% CI)			**33**			**31**	**100.0%**	**-1.99 [-4.25, 0.27]**
Heterogeneity: Not applicable								
Test for overall effect: Z = 1.72 (P = 0.08)								
Test for subgroup differences: Not applicable								



Footnotes

(1) Study does not report this outcome, probably because the outcome was not assessed.

(2) Study does not report this outcome, probably because the outcome was not assessed.

(3) Study does not report this outcome, probably because the outcome was not assessed.

(4) Study does not report this outcome, probably because the outcome was not assessed.

4.25 Prevention of falls

4.25.1 Description of the condition

Fall prevention has remained a high priority in the health promotion of older populations with approximately one-third of community-dwelling people over the age of 65 reported to fall each year (450-452). Falls can have serious consequences, such as fractures and head injuries, and the rate of such fall-related injuries increases with age (453). Around 10% of falls result in a fracture (454), with fall-associated fractures in older people a significant source of morbidity and mortality (452) (455). Even less serious fall-related injuries, such as bruising, lacerations and sprains can lead to pain, reduced function and substantial health care costs (455).

Across Australia, fall-related injuries represents one of the single largest causes of hospital presentations; with 27 000 hospitalisations and more than 400 deaths occurring from falls in New South Wales each year (456). For people aged 65 years or older, the average health system cost per fall injury in Australia is estimated to be US $1049 (457). In addition to the substantial financial costs from fall-related injuries, there are also significant psychological impacts (physical and emotional) associated with a fear of falling and loss of balance confidence related to a reduction in physical activities and social interactions (458).

A review of risk factors associated with falling noted women are more at risk of falling than men (459) and estimated that 15% of falls result from an external event, a similar proportion from one identifiable source (such as a syncope), and over 60% resulted from several interacting factors (such as muscle weakness, arthritis, gait or balance deficit, visual deficit, depression, cognitive impairment, and use of psychotropic medication) (459). There are a variety of different interventions and approaches that have been investigated to prevent falls and fall-related injuries in people aged over 65 years (460-463), with strong evidence that interventions such as group and home-based exercise programs (that generally comprise balance and strength-based training) effectively reduced falls (460).

4.25.2 Description of studies

Four citations (464-467), corresponding to three RCTs (Barker 2016, Josephs 2016, Roller 2018) were identified in the literature search. There were eight ongoing studies (468-475) and one study awaiting classification (476) that was identified in the Department's public call for evidence (not in English). An overview of the PICO criteria of included studies is provided in Appendix D10.4.1.

All three studies were carried out in community-dwelling older adults (aged older than 60 years) who were assessed to be at risk of falls. Studies were conducted in Australia (Barker 2016) or in the USA (Josephs 2016, Roller 2018). Sample sizes range from 24 to 55 (total 128 participants). Two studies (Josephs 2016, Roller 2018) had inclusion criteria requiring a Timed Up and Go score greater than 13.5 seconds which is associated with increased falls risk (477). Barker 2016 enrolled participants who were assessed to be at risk of falls based on a telephone interview developed by the study authors.

Two studies (Barker 2016, Roller 2018) compared Pilates with no intervention or inactive control including standard of care. One study (Josephs 2016) compared Pilates to conventional balance exercise training. Interventions ranged from 10 to 12 weeks, with one study (Barker 2016) also including a follow-up period of 12 weeks post-intervention. Pilates exercises in two studies (Barker 2016, Josephs 2016) involved two 60-minute sessions per week, while in one study (Roller 2018) the 45-minute Pilates exercises were offered once per week. Pilates classes across all three studies were limited to a maximum of four to six participants at a time, with the interventions including equipment such as reformer or chair.

Results for Pilates versus inactive control (no intervention, waitlist or usual care, if considered inactive) are provided in the Summary of Findings tables (see 4.23.4.1) (and Appendix F2).

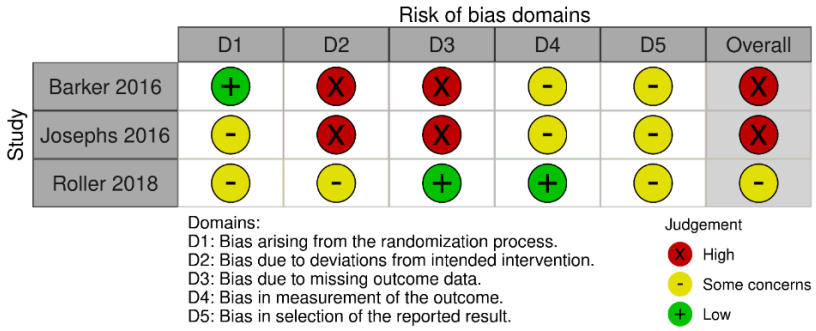
Results of the study (Josephs 2016) that compared Pilates with an active comparator are presented in Appendix F2.

