OREGON HEALTH AND SCIENCE UNIVERSITY
Office of Clinical Integration and Evidence-Based Practice
Acute Low Back Pain
***Evidence Summary***

**Date started:** November 2017
**Date completed:** September 2018


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**Objective:** To critically review the evidence on acute and subacute low back pain.

**Target Guideline Users:** All clinicians caring for patients presenting with acute or subacute low back pain in any setting within the OHSU health system

**Inclusion Criteria:**
- Patients >/= 18 years with subacute or acute low back pain, or with chronic back pain experiencing a new, discrete flare

**Exclusion Criteria:**
- Pregnant women
- Pediatric patients </= 18 years
- Patients with cervical or thoracic back pain
- Patients with non-spinal pain

**Definitions:**
*Acute Back Pain:* Pain lasting less than 4 weeks
*Subacute Back Pain:* Pain lasting 4 – 12 weeks
*Chronic Back Pain:* Pain lasting more than 12 weeks

## Review Preparation:

1. What historical or clinical features or "red flag" protocol is most effective in identifying patients with low back pain for whom diagnostic imaging should be obtained?
2. What validated risk assessment tool (i.e., OMSPQ, STarT Back, DRAM) is the most accurate in identifying people with low back pain at risk of poor outcomes or delayed improvement?
3. What are the comparative harms and benefits of routine imaging vs. usual care in patients with acute or subacute low back pain?
4. What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? *Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, antiseizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications.*
5. What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? *Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.*

## Quality Measures:

Outcome

- # of patients with acute LBP
- Total cost of care for acute low back pain
- Opioid use for acute LBP
- Advanced imaging use for acute LBP
- Patient functional assessment: before/after 4-week treatment
- # missed pathologies
- Patient satisfaction with acute LBP treatment

Process

- # Red Flag Protocols Completed
- # Red Flag vs. Non-Red Flag Patients
- # Patients with complete Start Back Assessment: % low, med-high risk
- # Patient Referrals
- Treatment Adherence
- # Patients Referred to Surgical Intervention

## Acute Low Back Pain
## Existing External Guidelines/Pathways/Order Sets

**Existing External Guidelines**

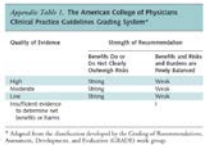
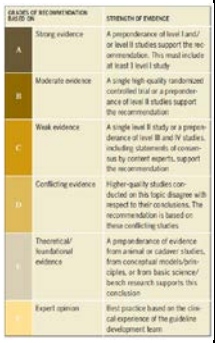
| External Guideline | Organization and Author | Last Update |
|---|---|---|
| Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and American Pain Society | American College of Physicians and American Pain Society | 2007 |
| Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain | American Pain Society | 2009 |
| Low Back Pain: Clinical Practice Guidelines Linked to the International Classification of Functioning, Disability, and Health from the Orthopaedic Section of the American Physical Therapy Association | American Physical Therapy Association | 2012 |
| HERC Advanced Imaging for Low Back Pain | Health Evidence Review Commission (HERC) | 2012 |
| HERC Pharmacological Interventions | Health Evidence Review Commission (HERC) | 2014 |
| HERC Non-Pharmacological Interventions | Health Evidence Review Commission (HERC) | 2014 |
| ACR Appropriateness Criteria for Low Back Pain | American College of Radiology | 2015 |
| Guidelines for Osteopathic Manipulative Treatment (OMT) for Patients With Low Back Pain | American Osteopathic Association | 2016 |
| Low back pain and sciatica in over 16s: assessment and management | The National Institute for Healthcare Excellence (NICE) | 2016 |
| Pain: assessment, non-opioid treatment approaches and opioid management | Institute for Clinical Systems Improvement (ICSI) | 2016 |
| Corticosteroid Injections: Low Back Pain | Health Evidence Review Commission (HERC) | 2017 |
| Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians | American College of Physicians | 2017 |
| Adult Acute and Subacute Low Back Pain. | Institute for Clinical Systems Improvement (ICSI) | 2018 |

