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# Effectiveness of interventions for non-specific low back pain in older adults. A systematic review and meta-analysis

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## Abstract

**Objectives** Systematically review the literature about all available interventions to manage non-specific low back pain (NSLBP) in older adults (≥60 years).

**Design** We searched the Medline, EMBASE, CINAHL, LILACS, PEDro, and Cochrane CENTRAL databases reference lists for randomized controlled trials (RCTs) testing interventions for NSLBP. Two independent reviewers extracted data, assessed the risk of bias and completeness of the description of interventions.

**Results** Eighteen (RCTs) fulfilled the eligibility criteria. Evidence about interventions to manage NSLBP in older adults is weak. Very low to moderate quality evidence showed that complementary health approach (i.e., manual therapy, acupuncture, mindfulness, yoga), percutaneous electrical nerve stimulation (PENS), education, exercise or pharmacological agents were not effective to produce a clinically significant reduction in pain and disability at short-term and intermediate-term compared to sham, usual care or minimal intervention. Interventions were moderately well-described according to the template for intervention description and replication (TIDieR) and the risk of bias was moderate 6.4 points on the 10-point PEDro Scale (SD = 1.44).

**Conclusion** Evidence about interventions for NSLP in older adults is limited and new studies are highly likely to change these results. This result may impact healthcare providers due to the lack of effective evidence based interventions, patients, and policy makers that will expend financial resources with interventions that provide in the best scenario a not significant improvement of the clinical symptoms. Researchers need to consider the importance of designing clinical trials targeting older adults and examine possible outcome modifiers present in this population allowing the recommendation of more efficacious evidence-based interventions.

**Systematic Review Registration Number** PROSPERO (CRD42016036686).


*Keywords:* Aged; Aged, 80 and over; Low back pain; Therapeutics; Rehabilitation

## Introduction

The 2010 global burden of disease study revealed that the prevalence and burden of low back pain (LBP) increase with age [1]. Age is also associated with lower recovery rates [2], higher risks of chronicity [3] and severe symptoms [4], which can contribute to the fact that most persons with NSLBP seeking healthcare are older adults [5].

Current recommendations to manage LBP suggest to stratify patients into specific subgroups aiming to improve health outcomes [6]. Although older adults present specific biopsy-

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chosocial changes due to aging [7–9], the investigation of older adults as a subgroup is missing and they are underrepresented in RCTs [10]. As a consequence, older adults are embracing other alternatives such as complementary health approaches (i.e., acupuncture, massage, yoga, spine manipulation, and mindfulness) [11].

To date, little is known about the effectiveness of NSLBP interventions for older adults. The development of knowledge about how to treat LBP in older people is important since this population is growing worldwide [12] and LBP contributes to more years living with disability [13] besides the indirect risk of death [14] resulted from falls associated with LBP [15]. Two previous reviews have summarized the effectiveness of "physical therapy" interventions and exercises for older adults (65 years and older) presenting NSLBP [16,17]. In contrast, the present review searched for all type of interventions and duration of symptoms, in adults 60 years and older according to the United Nations [18] definition of elderly. Therefore, our aim was to systematically review all type of interventions compared to any control to decrease pain and disability in community-dwelling older adults with NSLBP at short, intermediate and long-term follow-up.

## Methods

### *Selection criteria*

This systematic review is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [19].

A PICOT approach [20] was applied to formulate the research question. All existing evidence from randomized controlled trials focusing on the management of NSLBP (i.e., no known pathoanatomical cause) in community dwelling older adults were considered for inclusion, independent of language and publication date. Studies recruiting participants presenting LBP in which the pain arises from problems beyond the lumbar spine (e.g. leaking aortic aneurysm); specific disorders (e.g. epidural abscess, compression fracture, spondyloarthropathy, malignancy, cauda equine syndrome); or radicular pain, radiculopathy, or spinal canal stenosis were excluded [21]. Remaining cases were considered NSLBP. We included only papers published in peer-reviewed journals through September 2018. The protocol for this systematic review was prospectively registered on PROSPERO CRD42016036686.

Studies were included according the following inclusion criteria: (a) older adult (≥60 years) population with acute (<4 weeks), subacute (>4 weeks but <12 weeks) or chronic (>12 weeks) NSLBP, (b) randomized controlled trials, and (c) reporting at least one clinical outcome as: (1) pain intensity, (2) functional status/disability, or (3) perceived recovery. Articles reporting pilot, feasibility or preliminary studies, and data on individuals under 60 years or institutionalized subjects were not considered.

### *Search strategies*

Electronic database searches were conducted in Medline, EMBASE, *Cumulative Index to Nursing and Allied Health Literature* (CINAHL), Latin American and Caribbean Health Sciences Literature (LILACS), Physiotherapy Evidence Database (PEDro), and Cochrane Central Register of Controlled Trials (CENTRAL). Search strategies followed the recommendations of the Cochrane Back Review Group [22]. Detailed search strategies used in each database are described in a supplement (Supplementary file 1). Additionally, the reference lists from eligible studies were screened to identify possible additional relevant trials.

Two independent reviewers (PN, AA) screened the retrieved articles for eligibility. A third reviewer was consulted in case of disagreement providing consensus through discussion or arbitration.

A standardized data extraction form was used to collect the following information: authors, year of publication, population, sample size, interventions, comparisons, follow-up, and outcomes. Self-reported outcomes for pain and disability/function were assessed in this review. Authors were contacted by email in case of insufficient data and further data were requested.

### *Risk of bias assessment*

The risk of bias in the eligible studies was assessed using the PEDro scale [23]. The PEDro scale is an 11-item (higher scores = lower risk of bias) valid tool to measure the risk of bias and statistical reporting of clinical trials [24,25]. The PEDro score was extracted directly from the PEDro database (www.pedro.org.au) since all eligible studies were already indexed in the database, which provides a reliable rating score.

### *Description of interventions*

Information on interventions was extracted using the Template for Intervention Description and Replication (TIDieR) [26]. The TIDieR is a checklist of 12 items that was developed aiming to improve the reporting of interventions.

### *Quality of evidence*

We assessed the overall quality of the evidence and the strength of the recommendation for each outcome using the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) approach, as recommended in the Cochrane Handbook for Systematic Reviews of Interventions [27]. The GRADE approach establishes the quality of evidence as high, moderate, low and very low. Five domains that are able to decrease the quality of the evidence are: study design and risk of bias; consistency of results; directness (generalizability of the findings); precision (i.e., sufficient

data to produce narrow confidence intervals) and other factors (e.g. reporting bias, publication bias).

The quality of evidence was then classified for each outcome according to the following criteria:

High quality evidence: consistent findings among at least 75% of eligible studies with low risk of bias; consistent, direct and precise data and no known or suspected publication biases. Further research is unlikely to change either the estimate or confidence in the results.

Moderate quality evidence: one of the GRADE domains is not met. Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality evidence: two of the GRADE domains are not met. Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality evidence: three of the GRADE domains are not met. We are very uncertain about the results. Single studies with a sample size smaller than the optimal information size (n = 300) [28] were considered to yield very low quality evidence if there was also a high risk of bias (PEDro score <6) or low-quality evidence if there was a low risk of bias (PEDro score ≥6).