4.25.3 Risk of bias - per item

The risk of bias for each item in the included RCTs is summarised in Figure 91. Details are provided in Appendix D10.4.1.

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

Figure 91 Risk of bias summary: review authors' judgements about each risk of bias item for each included study: Falls prevention



4.25.4 Main comparison (vs control)

Two studies (Barker 2016, Roller 2018) were eligible for this comparison and contributed data to four outcomes. There was one additional study published in a language other than English (awaiting classification) and three ongoing studies (complete but results not available) that compared Pilates with no intervention in people at risk of falls (total 241 participants) that could have contributed data to some of the outcomes considered critical or important to this review (see Appendix C6).

4.25.4.1 Summary of findings

Pilates compared to control (no intervention, wait list or usual care) for Prevention of falls

Patient or population: Prevention of falls
Setting: Community or Care home
Intervention: Pilates
Comparison: Control (no intervention, wait list or usual care)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Evidence statement
	Risk with control	Risk with Pilates				
Falls assessed with: Rate of falls per 1000 person days (higher is worse) follow-up: 24 weeks	No difference in rate of falls per 1000 person days between Pilates and control (incidence rate ratio 1.17; 95% CI 0.43 to 3.16; *p* = 0.754). It is likely the reported results were calculated on transformed values.		-	44 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on the rate of falls in health adults at risk of falls.**
Falls injury assessed with: Falls injury rate per 1000 person days (higher is worse) follow-up: 24 weeks	No difference in rate of falls injury per 1000 person days between Pilates and control (incidence rate ratio 0.36; 95% CI 0.09 to 1.38; *p* = 0.136). It is likely the reported results were calculated on transformed values.		-	40 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,d,e	The evidence is very uncertain about the effect of Pilates on the rate of falls injury in older adults at risk of falls.**
Balance (static) assessed with: Berg Balance Scale (higher is better) Scale from: 0 to 56 follow-up: 10 weeks	The mean balance was **52.7** points	MD **0.52 points higher** (0.99 lower to 2.03 higher)	-	55 (1 RCT)	⊕◯◯◯ VERY LOW a,b,c,e,g	The evidence is very uncertain about the effect of Pilates on balance in older adults at risk of falls.***
Physical function - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on physical function in older adults at risk of falls is not known.
Quality of life - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on quality of life in older adults at risk of falls is not known.
Functional mobility assessed with: Timed Up and Go (higher is worse) follow-up: 10 to 12 weeks	The mean functional mobility ranged from **9.98 to 11.54** seconds	MD **0.62 seconds lower** (1.71 higher to 0.46 lower)	-	104 (2 RCTs)	⊕◯◯◯ VERY LOW b,c,e,f,h	The evidence is very uncertain about the effect of Pilates on functional mobility in older adults at risk of falls.****
Psychological consequences - not reported	-	-	-	(0 studies)	-	No studies found. The effect of Pilates on psychological consequences in older adults at risk of falls is not known.

Pilates compared to control (no intervention, wait list or usual care) for Prevention of falls

Patient or population: Prevention of falls
Setting: Community or Care home
Intervention: Pilates
Comparison: Control (no intervention, wait list or usual care)

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

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).
** AN IRR > 1 indicates that the incident rate is greater in the Pilates group compared to control.
*** The MCID in older adults is 6.5 points (449). Participants in both groups are not at high risk of falling (score >45). The measure is unlikely to be sufficiently sensitive to detect true change in balance stability for this population.
**** The MCID is unknown^ noting that participants in both groups are not at high risk of falling (TUG time is less than 13.5 seconds) therefore the clinically relevance is not clear (in people with chronic stroke or Parkinson's disease the MCID ranges between 2.9 to 3.5 seconds (128, 154).

Effect estimates were considered on three levels: small (MD <10% of the scale), moderate (MD between 10% to 20% of the scale) or large (MD more than 20% of the scale).
^ In the absence of an MCID, effect estimates were considered based on the SMD: where an SMD of 0.2 represents a small difference, 0.5 is moderate, and 0.8 is a large difference.