The thirteen published clinical guidelines were evaluated for this review using the **University of Pennsylvania's Center for Evidence-Based Practice Trustworthy Guideline rating scale.** The scale is based on the Institute of Medicine's "Standards for Developing Trustworthy Clinical Practice Guidelines" (IOM), as well as a review of the AGREE Enterprise and Guidelines International Network domains.

| Guideline Issuer and Date | American College of Physicians and American Pain Society 2007 | American Pain Society 2009 | American Physical Therapy Association 2012 | HERC Advanced Imaging for Low Back Pain 2012 | HERC Pharmacologic Interventions 2014 | HERC Non-Pharmacological/Non-Invasive Interventions 2014 | American College of Radiology 2015 | American Osteopathic Association 2016 | NICE 2016 | ICSI Non-opioids 2016 | HERC Corticosteroid Injections 2017 | American College of Physicians 2017 | ICSI 2012 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1. Transparency | B | A | A | B | B | B | C | B | A | A | **B** | **A** | A |
| 2. Conflict of interest | A | A | NR | NR | NR | NR | NR | A | C | A | A | A | A |
| 3. Development group | A | A | B | NR | NR | NR | B | C | A | A | NR | A | A |
| 4. Systematic Review | A | A | A | B | B | B | B | B | B | A | B | A | A |
| 5. Supporting evidence | A | A | A | A | A | A | C | B | A | A | A | A | A |
| 6. Recommendations | A | A | A | A | B | B | C | B | B | A | B | A | A |
| 7. External Review | NR | A | A | NR | NR | NR | NR | B | NR | A | NR | A | A |
| 8. Currency and updates | C | A | B | C | C | C | B | A | B | A | B | A | A |

See appendix B for full description of the Trustworthy Guideline grading system.

## Guideline Evidence Evaluation Systems

| | American College of Physicians and American Pain Society 2007 | American Pain Society 2009 | American Physical Therapy Association 2012 | HERC Advanced Imaging for Low Back Pain 2012 | ICSI 2012 | HERC Pharmacologic Interventions 2014 | HERC Non-Pharmacological/Non-Invasive Interventions 2014 |
|---|---|---|---|---|---|---|---|
| **Evidence Evaluation** | Recommendations are graded by using the ACP's clinical practice guidelines grading system, adapted from the classification developed by the Grading Of Recommendations, Assessment, Development, and Evaluation (GRADE) work group  | Evidence was assigned an overall grade using methods adapted by the ACP from the Grading of Recommendations, Assessment, Development, and Evaluation Working Group  | Evidence was graded according to Centre for Evidence-Based Medicine, UK criteria for diagnostic, prospective, and therapeutic studies.  | Evidence evaluation system not described.<br><br>Stated that recommendations were based on evidence-based guideline developed by the Evidence-based Guideline Subcommittee and a health technology assessment developed by the Health Technology Assessment Subcommittee, stated that coverage guidance may utilize an existing evidence report produced in the last 5 years by the Agency for Healthcare Research and Quality, the Medicaid Evidence-based Decisions Project or the Washington Health Technology Assessment Program | Uses the GRADE methodology to determine the quality of evidence:<br><br>High Quality Evidence: Further research is very unlikely to change our confidence in the estimate of the effect.<br><br>Moderate Quality Evidence: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.<br><br>Low Quality Evidence: 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 or any estimate of effect is very uncertain. | Evidence evaluation system not described.<br><br>Stated that recommendations may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years. | Evidence evaluation system not described.<br><br>Stated that recommendations may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Heath Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years. |