### *Data analysis*

Pain and disability scores were transformed to a 0 to 100-point scale. Outcome data were extracted for short-term (up to six weeks after randomization) and intermediate-term (more than 6 weeks and less than 12 months after randomization) follow-up. Results from continuous data are presented as mean differences (MD) and 95% confidence interval (CI). When this information was not provided, the size of the treatment effect (i.e., difference between intervention A and intervention B) and the 95% CI, was calculated using the mean value, standard deviation and the number of participants in each group through a confidence interval calculator [29]. A negative effect size indicated that the experimental intervention was more beneficial than the comparator. We evaluated the overall quality of evidence using the GRADE approach and for effect sizes we used three levels: small (mean difference (MD) <10% of the scale), moderate (MD 10% to 20% of the scale) or large (MD >20% of the scale) [30]. Furthermore, we used the size of the effect to determine whether the results were clinically relevant or not, where a reduction of 25 points (0 to 100 scale) in the MD was considered to represent the minimally clinically important change (MCIC) [31].

The $Chi^2$ and $I^2$ statistics were used to measure the heterogeneity between the eligible studies. Non-significant values in the Chi-squared test ($p > 0.05$) and $I^2$ scores of lower than 40% were considered unimportant [27]. Where possible, data were pooled and a meta-analysis was performed using a random effect model. All data synthesis was conducted with RevMan version 5.3.

## Results

The search strategy retrieved 5541 studies. After the selection process (Fig. 1), 18 randomised controlled trials [32–49] (reference list present as a Supplement) with a pooled sample size of 1857 participants (mean sample size = 107.16, SD = 72.85) were considered eligible for data analysis. Most of the eligible studies described that older people with chronic symptoms (>3 months) were the targeted population. None of the trials reported long-term outcomes which would be important to consider especially in older patients. Interventions regarding surgery were not found. A summary description of all eligible studies is presented in Table 1.

The type of intervention varied substantially across the studies (Table 1). The most investigated interventions were from the group of complementary health approaches (CHA) as acupuncture (2 trials, pooled n = 91) [32,35], manual therapy (4 trials, pooled n = 550) [34,39,43,44], mindfulness (1 trial, n = 282) [37], and Yoga (1 trial, n = 176). Others were, PENS (3 trials, pooled n = 289) [36,40,41] exercise (2 trial, pooled n = 157) [46,47], education (2 trial, pooled n = 155), pharmacological agents (1 trials, n = 70) [49], low level laser therapy (1 trial, n = 85) [38], and thermotherapy (1 trial, n = 80) [33].

### *Outcomes*

Pain intensity was measured using the Visual Analogue Scale (VAS) [32–36,43], McGill Pain Questionnaire, McGill Pain Questionnaire short-form [39–41], Numerical Rating Scale (NRS) [37,44,46,48,49], or Pain Functional Rating Index (PFRI) [45]. Low back pain disability was evaluated using the Roland Morris Disability Questionnaire (RMDQ) [36,40–43,47], Oswestry Disability Index (ODI) [34,39,44], Modified Von Korff (MVK) Scales [48], Hannover Functional Ability Questionnaire (FFbHR) [45], or the Pain Disability Assessment Scale (PDAS) [49].

### *Risk of bias*

The risk of bias of the eligible studies is presented in Table 2. These trials were considered of moderate quality, with a mean of 6.17 points (SD = 1.3) on the 10-point PEDro Scale (range 3 to 8). The items least frequently satisfied were blind therapist one trial [38] and blind subjects 3 trials [32,34,38].

### *Description of the interventions*

The analysis concerning the completeness of the description of the interventions (TIDieR) revealed that interventions are usually well-described including identification with a brief name or phrase, and description of materials, procedures, mode of administration, frequency and intensity

Table 1
Characteristics of all included studies.

| Study | Population | Intervention group | Comparison group |
|---|---|---|---|
| Inoue [32] | n = 31<br>Low back pain (not specified the time duration)<br>Age (yr) = exp 68 (SD 6), con 70 (SD 8) | Acupuncture – therapists inserted a stainless steel needle to a depth of 20 mm at the most painful point and stimulated the needle with the sparrow pecking method (lifting and thrusting) for 20 seconds. | Sham acupuncture – therapists tapped the end of a guide tube on the skin at the most painful point, without a needle, and then acted as if they were inserting a needle there |
| Giemza [33] | n = 80<br>Men with chronic low back pain (>3 m)<br>Mean age of both groups, age (yr) = 70.1 | Whole body cryotherapy five times per week during one week. The treatments were conducted in a Cryogenic chamber with treatment lasting 3 minutes. Participants subject spent approximately 30 s in a vestibule at a temperature of −60 °C to adapt to the cold. Next, the subject moved to the main chamber at a temperature −120 °C for 3 minutes. | Same protocol as the experimental group, however, two times per week. |
| Dougherty [34] | n = 136<br>Non-specific low back pain (≥3 months)<br>Age (yr) = exp 76.99 (SD 6.77), con 77.04 (SD 6.81) | Spinal manipulative therapy – two times per week during 4 weeks. Participants received a high-velocity, low-amplitude spinal manipulation, and/or flexion distraction therapy and/or mobilization alone or in combination based on the clinician's judgment. In addition, participants received a brochure with stretching and strengthening exercises. | Sham "detuned ultrasound", applied over the lumbar spine for 11 minutes two times per week during 4 weeks. Participants also received the brochure with stretching and strengthening exercises. |
| Grant [35] | n = 60<br>Chronic low back pain (>6 m)<br>Age (yr) = exp 75, con 72 | Acupuncture two times per week during 20 minutes for 4 weeks. Acupuncturist selected the points for each participant as in routine clinical practice, using only points on the back. Six needles were used on average at each treatment with a minimum of two and a maximum of eight. | Home application of TENS during 30 minutes as required (maximum of 6 hours per day) using 50 Hz stimulation with the intensity adjusted according participants' tolerance. Participants also meet the physiotherapist twice per week during 20 minutes, to review the symptoms, discuss the treatment and the optimum use of the device. |
| Meng [36] | n = 47<br>Non-specific chronic low back pain (≥3 months)<br>Age (yr) = exp 75 (SD 2), con 70 (SD 6) | Acupuncture treatments twice a week for 5 weeks. Ten to 14 needles with electrical stimulation at 4–6 Hz and pulse duration of 0.5 ms were applied in standard acupoints for 20 minutes.<br><br>Standard care – participants were allowed to maintain their standard therapy prescribed by their physician. Prohibited therapies were narcotic medications, muscle relaxants, TENS, epidural steroid injections and trigger point injections. | Standard care – participants were allowed to maintain their standard therapy prescribed by their physician. Prohibited therapies were narcotic medications, muscle relaxants, TENS, epidural steroid injections and trigger point injections. |
| Morone [37] | n = 282<br>Chronic low back pain (≥3 months)<br>age (yr) = exp 75 (SD 7.2), con 74 (SD 6.0) | Mindfulness – 8-week program. Four methods of mindfulness meditation were taught taking regular activities such as sitting, walking, and lying down and transform them into a meditation through directed breathing and mindful awareness of thoughts and sensations. The methods used included the body scan, sitting practice, walking meditation, and mindful stretching. To encourage proficiency with the meditation method after completion of the intervention, monthly 60-minute booster sessions were held. | 10 keys to health aging – 8-week health education program teaching an interactive, dynamic program to older adults on key health topics relevant to healthy aging such as hypertension management.<br>The same chair stretches taught in the intervention were taught in the control program. To ensure that the control group received an equal amount of attention and social support, they also received monthly booster classes, which met monthly for 1 hour. |