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

GRADE Working Group grades of evidence
High certainty: we are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Explanations

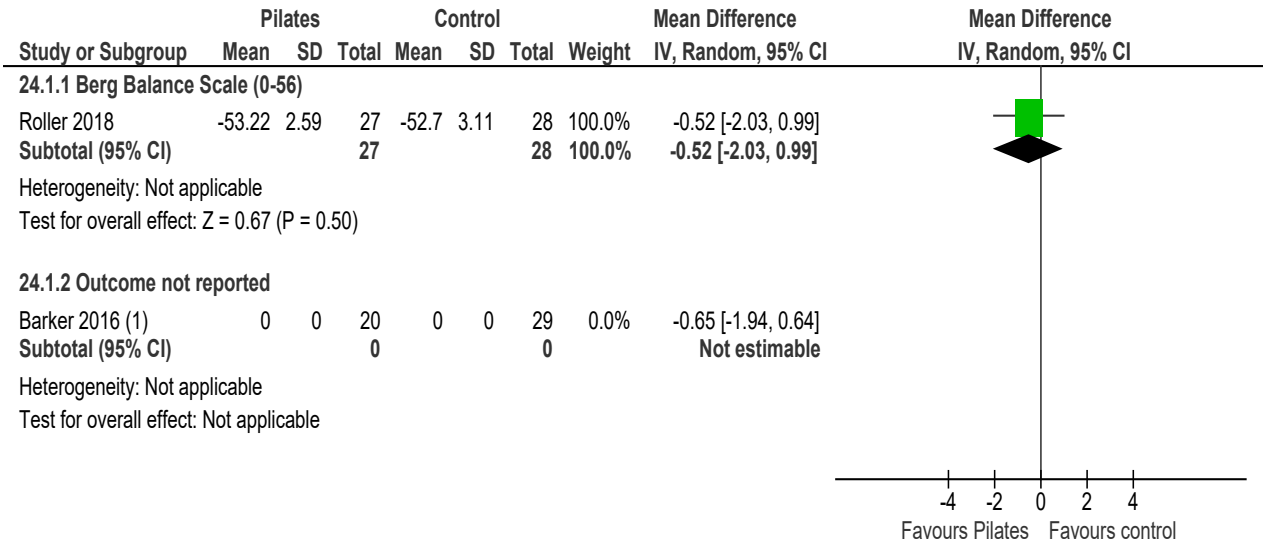
a. One study (100% weight) at high risk of bias. Certainty of evidence downgraded.
b. Single study. Inconsistency not assessed. Certainty of evidence not downgraded.
c. No serious indirectness. The available evidence is directly generalisable to the Australian population with few caveats. The evidence is in people aged over 60 years with a history of falls. Certainty of evidence not downgraded.
d. Serious imprecision. Single study (fewer than 50 participants). Wide confidence intervals (upper and lower bounds overlap with important and no important difference). Certainty of evidence downgraded.
e. Publication bias suspected. Evidence is limited to a small number of small trials. Certainty of evidence downgraded.
f. No serious risk of bias. Certainty of evidence not downgraded.
g. Serious imprecision. Single study (60 participants). Wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded.
h. Serious imprecision. Wide confidence intervals (lower bound overlaps with no important difference). Certainty of evidence downgraded.

4.25.4.2 Forest plots

Outcome results related to balance for people at risk of falling are presented in Figure 92.

Outcome results related to functional mobility for people at risk of falling are presented in Figure 93.