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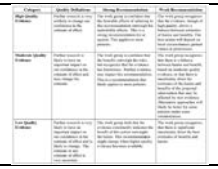
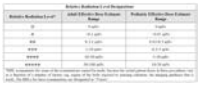
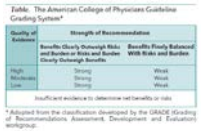
| | | | | |  | | |

| | American College of Radiology 2015 | American Osteopathic Association 2016 | NICE 2016 | ICSI Non-opioids 2016 | HERC Corticosteroid Injections 2017 | American College of Physicians 2017 |
|---|---|---|---|---|---|---|
| **Evidence Evaluation** | Rating Scale:<br>1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7, 8, 9 Usually appropriate<br>  | Uses GRADE approach<br>  | Evidence evaluation system not described, no formal rating of recommendations | The Institute for Clinical Systems Improvement (ICSI) uses a modified GRADE (Grading of Recommendations Assessment, Development and Evaluation) methodology as a way to systematically review the evidence and develop recommendations. After gathering the evidence through literature searches, the work group found a paucity of systematic reviews and randomized controlled trials (RCTs), making the application of GRADE methodology challenging. As an evolving field, there is still much about pain treatment, particularly use of opioids, that remains unstudied or understudied. | Evidence is evaluated using an adaptation of the GRADE methodology<br>High: The subcommittee is very confident that the true effect lies close to that of the estimate of the effect.<br>Moderate: The subcommittee is moderately confident in the estimate of effect: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.<br>Low: The subcommittee's confidence in the estimate of effect is limited: The true effect may be substantially different from the estimate of the | This guideline was developed by ACP's Clinical Guidelines Committee (CGC) according to ACP's guideline development process. The CGC used the evidence tables in the accompanying evidence reviews and full report when reporting the evidence and graded the recommendations using the ACP's guideline grading system<br>  |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | Given this, GRADE methodology could not be applied to this document. Instead, the work group used the best available evidence to reach consensus recommendations. For each recommendation, the relevant resources used to support that recommendation are noted. | effect.  | |

## Review of Relevant Evidence: Search Strategies and Databases Reviewed

| Search Strategies | Document Strategies Used |
|---|---|
| **Search Terms/Strategies Used:** | PICO Questions 1, 2, 3, 4, 5: See Appendix C |
| **Years Searched - All Questions** | PICO Questions 1, 2, 3: January 2008 – January 2018; PICO Questions 4, 5: April 2015 – January 2018 |
| **Language** | English |
| **Age of Subjects** | Adults, >/= 18 years |

## Evidence Found with Searches

| Check type of evidence found | Summary of Evidence – All Questions | Number of articles obtained |
|---|---|---|
| ☒ | Systematic reviews/Meta-analysis | 26 |
| ☒ | Randomized controlled trials | 33 |
| ☒ | Non-randomized studies | 16 |
| ☒ | Government/State agency regulations | 4 |
| ☒ | Professional organization guidelines/white papers, etc. | 8 |

**Evaluating the Quality of the Evidence**

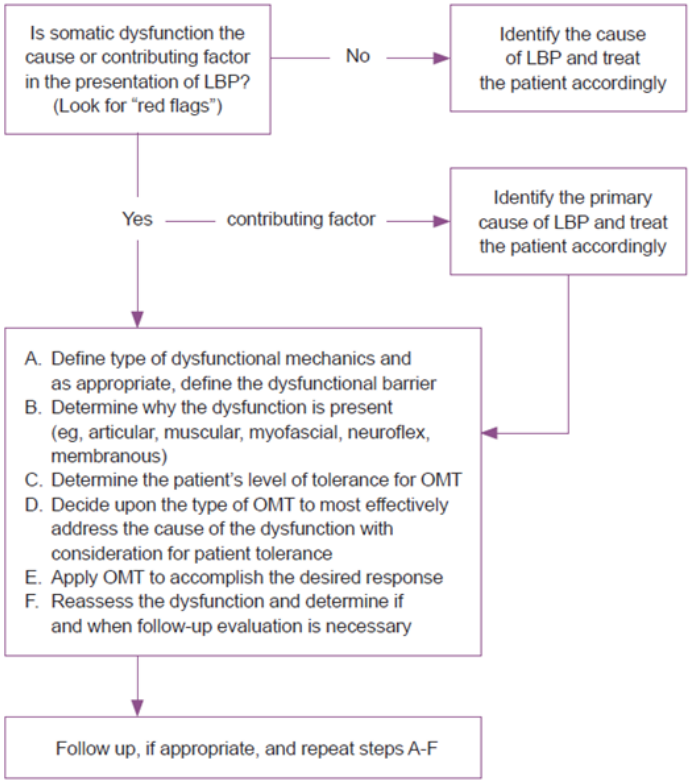
The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. The table below defines how the quality of the evidence is rated and how a strong versus weak recommendation is established. For more detailed information, see Appendix A.