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|---|---|---|---|
| Soriano [38] | n = 85<br>Chronic low back pain (>3 months)<br>age (yr) = exp 63.2, con 64.3 | Laser therapy – 5 × /week × 2 weeks. Pulsed GaAs diodo laser, wavelength 904 nm, pulse frequency 10.000 Hz and pulse width 200nsec, peak power 20W, average power 40 mW, spot size 150 $\mu m^2$ in area and angle of divergence of 6°. The laser was applied using the point contact irradiation technique with a dose of approximately 4J/$cm^2$ per point, which were separated by 2 cm. | Sham laser – participants were irradiated with a deactivated laser system 5 × /week × 2 weeks. |
| Sritoomma [39] | n = 140<br>Chronic low back pain (>12 weeks)<br>Age (yr) = not available | Swedish massage with ginger oil – massage combined with aromatic ginger oil using the following five basic strokes: effleurage, petrissage, friction, tapotement and vibration. | Traditional Thai massage – based on meridians energy-line theory. The massage therapist stretched the muscles, applied pressure with the palms, thumbs and elbows, all techniques addressing the energy pathway and points. |
| Weiner [40] | n = 34<br>Chronic low back pain (≥3 months)<br>Age (yr) = exp 74.1 (SD 4.6), con 73.5 (SD 5.7) | PENS + PT – 30′, 2 × /week × 6 weeks. Application of acupuncture needles and electrical stimulation occurred at the appropriate dermatomal, myotomal, and sclerotomal levels. Stimulation frequencies ranged from 2 to 200 Hz; Intensity of the electrical stimulation was maintained below the pain threshold.<br>PT – included modalities of manual therapy, stretching exercise and flexibility exercise, education addressing the topics of the anatomical and pathological bases for the pain condition, importance of active participation of the subject in managing the pain, and the use of flare management techniques. | Sham PENS + PT – 30′, 2 × /week × 6 weeks. Acupuncture needles were applied using a technique identical to that used in the PENS group, but no electrical stimulation was provided.<br>PT – same program as applied in the experimental group. |
| Weiner [41] | n = 200<br>Chronic low back pain (≥3 months)<br>Age (yr) = exp 73.9 (SD 5.2), con1 73.3 (SD 6.0), con2 74.1 (SD 5.6), con3 74.3 (SD 6.4) | PENS + exercise – 2/weeks × 6 weeks. PENS was administered for 30′ using 10 needles for each session, placed bilaterally at dermatomal, myotomal, scleratomal, and sympathetic levels corresponding to T12, L3, L5, and S2, and the motor point for the piriformis muscle. Participants also had two needles placed at the T12 level. The exercise program included both general conditioning (strength and flexibility) and aerobic components sessions lasted for 60 minutes. The program also had a home component consisting of flexibility exercises and a graded walking program performed three times a week for 6 weeks. | Sham PENS + exercise – 2/weeks × 6 weeks. PENS was administered for 30′ replicating the positioning and number of needles in the experimental group. However, electrical stimulation was applied only at the T12 dermatome. Five minutes followed the initiation of electrical stimulation, the electrostimulator unit was turned off to avoid the delivery of potentially therapeutic microcurrent. |
| Costantino [42] | n = 56<br>Chronic non-specific low back pain (>3 months)<br>Age (yr) = exp 73.63 (SD 3.36), con 73.3 (SD 3.55). | Back school – sessions of one hour, 2 times per week during 12 weeks. Education about the anatomy of spinal column, its functioning and ergonomic position and the basis of the pain-inducing mechanism, psychological aspects and stress management (first session). Following sessions, muscle stretching (iliopsoas muscle), muscular strengthening (rectus, external and internal oblique abdominis, erector spinae, gluteal, and quadriceps muscles), and exercise for trunk flexion/extension, and pelvic tilt associated with proper breathing. | Hydrotherapy – sessions of one hour, 2 times per week during 12 weeks. During each session participants performed bilateral stretching (iliopsoas, gastrocnemius, hamstrings and posterior muscle chain) and selective muscle strengthening (abdominal, erector spinae, and hip abductor/adductor muscles). |

Table 1 (*Continued*)

| Study | Population | Intervention group | Comparison group |
|---|---|---|---|
| Hondras [43] | n = 225<br>Subacute non-specific low back pain (≥4 weeks)<br>Age (yr) = exp1 63.0 (SD 6.0), con1 63.8 (7.6), con2 62.3 (SD 6.1) | High-velocity low amplitude spinal manipulation – max of 12 visits, up to 3 times per week for the first 2 weeks, 2 times per week for the third and fourth weeks, and once per week during weeks 5 and 6. The HVLA-SM was designed as the side-lying diversified lumbar spine "adjustment" or maneuver.<br><br>Home exercise – at week 3 participants received 30 minutes of standardized instructions for a home exercise program based on 7 exercises including flutter kick, buttocks pinch, pillow squeeze, cat stretch, pelvic tilt, press up extension, and double knee to chest. | Con1 – Low-velocity variable amplitude spinal mobilization – max of 12 visits, not to exceed 3 times per week for the first 2 weeks, 2 times per week for the third and fourth weeks, and once per week during weeks 5 and 6. LVVA-SM was designed as the flexion-distraction technique or Cox Technique with the application of up to 15 slow repetitions of flexion depending on participant tolerance.<br>Con 2 – Minimal conservative medical care – meetings with the medical provider for 3 times during the 6 weeks (weeks 1, 3, and 6) to provide, adjust and/or change medicine prescription.<br><br>Home exercise – same routine as the experimental group where indicated to all controls. |
| Learman [44] | n = 49<br>Non-specific low back pain (≤4 weeks)<br>Age (yr) = exp 63.8 (SD 10.1), con 65.0 (SD 8.2) | Spine manipulation with thrust – 2 sessions (1 to 4 days apart). Technique was not described because the intent was to use a pragmatically prescribed intervention that was adjusted by the physiotherapist according to the results of the assessment with patient feedback.<br><br>Physiotherapy – After completion of the manual therapy sessions, participants were treated with strengthening exercises, movement-based methods, or other intervention, as long as the clinician felt it fit within the treatment plan of the patient. Patients were discharged once the clinician felt the patient had met their maximal improvement within the current treatment program. There was no limitation on total visits.<br>Home exercise program – included standing hamstring stretches, cat and camel, quadruped pelvic rocking, prone press-ups, and supine lying piriformis stretches performed for 10 repetitions, 3 times daily | Spine manipulation without thrust 2 sessions (1 to 4 days apart). Maitland's concepts were applied using passive, low-velocity oscillatory movements within the available physiologic range. The techniques consisted of grade I through grade IV and included side-lying rotational techniques, unilateral or central posterior to anterior glides.<br>Physiotherapy – based on the same principles as the experimental group<br><br>Home exercises – same program as the experimental group. |
| Teut [45] | n = 176<br>Chronic low back pain (≥6 months)<br>Age (yr) = exp1 73.0 (SD 5.6), exp2 72.4 (SD 5.7), con 72.6 (6.0) | Exp1 Yoga – 45′, 2/week × 12 weeks. Each class included physical, breathing, and concentration exercises that occurred while sitting, standing, and lying.<br><br>Exp2 Qigong – 90′, 1/week × 12weeks. A standardized program of qigong ("Dantian") and Nei Yang Gong exercises from the Training System Liu Ya Fei was applied. Additionally, self-massage was part of the training. | Wait list – Participants in the control group received no additional intervention for 6 months. |