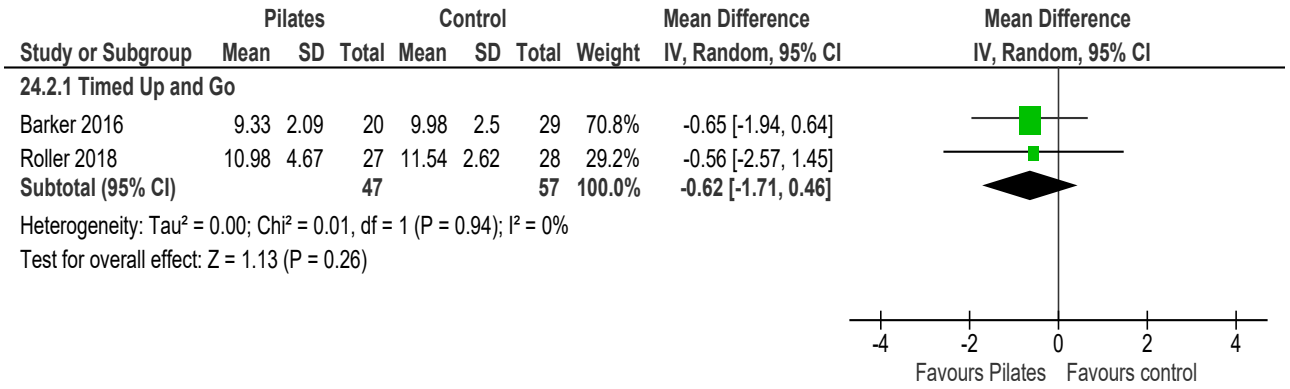
Figure 92 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Healthy adults at risk of falls – Balance



Footnotes

(1) Study does not report this outcome. Dynamic balance assessed using stabilometry.

Figure 93 Forest plot of comparison: Pilates vs control (no intervention, waitlist, usual activities): Healthy adults at risk of falls – Functional mobility



5 Discussion

5.1 Summary of main results

We conducted a systematic review of RCTs and NRSIs to evaluate the effectiveness of Pilates for 26 clinical or preclinical conditions prioritised (by NTWC) as most relevant to the practise of Pilates in Australia. We identified 105 studies (57 RCTs, 40 quasi RCTs, and 8 NRSIs), which were included in the results. Of these studies, 66 studies (65 RCTs and 1 NRSI) compared Pilates exercises with the main comparator of interest, 'inactive control.' Out of the 26 conditions prioritised by NTWC, 22 studies that included either critical or important outcomes were included in the final analysis and are presented in the summary of findings tables.

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

Studies were assessed using the GRADE framework. GRADE combines information to assess overall how certain systematic review authors can be that the estimates of the effect (reported across a study/s for each critical or important outcome) are correct.

Certainty of evidence is interpreted as follows:

Certainty	Definition
High certainty	The authors have a lot of confidence that the true effect is similar to the estimated effect.
Moderate certainty	The true effect is probably close to the estimated effect.
Low certainty	The true effect might be markedly different from the estimated effect.
Very low certainty	The true effect is probably markedly different from the estimated effect.

This review identified 15 prioritised conditions for which the evidence provided moderate or low certainty about the effect of Pilates on an outcome considered critical or important by NTWC. The evidence provides:

- moderate certainty that Pilates:
    - improves incontinence-related quality of life in men after radical prostatectomy (from two studies, 126 participants).
    - provides a moderate reduction (10-20%) in disability (12 studies, 937 participants) and a slight improvement (<10%) in overall quality of life (one study, 295 participants) in people with chronic low back pain.

- low certainty that Pilates provides:
    - a large decrease (>20%) in pain in people with chronic low back pain (12 studies, 1062 participants).
    - a large improvement (>20%) in sleep quality in women with symptoms of menopause (one study, 72 participants).
    - a large improvement (>20%) in knee stability in people rehabilitating after knee injury (one study, 50 participants)
    - a large improvement (>20%) in physical functioning in people at risk of age-related decline (2 studies, 60 participants).

  - a moderate improvement (10-20%) in physical wellbeing in people with postviral arthropathies (one study, 42 participants).
  - a moderate reduction (10-20%) in neck-related disability in people with chronic neck pain (two studies, 101 participants).
  - a moderate improvement (10-20%) in some (but not all) measures of quality of life for people with chronic neck pain (one study, 64 participants).
  - a moderate improvement (10-20%) in vasomotor symptoms (one study, 74 participants) and physical symptoms (one study, 74 participants) in women with symptoms of menopause.
  - a moderate improvement (10-20%) in trait anxiety in people at risk of mental health conditions (one study, 62 participants).
  - a moderate improvement (10-20%) in mental wellbeing in sedentary adults at risk of metabolic disorders or weight problems (one study, 99 participants).
  - a slight improvement (<10%) in activities of daily living in women with type 2 diabetes (one study, 24 participants).
  - a slight improvement (<10%) in quality of life in people with osteoporosis (one study, 40 participants).
  - a slight improvement (<10%) in mental wellbeing in people with multiple sclerosis (one study, 30 participants).
  - a slight improvement (<10%) in state anxiety in people at risk of mental health conditions (one study, 62 participants).
  - a slight improvement (<10%) in physical wellbeing (except pain) in sedentary adults at risk of metabolic disorders or weight problems (one study, 99 participants)

- moderate certainty that Pilates provides little (to no) benefit in:
  - the functional capacity of people with low back pain (from two studies, 382 participants).