| **Recommendation** | |
|---|---|
| **STRONG** | Desirable effects clearly outweigh undesirable effects or vice versa |
| **CONDITIONAL** | Desirable effects closely balanced with undesirable effects |
| **Quality** | **Type of Evidence** |
| **High** | Further research is very unlikely to change our confidence in the estimate of effect. |
| **Moderate** | Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. |
| **Low** | 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** | Any estimate of effect is very uncertain. |

**Question #1. What historical or clinical features or "red flag" protocol is most effective in identifying patients with low back pain for whom diagnostic imaging should be obtained?**

**Guideline Recommendations:**

**American Osteopathic Association 2016** guideline included following algorithm that includes recommendations for defining dysfunction and determining why the dysfunction is present, "looking for red flags". No red flag protocol recommended in recommendation **(Level of evidence not included).**




The **American College of Radiology 2015** guideline recommends that an MRI of the lumbar spine should be considered for those patients presenting with red flags raising suspicion for a serious underlying condition, such as cauda equina syndrome (CES), malignancy, or infection. In addition, in patients with a history of low-velocity trauma, osteoporosis, or chronic steroid use, initial evaluation with radiographs is recommended. **(Level of evidence not included).**

The **Institute for Clinical Systems Improvement 2012** guideline on low back pain, adult acute and subacute stated to conduct an evaluation by collecting history and physical examination, documenting presence/absence of "red flags". For "red flag" protocol consider conducting evaluations for cancer, infection, fracture, rule out cauda equine, and consider other non-spine pain origins. **(Level of evidence not included).**

The **2012 Health Evidence Review Commission (HERC) Advanced Imaging for Low Back Pain** guideline recommends that if patients have severe or progressive neurologic deficits, or clinicians suspect serious underlying condition (e.g. cancer or infection) prompt workup with MRI (first choice) or CT should be covered. **(Strong recommendation, Moderate-quality evidence).**

**The 2012 American Physical Therapy Association** guideline recommends that clinicians should consider diagnostic classifications associated with serious medical conditions or psychosocial factors and initiate referral to the appropriate medical practitioner when (1) the patient's clinical findings are suggestive of serious medical or psychological pathology, (2) the reported activity limitations or impairments of body function and structure are not consistent with those presented in the diagnosis/classification section of these guidelines, or (3) the patient's symptoms are not resolving with interventions aimed at normalization of the patient's impairments of body function. **(Recommendation based on strong evidence).**

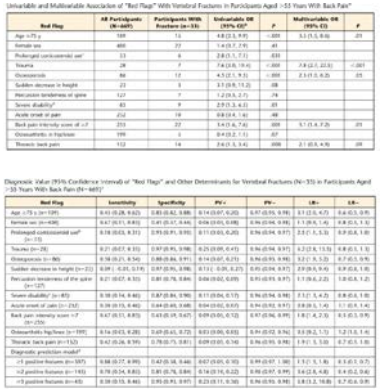
The **American College of Physicians and American Pain Society 2007** guideline recommended that clinicians should perform diagnostic imaging and testing for patients with low back pain when severe or progressive neurologic deficits are present or when serious underlying conditions are suspected on the basis of history and physical examination **(strong recommendation, moderate-quality evidence).**