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|---|---|---|---|
| Cruz-Diaz [46] | n = 97<br>Chronic low back pain (not defined the symptoms duration)<br>Age (yr) = exp 72.81 (SD 3.47), con 69.58 (SD 2.21). | Physical therapy sessions plus Pilates – PT two times per week during six weeks. Each session consisted in the application of TENS with a pulse frequency of 100 Hz for 40 min, and 20 minutes of massage and stretching of the low-back zone. One hour of Pilates sessions was applied two times per week. | PT sessions only (same PT routine as in the experimental group). |
| Vincent [47] | n = 60<br>Chronic low back pain (≥6 months)<br>Age (yr) = exp 68.6 (SD 7.3), con1 67.5 (SD 6.4), con2 68.7 (SD 7.1) | Total body exercise – 3/week × 4 months. Training sessions comprised 1 × 15 repetitions of leg press, leg curl, leg extension, chest press, seated row, overhead press, triceps dip, lumbar extension, biceps curl, calf press, abdominal curl, and lumbar extension exercise. | Con1 – Lumbar extension exercise. During the first 2 weeks, participants performed two sets of lumbar extensions once a week. From week 2 until the end of the study, participants performed one set of lumbar extensions (15 repetitions) three times a week<br>Con2 – Standard care – normal medical care and follow-up during the 4-month study, with no resistance exercise intervention. |
| Haas [48] | n = 101<br>African or white American with chronic low back pain (≥3 months)<br>Age (yr) = exp 78.6 (SD 7.5), con 75.5 (SD 7.5) | Chronic disease self-management program – applied through a 6-week workshop lasting 2½ hours. The course content included general principles of chronic conditions; overview of self-management principles; symptoms; care-seeking options; community resources; exercise; relaxation; nutrition; medication and side-effects; skills building; learning from others; sharing with others; goal setting; action plans; feedback; and problem-solving. | Wait list |
| Miki [49] | n = 127 randomized (70 completed the study)<br>Acute low back pain (<12 weeks) **Characteristics of participants who completed the study (n = 70)**<br>Age (yr) = exp 66.03 (SD 2.97), con1 70.17 (SD 3.03) | Acetaminophen group – participants received 600 mg acetaminophen 4 times daily for 4 weeks randomization procedure. | Loxoprofen group – participants received 60 mg loxoprofen 3 times daily for 4 weeks, which is the traditional dosage in Japan.<br><br>All treatment was provided to both groups by a single orthopedist throughout study. |

*Exp – experimental, Con – control, SMT – spine manipulation therapy, WBC – whole body cryotherapy, US – ultrasound, PENS – percutaneous electrical neurostimulation, PT – physical therapy.

Table 2
Methodological quality of eligible studies (n = 11), PEDro scale.

| Study | Eligibility criteria[a] | Random allocation | Concealed allocation | Baseline comparability | Blind subjects | Blind therapists | Blind assessors | Adequate follow-up | Intention-to-treat analysis | Between-group comparisons | Point estimates and variability | Pedro score (0 to 10) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Inoue [32] | Y | Y | N | Y | Y | N | Y | Y | N | Y | Y | **7** |
| Giemza [33] | Y | Y | N | Y | N | N | N | N | N | Y | N | **3** |
| Dougherty [34] | Y | Y | N | Y | Y | N | Y | Y | Y | Y | Y | **8** |
| Grant [35] | Y | Y | Y | N | N | N | Y | Y | N | N | Y | **5** |
| Meng [36] | Y | Y | Y | Y | N | N | N | Y | Y | Y | Y | **7** |
| Morone [37] | Y | Y | Y | Y | N | N | Y | Y | Y | Y | Y | **8** |
| Soriano [38] | N | Y | N | Y | Y | Y | Y | N | N | Y | Y | **7** |
| Sritoomma [39] | Y | Y | Y | Y | N | N | N | Y | Y | Y | Y | **7** |
| Weiner [40] | Y | Y | N | Y | N | N | Y | Y | Y | Y | Y | **7** |
| Weiner [41] | Y | Y | N | Y | N | N | Y | Y | N | Y | Y | **6** |
| Costantino [41] | N | Y | N | Y | N | N | N | Y | Y | Y | Y | **6** |
| Hondras [43] | Y | Y | Y | Y | N | N | N | N | Y | Y | Y | **6** |
| Learman [44] | Y | Y | N | Y | N | N | N | Y | N | Y | Y | **5** |
| Teut [45] | Y | Y | Y | Y | N | N | N | Y | Y | Y | Y | **7** |
| Cruz-Diaz [46] | N | Y | N | Y | N | N | Y | Y | N | Y | Y | **6** |
| Vincent [47] | Y | Y | Y | Y | N | N | Y | N | N | Y | Y | **6** |
| Haas [48] | Y | Y | Y | Y | N | N | N | N | Y | Y | Y | **6** |
| Miki [49] | Y | Y | N | Y | N | N | N | N | N | Y | Y | 4 |
| **Total** | **14** | **17** | **8** | **16** | **3** | **1** | **9** | **12** | **9** | **16** | **16** | |

Y: yes; N: no.
[a] Does not contribute to the total score.