- low certainty that Pilates provides little (to no) benefit in:
  - mental wellbeing (one study, 45 participants) and fatigue (one study, 45 participants) in women with type 2 diabetes.
  - physical wellbeing (one study, 30 participants) and functional mobility (three studies, 80 participants) in people with multiple sclerosis.
  - functional mobility (one study, 20 participants) in stroke recovery.
  - global perceived effect (one study, 55 participants), physical functioning (one study, 55 participants), quality of life (one study, 55 participants) and spinal mobility (one study, 55 participants) in people with spondyloarthropathies.
  - static balance in people with osteoporosis (one study, 40 participants).
  - non-narcotic analgesic use (one study, 60, participants) in people with low back pain.
  - general health perception in people at risk of age-related mental decline (one study, 64 participants).

The evidence provides very low certainty of the effect of Pilates versus inactive control (no intervention, wait list or usual care) for 51 out of the 196 critical or important outcomes prioritised for analysis in this review. For these outcomes, the estimate of effect did not reach statistical significance, nor was a clinically important difference observed (this possibly relates to study design, size, or duration of the study).

There were no outcomes reported across studies for 122 out of 196 critical or important outcomes prioritised in this review, and therefore the effect of Pilates on these outcomes is unknown.

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

Overall, the evidence suggests that Pilates may provide people who practise it with a slight or small benefit, for a small number of relevant outcomes (up to three for a given condition) when compared with inactive control (no intervention, wait list or inactive control), however the size of the effect estimate is uncertain, and the duration of the effect is unknown. Other than pain and disability outcomes for chronic low back pain, for which there were over 10 studies each, the effect estimates were based on one or two small studies (typically 40 to 100 total participants) with concerns of bias that may favour the intervention (Pilates). For several outcomes, a clinically important difference was not observed (possibly relating to study design, size or duration).

5.2 Overall completeness and applicability of evidence

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

There were 33 studies that met the eligibility criteria for the review but were conducted in conditions not prioritised for analysis or synthesis by NTWC. The studies are listed in an inventory titled *Citation details of studies from non-priority populations* (Appendix C3, Table C.3) with a narrative description of studies provided in Appendix C6.

Studies published in a language other than English were not translated and were not included in the synthesis but were listed in an inventory for completeness (Appendix C4.2). Databases in languages other than English were not searched. There were 51 publications identified in a language other than English.

The available evidence was from a range of countries including Australia, Brazil, Canada, India, Iran, Ireland, Israel, Korea, Spain, Turkey, Ukraine, United Kingdom and the United States. All studies examined Pilates exercises delivered in a manner that would be considered generally applicable to the Australian context. Participant ages generally ranged between 18 to 75 years, many studies focused on conditions in older adults (50 years or older) or were conducted with women only. Most studies evaluated group Pilates classes that were 45 to 60 minutes in duration. Sessions gradually increased in intensity over the course of treatment, which varied from between one and five sessions per week, with the addition of equipment such as balls or bands and apparatus also commonly reported. The treatment provider was often not specified, but when reported, tended to be experienced instructors or physical therapists trained in the Pilates method. The study duration typically lasted four to 12 weeks, with a handful of studies examining Pilates exercises delivered for between 16 and 24 weeks. No studies provided any longer-term data (Pilates practised for more than 6-months).

In general, the included studies provided a clear description of the condition, outcomes and interventions used in the study. However, for the studies assessing the 22 prioritised conditions for Pilates versus inactive control (no intervention, wait list or usual care), 95 (~57%) out of the 169 outcomes prioritised as critical or important, were not measured or reported in studies. A further four priority conditions did not have any available evidence for the 27 critical or important outcomes prioritised by NTWC (women receiving treatment for breast cancer; hypertensive heart disease; chronic widespread pain; shoulder pain).

We identified a few studies with missing outcome information or information that was not translatable (such as that included in graphs). However, as per the protocol, we made no requests to authors for this information and did not attempt to translate information contained in graphs. It is considered unlikely this information would have impacted the overall conclusions of this review.