**References:**


1. (2016). "American Osteopathic Association Guidelines for Osteopathic Manipulative Treatment (OMT) for Patients With Low Back Pain." Journal of the American Osteopathic Association **116**(8): 536-549.
2. Chou, R., et al. (2007). "Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society." Annals of Internal Medicine **147**(7): 478-491.
3. Delitto, A., et al. (2012). "Low Back Pain: Clinical Practice Guidelines Linked to the International Classification of Functioning, Disability, and Health from the Orthopaedic Section of the American Physical Therapy Association." The Journal of orthopaedic and sports physical therapy **42**(4): A1-57.
4. Goertz M., et al., (2012). Low back pain, adult acute and subacute. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI). Nov. 91 p.
5. Livingston, C., Little, A., King, V., Pettinari, C., Thielke, A., Vandegriff, S., & Gordon, C. (2012). State of Oregon Evidence-based Clinical Guidelines Project. Advanced imaging for low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain). Salem: Office for Oregon Health Policy & Research.
6. Patel, N. D., et al. (2016). "ACR Appropriateness Criteria Low Back Pain." J Am Coll Radiol 13(9): 1069-1078.


**Primary Literature:**

| | |
|---|---|
| **PICO Question:** What historical or clinical features or "red flag" protocol is most effective in identifying patients with low back pain for whom diagnostic imaging should be obtained? | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies,* |
| **Outcome:** Identifying patients for diagnostic imaging | |

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | *populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect<br>*(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*<br><br>☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias<br>*(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br><u>Increase Quality Rating if:</u><br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |
|---|---|---|---|---|---|---|
| **Total # of Studies: 1# of Systematic Reviews 1 # of Non-Randomized Studies: 1 # of Diagnostic Studies: 1** | | | | | | |
| Enthoven, W. T., et al. (2016). *Physical Therapy* | (1) to identify the prevalence of physician-specified causes of back pain and (2) to assess associations between "red flags" and vertebral fractures, as diagnosed by the patients' general practitioner (GP), in older adults with back pain. | Prospective cohort study. Patients (aged >55 years) with back pain were included when consulting their GP. A questionnaire was administered and a physical examination and heel bone densitometry were performed, and the results determined back pain and patient characteristics, including red flags. Participants received a radiograph, and reports were sent to their GP. The final diagnoses established at 1 year were collected from the GP's patient registry. | 669 participants | ***Association between "Red Flags" and vertebral fractures:*** **Age** had a positive predictive value of 0.14 (95% confidence interval [CI] =0.07, 0.20) and a positive likelihood ratio of 3.1 (95% CI=2.0, 4.7). **Osteoporosis** had a similar positive predictive value of 0.14 (95% CI =0.07, 0.21) and likelihood ratio of 3.2 (95% CI=I.9, 5.2). The positive predictive value and the positive likelihood ratio of **trauma** were 0.25 (95% CI=0.09, 0.41) and 6.2 (95% CJ=2.8, 13.5), respectively.<br><br>The negative likelihood ratio for trauma was 0.8 (95% CI=0.5, 1.3), which lowers the probability of a vertebral frac-ture if there was no trauma from .05 to .04. A diagnostic prediction model with 4 red flags combined did not increase these diagnostic values.<br><br>  | Study Limitations =<br>☐ None<br>***Diagnostic Studies***<br>☒ Patients not enrolled in consecutive or random manner<br>☐ Case-control study<br>☒ No independent, blind comparison between index test and reference test<br>☐ Not all patients received reference test<br>☐ Reference test not likely to correctly classify target condition<br>☐ Failure to include all patients in analysis | |
| Downie, A., et al. (2013). *BMJ : British Medical Journal* | To review the evidence on diagnostic accuracy of red flag signs and symptoms to | Systematic Review. | 14 studies ( 5 relating to fracture and 6 relating to malignancy with 3 | **Red Flags for Spinal Fracture:** The red flags with the highest post-test probability for detection of fracture were older age (9%, 95% confidence interval 3% to 25%), prolonged use of corticosteroid drugs | Study Limitations =<br>☐ None<br>***Systematic Review*** | |