Table 3
Completeness of the description of interventions.

| Study | Brief name | | Rationale | | Materials | | Procedures | | Provider | | How | | Where | | When/How much | | Tailoring | | Modifications | | How well (planned) | | How well (actual) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Ex | CG | Ex | CG | Ex | CG | Ex | CG | Ex | CG | Ex | CG | Ex | CG | Ex | CG | Ex | CG | Ex | CG | Ex | CG | Ex | CG |
| Inoue [32] | Y | Y | N | N | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | N | N | N | ? | ? | ? | ? | ? | ? |
| Giemza [33] | Y | Y | N | N | Y | Y | N | N | Y | Y | Y | Y | N | N | Y | Y | N | N | ? | ? | ? | ? | ? | ? |
| Dougherty [34] | Y | Y | N | N | Y | Y | N | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | ? | ? | ? | ? | ? | ? |
| Grant [35] | Y | Y | N | N | Y | Y | Y | Y | Y | Y | Y | Y | N | N | Y | Y | Y | N | ? | ? | ? | ? | ? | ? |
| Meng [36] | Y | Y | Y | N | Y | N | Y | N | Y | Y | Y | N | Y | N | Y | Y | N | N | ? | ? | ? | ? | ? | ? |
| Morone [37] | Y | Y | N | N | Y | Y | Y | Y | N | N | N | N | N | N | Y | Y | N | N | ? | ? | ? | ? | ? | ? |
| Soriano [38] | Y | Y | N | N | Y | Y | Y | Y | N | N | Y | Y | N | N | Y | Y | N | N | ? | ? | ? | ? | ? | ? |
| Sritoomma [39] | Y | Y | N | N | Y | Y | Y | Y | Y | Y | Y | Y | N | N | Y | Y | N | N | ? | ? | ? | ? | ? | ? |
| Weiner [40] | Y | Y | N | N | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | N | ? | ? | ? | ? | ? | ? |
| Weiner [41] | Y | Y | Y | N | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | N | ? | ? | ? | ? | ? | ? |
| Costantino [42] | Y | Y | N | N | NA | NA | Y | Y | N | N | N | N | N | N | Y | Y | N | N | ? | ? | ? | ? | ? | ? |
| Hondras [43] | Y | Y | N | N | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | N | ? | ? | ? | ? | ? | ? |
| Learman [44] | Y | Y | N | N | NA | NA | Y | Y | Y | Y | Y | Y | N | N | Y | Y | Y | Y | ? | ? | ? | ? | ? | ? |
| Teut [45] | Y | Y | N | N | N | N | N | N | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | ? | ? | ? | ? | ? | ? |
| Cruz-Diaz [46] | Y | Y | N | N | NA | NA | N | N | N | N | N | N | N | N | Y | Y | N | N | ? | ? | ? | ? | ? | ? |
| Vincent [47] | Y | Y | Y | N | Y | NA | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | N | ? | ? | ? | ? | ? | ? |
| Haas [48] | Y | NA | N | NA | N | NA | N | NA | Y | NA | Y | NA | Y | NA | Y | NA | N | NA | ? | ? | ? | ? | ? | ? |
| Miki [49] | Y | Y | Y | Y | N | N | Y | Y | Y | Y | Y | Y | N | N | Y | Y | N | N | ? | ? | ? | ? | ? | ? |

Ex: experimental group, CG: CG: control group, Y: yes, N: no, N/A: not applicable,?: not reported.

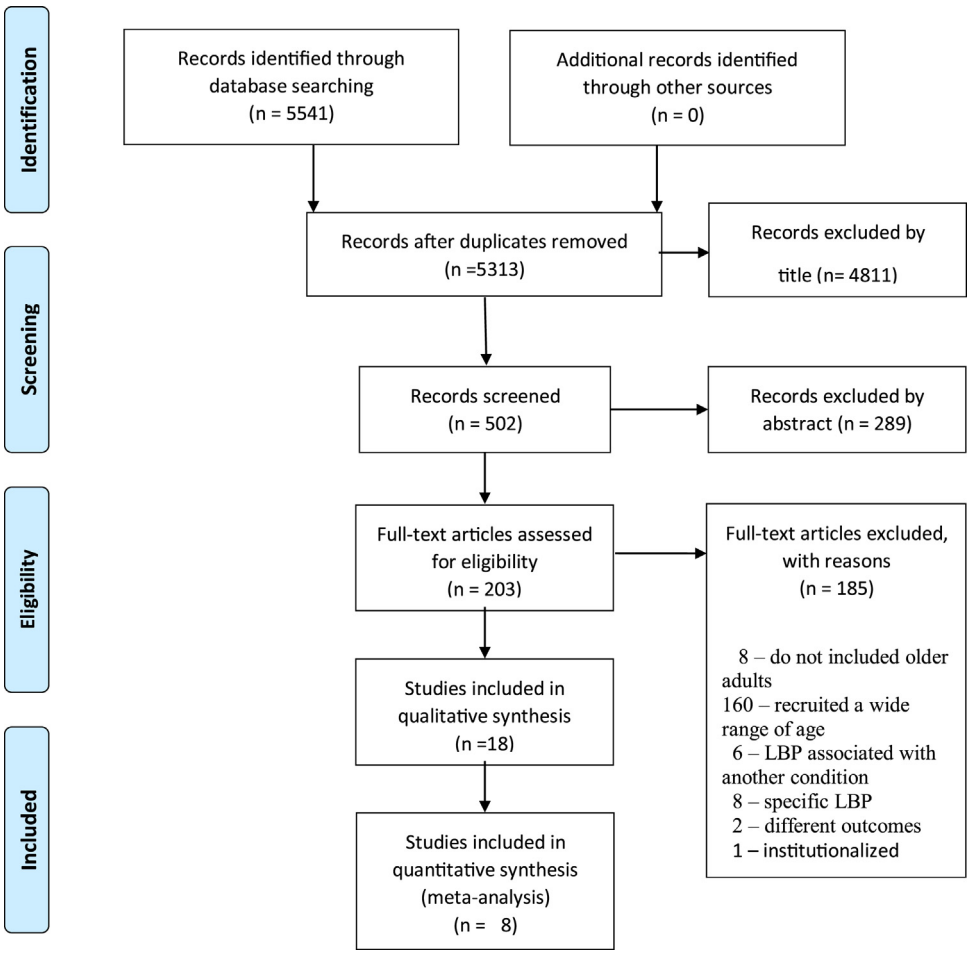


Fig. 1. Diagram flow of the eligibility assessment.

(Table 3). However, the rationale for the use of a specific intervention was described in only four studies [36,41,47,49].

### *Effects of interventions*

#### *Complementary health approach*

Trials investigating interventions that are classified as CHA were pooled in a meta-analysis. The number of trials included in the meta-analysis varied for each comparison and outcome. We included a total of eight trials with low risk of bias in the meta-analysis for pain at short-term [32,34,35,37,39,43–45] and six trials at intermediate-term [34,35,37,39,44,45].

#### *Outcome: pain intensity*

For the outcome pain (Figs. 2 and 3), there is low quality evidence (downgraded due to inconsistence and imprecision) that there is a small, but no clinically important effect of CHA compared to minimal intervention or sham at short (MD = −2.96, 95% CI −5.87 to −0.04, eight three trials, $p = 0.05$) and intermediate-term follow-up (MD = −4.12, 95% CI = −6.35 to −1.93, six trials, $p = 0.002$).

#### *Outcome: disability*

In total, for disability (Figs. 4 and 5), we included six trials with low risk of bias [34,37,39,43–45] that provided moderate quality evidence (downgraded due to inconsistence) that there is no clinical important difference on improving disability at short-term compared to minimal or sham interventions (MD = −2.00, 95% CI −4.07 to 0.06, $p = 0.06$), and moderate quality evidence for a small but not clinically important difference at intermediate-term (MD = −2.55, 95% CI −4.64 to −0.46, $p = 0.02$).