Studies included in this review are those published up until June 2020. Given the large amount of evidence for Pilates that remained unpublished or was not yet evaluated at the time of the search (82 studies with 2713 participants were awaiting classification, >50% of studies were in a language other than English and 116 studies (6368 target participants) were listed as ongoing) it is unknown whether these studies would meet the eligibility criteria for this review and therefore impact the overall results.

5.3 Certainty of the evidence

A large proportion of the studies included in this review had concerns with bias. Concerns of bias relating to the inability of studies to blind participants, and outcome assessors being aware of the intervention received, were considered reasonable and generally did not raise serious concerns when assessing the certainty of the evidence. For most studies we were unable to obtain and therefore assess published protocols or statistical analysis plans, and as per the protocol, did not attempt to contact study authors to obtain this information.

The absence of information about the randomisation procedure and allocation concealment contributed to higher risk of bias assessments as did the fact that many studies failed to report baseline characteristics or account for missing outcome data. With small sample sizes (ranging from 5 to 296 participants) (5), the robustness of the data was compromised by authors excluding participants with missing outcome data from the analysis (including baseline data), and in some cases excluding participants who did not meet a certain level of class attendance. Where studies accounted for participants that explained the missingness of the data, a judgement regarding the proportion and relationship of the missing data to participant health status was made. Based on studies of dropout in exercise interventions (478, 479), and in the absence of reasons for the missing data it was considered likely that dropouts were due to prognostic or treatment responses and the proportion of the missing data in relation to the outcome was then considered.

An intention-to-treat analysis or per-protocol analysis was not clearly stated for most studies eligible for inclusion in the analysis. Five studies reported having conducted both kinds of analysis, and in all cases the conclusion reported was the same regardless of which analysis was used. Additional details are outlined in Appendix F1.

The certainty of evidence across outcomes was generally downgraded for issues with imprecision (related to sample size and wide confidence intervals) and suspected publication bias (relating to the likelihood that studies with negative outcome results were not published at the time of the search).

5.4 Potential biases in the review process

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

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

Data collection was performed by two researchers, the first researcher collected data using data extraction forms and the second researcher checked for completeness and accuracy in data extraction.

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

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

5.5 Agreements and disagreements with other studies or reviews

There is only one published Cochrane review that is specific to Pilates and is focused on people with chronic low back pain (updated March 2014) (11). The review found there is some low certainty evidence for the effectiveness of Pilates in improving pain, disability and function in the short-term (less than 3 months from randomisation) when compared with minimal intervention. The results for pain and disability are in agreeance with the evidence reported in our review (at end of treatment), but the certainty of evidence for disability differs because our data includes additional studies published after the Cochrane review (increased from five to 12 studies leading to moderate certainty). For function, our results suggest the clinical importance of the effect is not reached. Our results are also generally consistent with other reviews of Pilates in people with low back pain published prior to the Cochrane review (480, 481).

Numerous other systematic reviews published up until June 2021, cover conditions such as breast cancer, multiple sclerosis, stroke recovery, obesity and weight loss, falls risk, and age-related physical decline (482-502). The majority of these SRs report that Pilates may be an effective exercise intervention to achieve a desired outcome, such as reducing pain or disability (484), improving balance stability (485, 488), or physical functioning (500, 501) in people with certain conditions. In contrast, some of the reviews state there is evidence of no benefit for an outcome such as bone mineral density in postmenopausal women (489) or waist circumference in people with weight problems (502). As concluded in this review, SR authors state that there is an absence of high certainty evidence, with the limited number of studies, small sample size and heterogeneous outcomes making is difficult to definitively conclude the effectiveness of Pilates as an exercise intervention.

5.6 Limitations

5.6.1 At study and outcome level

The main limitation at the study and outcome level, is the low number of trials and small sample sizes per comparison for all conditions except low back pain, which reduce the statistical precision of the effect estimate and prevented any subgroup or sensitivity analyses. An additional limitation is that it was not possible to statistically assess publication bias using funnel plots (except for low back pain, see Appendix D4.7) as there were fewer than 10 studies included across most outcomes.

5.6.2 At review level

This review is limited to assessment of the evidence for certain conditions and groups of people to inform the Australian Government about health policy decisions for private health insurance rebates. This review is not designed to assess all the reasons that people practise Pilates, or the reasons practitioners prescribe Pilates and is not intended to inform individual choices about practising Pilates.