### *Other interventions*

#### *Percutaneous neurostimulation (PENS)*

*Outcome: pain intensity.* Based on two trials [36,41], there is low quality evidence of a moderate but not clinically significant effect on reducing pain for PENS plus physiotherapy (PT) compared to sham PENS plus PT [41] (MD −12.91; 95% CI −22.56 to −3.26), and small but no clinically significant effect (MD −8; 90% CI −15.28 to −2.52) in favors of PENS compared to standard care [36] at short-term. One trial [40] provided low quality evidence that there is no effect for PENS plus exercise on reducing pain at short-term (MD

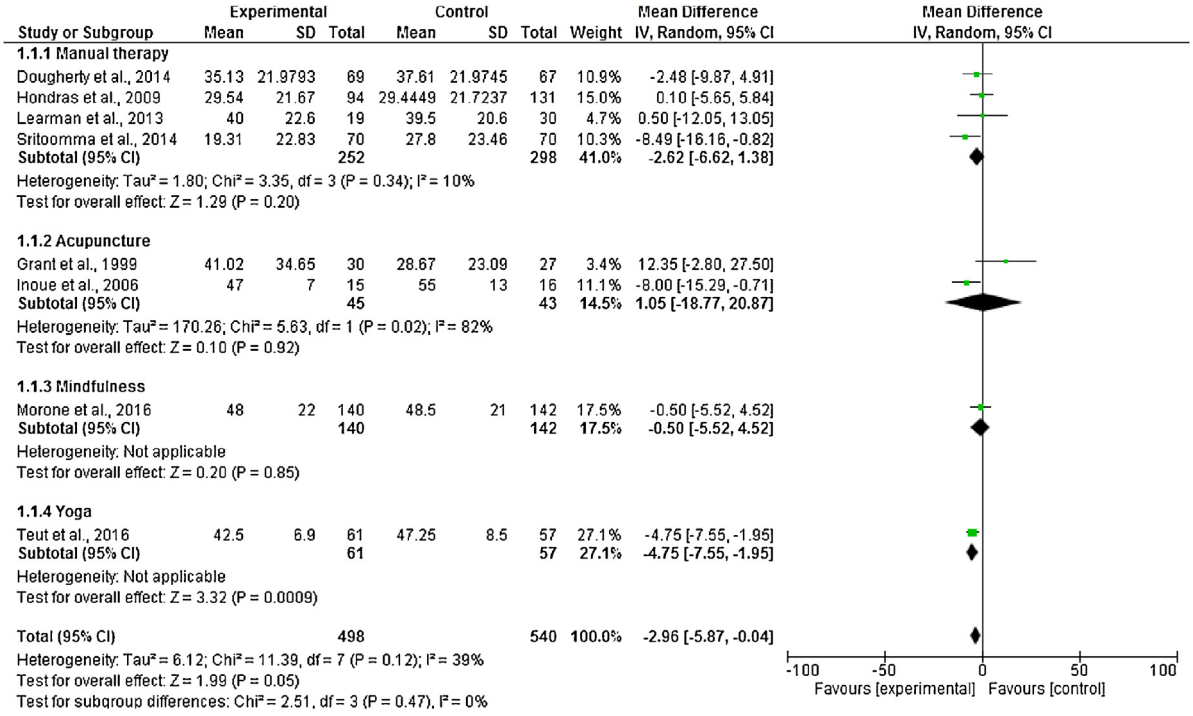


Fig. 2. Complementary health approach versus control for pain at short-term.

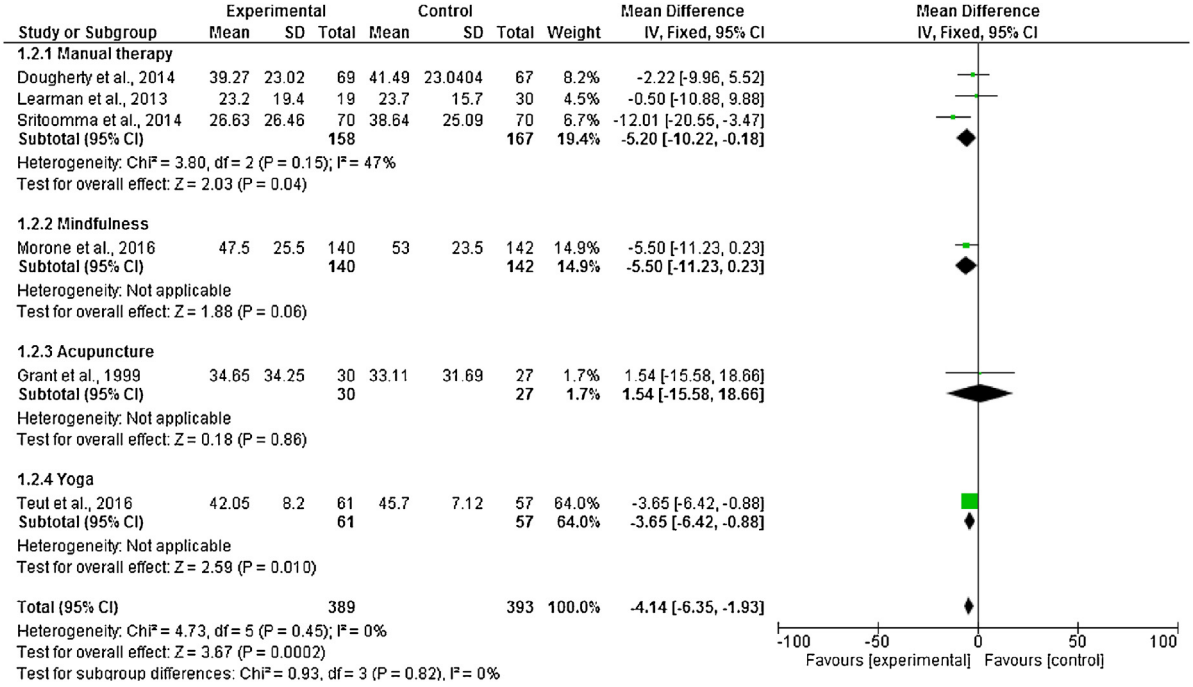


Fig. 3. Complementary health approach versus control for pain at intermediate-term.

−0.44 95% CI −3.94 to 3.05), compared to PENS, sham PENS or sham PENS plus exercise. For intermediate-term, there is low quality evidence [41] that there is a moderate but no clinically important effect on reducing pain (MD −12.51; 95% CI −21.62 to −3.40) for PENS plus PT compared to sham PENS plus PT, and no effect in pain reduction for PENS plus exercise [40] (MD = 0.21, 95% CI −4.98 to 1.84).