The main comparator of interest was Pilates compared to inactive control (no intervention, wait list or usual care, if inactive) with the outcomes assessed limited to those deemed critical or important by NTWC for each priority condition. This meant that most conditions were limited to evidence that assessed one to three of the critical or important outcomes, with four conditions having no available evidence for critical or important outcomes.

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

Given the limited evidence base, many of the estimates of effect were limited to one or two small studies, with participants ranging from five to 296 participants (5). A third of the evidence included in the synthesis was for the chronic low back pain population.

Given the limited number of studies spread across a diverse range of prioritised conditions, it is challenging to conclude the effectiveness of Pilates for the conditions prioritised. An additional limitation of this review is that a number of studies were ongoing, unpublished, or not translated at the time of the search; noting there are 19 studies in priority conditions that compared Pilates with control and were published in a language other than English that could have contributed data. This missingness of this data was considered unlikely to substantially change the overall conclusions of the review.

It was out of scope of the review to assess safety, however a previous review (6) reported that evidence regarding safety is generally lacking.

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

A final limitation is that the literature search was last conducted in June 2020, it is possible that given the identification of a number of studies awaiting classification and ongoing studies, there may be additional evidence that may (or may not) impact the overall conclusions of this review.

6 Authors' conclusions

6.1 Implications for policy

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

There is an absence of high certainty evidence examining the effectiveness of Pilates compared with no intervention, wait list or inactive control for the 26 priority conditions or outcomes that align with the reasons why consumers commonly practise Pilates in Australia.

A significant proportion of the evidence base in this report assessed the effect of Pilates on low back pain. Of the outcomes prioritised as critical or important in this review, for low back pain there were two outcomes (disability and quality of life) where the evidence provides moderate certainty of benefit and one outcome (pain) where the evidence provides low certainty of benefit. However, whilst the evidence for pain was considered low certainty, the number of studies and direction of effect across studies make it clear that there is an effect (reduction in pain), but there is uncertainty in how large this effect is. In contrast, the evidence provides moderate certainty that Pilates provides little to no benefit in one outcome (functional capacity) for low back pain, as the two included studies for this condition did not reach a clinically important effect.

For remaining conditions, there were one or two studies eligible for inclusion per critical or important outcome (in some instances no studies were identified) per outcome. For the outcomes prioritised as critical or important, the evidence provides moderate certainty of benefit for one outcome (quality of life) in men with urinary incontinence after radical prostatectomy. For ten conditions the evidence provides low certainty that Pilates provides a benefit for up to three relevant outcomes. For seven conditions, the evidence provides low certainty that Pilates provides little to no benefit for a small number of critical or important outcomes (four or less).

The effect of Pilates remains uncertain for up to seven outcomes in most populations including:

- breast cancer survivors
- people with nervous system disorders (HTLV-1 associated myelopathy or Parkinson's Disease, stroke recovery)
- people with musculoskeletal conditions (postviral arthropathies, knee osteoarthritis, ankylosing spondyloarthritis, spinal deformities, osteoporosis, chronic neck pain)
- postpartum mothers
- people recovering after knee injury or knee arthroplasty
- people at risk of metabolic disorders or weight problems
- people at risk of employment-related mental health conditions
- older adults with history of falls or balance impairment.

The effect of Pilates in women with breast cancer undergoing treatment, people with hypertensive heart disease, people with chronic widespread pain, or people with shoulder pain is unknown.

Implications for research

There is a need for more robust trials evaluating the effectiveness of Pilates compared with no intervention or inactive control. The available evidence could be enhanced by larger studies (more participants enrolled), improved registering and reporting of the methods use, analysis of results from all randomised participants (or better transparency of missing data), as well as measuring and reporting outcomes that are considered critical or important for decision-making. Many of the studies focused on the effect of Pilates in participants who received treatment for a short time period (12 weeks or less), so it is possible the benefits of Pilates may be more apparent in people who continue the practise for more than 12 weeks. Information regarding the sustainability of the effect is also unknown, with few studies providing any follow-up data.

There were 116 studies (6368 total target participants) identified in our search that were listed as ongoing, with 66 studies (4064 target participants) having an inactive control listed as a comparator group; 35 studies were in a priority population (total 1812 target participants). Evidence reported in these studies are expected to contribute to future updates where studies are completed, and results published, noting that some may never be completed and/or published.

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