*Outcome: disability.* Results from one trial showed that there is low quality evidence that there is a large but not clinically important effect on reducing disability in favors

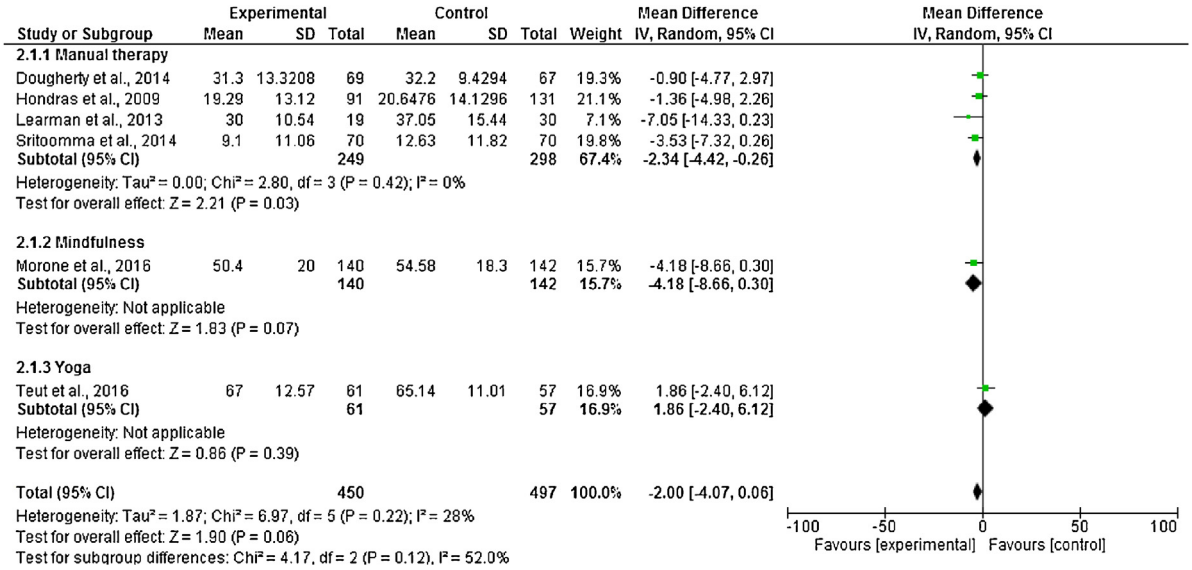


Fig. 4. Complementary health approach versus control for function at short-term.

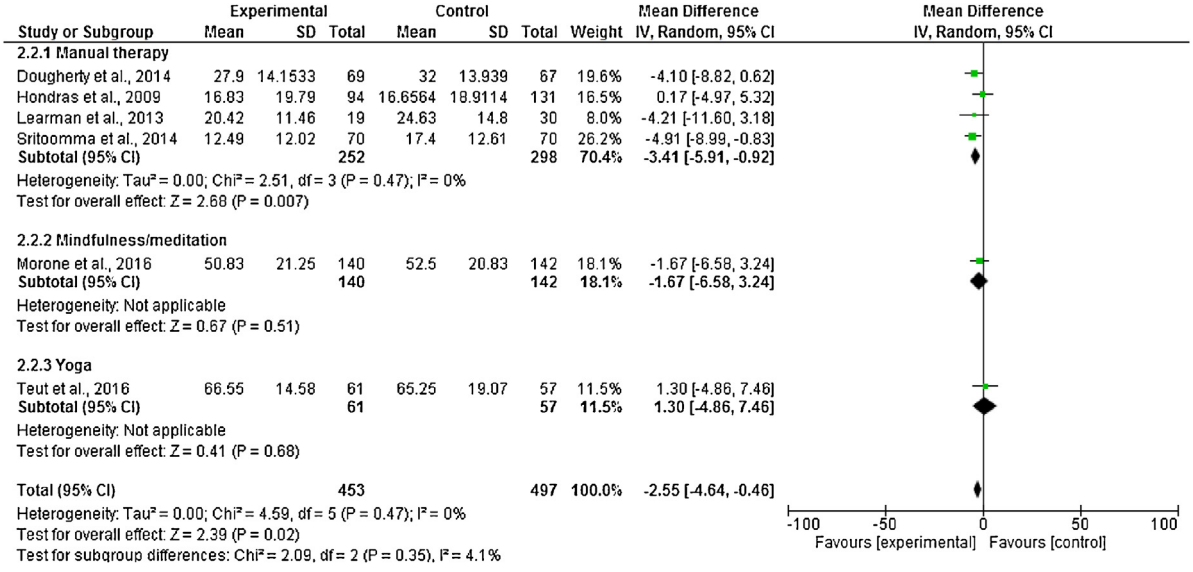


Fig. 5. Complementary health approach versus control for function at intermediate-term.

of PENS compared to usual care [36] (MD −23.59; 95% CI 34.84 to 12.34), and that there is a moderate, no clinically significant effect when comparing PENS plus PT to sham PENS plus PT [41] (MD −13.54; 95% CI −16.61 to −10.47) at short-term follow-up. There is low quality evidence that there is no clinical effect (MD = 0.80, 95% CI −5.55 to 7.16) when comparing PENS plus exercise to PENS, sham PENS, and sham PENS plus exercise. At intermediate-term follow-up, there is low quality evidence that there is a small but no clinical important effect for PENS on reducing disability when compared to usual care [36] (MD 2.62, 95 CI 0.73 to 4.51), and two trials [40,41] provided low quality evidence that there is no significant effect when comparing PENS plus PT to sham PENS plus PT (MD −12.21; 95% CI −25.37 to 0.95), and for PENS plus exercise compared to PENS, sham PENS and sham PENS plus exercise (MD −0.11; 95% CI −6.06 to 6.28).

### *Education*

#### *Outcome: disability*

At short-term, there is low quality evidence of no difference for back school compared to hydrotherapy (MD = 4.45, 95% CI −0.72 to 9.62) [42], and when comparing self-management to no intervention (MD = −3.00, 95% CI −15.02 to 9.02) [48].

*Pharmacological agents*

*Outcome: pain*

Based on a non-inferiority trial [49], there is very low quality evidence that acetaminophen and loxoprofen are not statistically different beyond a specified non-inferiority margin (0.84 points on a 0 to 10 points numerical rating scale) for acute LBP at short-term (MD −0.51, 95% CI −1.70 to 0.67).

*Outcome: disability*

At short-term, there is low quality evidence [49] that there is no difference between acetaminophen and loxoprofen for older adults with acute low back pain (change from baseline for acetaminophen $-4.14 \pm 2.13$, for loxoprofen $-7.11 \pm 1.94$; $p = 0.621$).

*Low level laser therapy*

*Outcome: pain intensity*

Based on low quality evidence, one study [38] demonstrated that low level laser therapy (LLLT) reduces pain compared to sham deactivated laser (OR 4.53, 95 CI% 1.44 to 14.26) at short-term follow-up.

*Thermotherapy*

*Outcome: pain intensity*

There is very low quality [33] of evidence that whole body cryotherapy (WBC) using a cryogenic chamber five times a week has a large effect on reducing pain compared to WBC two times a week at short-tem follow-up (MD 21.02; 95% CI −25,68 to −6.36).

*Exercise*

*Outcome: disability*

One study [47] provided low quality evidence that total body exercise improves disability at short-term follow-up compared to lumbar extension exercise, with a moderate but not clinically significant effect (MD −25.83, 95% CI 0.79 to 25.87), and with a small not clinically important effect (−5.41, 95% CI 5.7 to 16.54) when compared to standard care (i.e., education regarding physical activity and diet). The practice of Pilates exercise combined with PT resulted in a small and not clinically important reduction in pain at short-term (MD = 1.97, 96% CI −2.05 to −1.89) compared to PT alone.

## Discussion

*Summary of main results*

The aim of this systematic review was to examine the effectiveness of interventions to manage pain and disability in older adults with NSLBP. In total, 18 RCTs representing a variety of strategies for management of NSLBP in older adults were included in this review. The quality of evidence ranged from very low to moderate quality primarily because there are only single studies.

In general, the pooled effects of the CHA demonstrated not clinically significant reductions in pain and disability at short and intermediate-term. The lack of studies with a low-risk of bias, precludes any strong conclusions; however, the principal findings for the CHA, which are based upon low to moderate quality evidence, suggest no clinically beneficial effect compared with sham, passive modalities or any other intervention for treatment of chronic low back pain (CLBP). These results are partially supported by two previous broader reviews investigating the efficacy of CHA for LBP [50] and CNSLBP [51] showing a small statistical but not clinically significant reduction in pain and disability immediately and at short-term after the application of CHA. However, may these results cannot be extrapolated to older adults since most of the trials included in these reviews encompassed young and middle aged participants from 18 to 65 years old.

Although some criticism might be levelled at our population, to our knowledge, this is the first review examining the whole spectre of interventions for LBP in older people. Two previous systematic reviews [16,17] investigated CLBP in older adults limited to physical and active therapies. In addition, these reviews present a low methodological quality according to the AMSTAR [52] score. The review of Ehrenbrusthoff *et al*. fulfilled only four of eleven (4/11) possible AMSTAR items, while the review of Kuss *et al*. fulfilled five items (5/11).

Our results showed that PENS combined with PT [41] is statistically but not clinically relevant to reduce pain at short and intermediate-term follow-up than sham PENS plus PT. This result is partly in concordance with a crossover RCT [53] that showed better results for PENS when compared to sham PENS for pain outcomes at short-term but not in subsequent follow-ups in subjects with CLBP. Our review also showed, a not clinically relevant effect on reducing pain in favors of PENS compared to usual care at short-term follow-up [36]. In contrast, a previous study [54] showed a higher effectiveness of PENS to decrease pain compared to TENS at short-term follow-up. For function, studies comparing PENS to sham PENS [41] or usual care [36] revealed that PENS improved function at short-term follow-up whilst previous evidence [53] revealed similar results at short-term favorable to PENS in comparison to TENS. However, the NICE guidelines [55] does not recommend offering PENS for patients over 16 years with LBP.

We found two studies [42,48] that provided very low-quality evidence that educational strategies are not efficient to reduce disability related to LBP. These results are in accordance with two recent systematic reviews that revealed that the effect of back school for LBP is insufficient [56] with a dubious benefit [57]. Whilst a review of self-management

strategies [58] showed only small, no clinically significant effects.

A single study investigating LLLT provided very-low quality evidence of a clinical important effect favouring LLLT compared to sham laser to reduce pain at short-term follow-up. The positive effect of LLLT compared to sham for NSLBP were also available in a previous systematic reviews [59]. However, more robust evidence [60] showed that studies with LLLT are methodologically weak, present small sample size and the control groups are in general no active interventions.

The use of continuous sessions of cryotherapy led to a large but no clinically significant reduction on pain when compared to intermittent applications at short-term However, results of three previous reviews [61–63] found a lack of sufficient evidence to evaluate the effects of cryotherapy for LBP.

We found very-low quality evidence [49] that the administration of acetaminophen or loxoprofen for a short-term was unable to provide clinically significant improvements on pain and disability symptoms for acute LBP at short-term. A recent Cochrane review [64] concluded based on high-quality evidence that paracetamol is no better than placebo for relieving acute LBP in either the short or longer term. Furthermore, there is guideline recommendation [55] to not offer paracetamol alone for managing LBP. Although there was a previous recommendation for using nonsteroidal anti-inflammatory drugs (NSAIDs) [55] for LBP, the recent published Danish guideline [65] presents a weak recommendation against paracetamol and NSAIDs based on moderate and low quality evidence respectively.

A short-term not clinically improvement in functional status was observed after the implementation of a total body exercise program compared to lumbar exercise alone and standard care. Results of a Cochrane review [66] showed that exercise is better than other interventions to improve function at short-term. However, a meta regression [67] concluded that exercises provide similar results to other forms of conservative treatments at short-term follow-up. In addition, a previous review targeting older adults [17] showed a low quality evidence for active therapies in providing small-to-moderate reduction in pain and small improvement in function.

### *Strengths and weaknesses of the study*

In this review, we used a systematic approach with two independent reviewers processing the articles for eligibility. In addition, a comprehensive search of several databases following the recommendations proposed by the Cochrane Back Review Group, and no language limitation was set to avoid missing relevant articles. Furthermore, the risk of bias of the included studies was assessed using the validated PEDro scale [68] and the quality of evidence was assessed using the GRADE statement [27].

A potential limitation of this review is the low number, high heterogeneity and small sample sizes per comparison among the trials that were included, which prevented us to provide robust estimates of the effects of the interventions. In addition, another limitation is the potential risk of publication bias. Although it was not possible to assess publication bias using funnel plots, we did an inspection of trial registries and did not find any potential indicator of publication bias. However, the mandatory requisition for trial registry is recent which may result in publication bias from past trials.

### *Implications*

To our knowledge, this is the most comprehensive systematic review investigating interventions for NSLBP in older adults. However, this review does not allow to formulate definitive conclusions about the effectiveness of the interventions. Even though there are studies indicating some positive results, the evidence is weak and not clinically relevant. Future research is highly likely to change any recommendation we would make. Also, efforts to design trials with low risk of bias, provide a detailed description of the interventions applied in all groups, and have an appropriate estimation of the sample size are necessary. The lack of effective evidence based interventions is a challenge for healthcare providers due to the difficulties in approaching older adults with NSLBP, affecting also patients, and policy makers that will expend financial resources with interventions that provide in the best scenario a not significant improvement of the clinical symptoms. Thus, is urgent the development of clinical trials targeting older adults with different symptoms duration and following them for long-term to allow the recommendation of evidence-based treatment to this growing population.

**Key messages**

- Clinical trials for older adults are usually based on passive interventions.
- Our results suggest that interventions for older adults with chronic non-specific low back pain are not clinically effective for reducing pain and disability at short or intermediate-term.
- Benefits of current treatments for low back pain in older adults are insufficient even when compared to sham or minimal interventions.

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*Conflict of interest disclosures*: None declared.

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## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.physio.2018.11.004.

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