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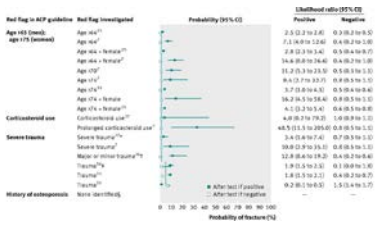
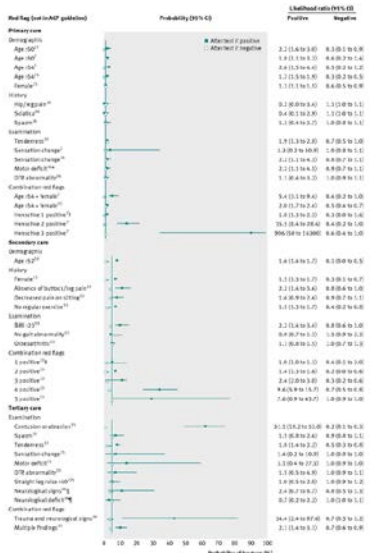
| | screen for fracture or malignancy in patients presenting with low back pain to primary, secondary, or tertiary care. | | reviewing both fracture and malignancy) | (33%, 10% to 67%), severe trauma (11%, 8% to 16%), and presence of a contusion or abrasion (62%, 49% to 74%). Probability of spinal fracture was higher when multiple red flags were present (90%, 34% to 99%).<br>  <br>  <br>**Red Flags for Spinal Malignancy:** The red flag with the highest post-test probability for detection of spinal malignancy was history of malignancy (33%, 22% to 46%). | ☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies | |

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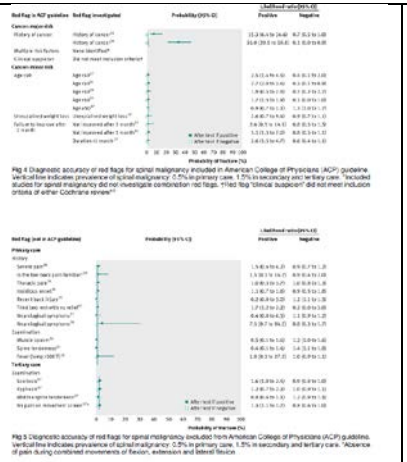
| | | | |  | | |
| Ferrari et al. (2016) *Canadian Family Physician* | To evaluate an a priori threshold for advanced imaging in patients with spinal pain. | Prospective cohort study. Patients with spinal pain in any region for 6 to 52 weeks were assessed to determine if radiologic studies beyond x-ray scans were indicated, including MRI, CT, and radionuclide bone scans. An a priori threshold was set before MRI, CT, or bone scans would be considered. Those who did not have MRI, CT, or bone scans ordered were followed for at least 1 year to determine if any of them went on to be diagnosed with a more serious spinal disorder (eg, infection, fracture, spondylitis, tumour, neurologic compression). | 1003 patients | Of the 1003 participants, 110 met an a priori threshold for undergoing at least 1 of MRI, CT, or bone scan. In these 110 participants, there were 24 newly diagnosed cases of radiculopathy (n = 12), including a case of cauda equina syndrome; spondyloarthropathy (n = 6); occult fracture (n = 2); solitary metastasis (n = 1); epidural lipomatosis (n = 1); osteomyelitis (n = 1), and retroperitoneal hematoma (n = 1), each of which was considered likely to be the cause of the patient's spinal symptoms. The remaining 893 participants were followed for at least 1 year and none showed evidence of a non-benign cause of his or her spinal pain. | Study Limitations =<br>☒ None<br>***Non-Randomized Studies***<br>☐ Failure to develop and apply appropriate eligibility criteria<br>☐ Flawed measurement of both exposure and outcome<br>☐ Failure to adequately control confounding<br>☐ Incomplete or inadequately short follow-up<br>☐ Differences in important prognostic factors at baseline | |

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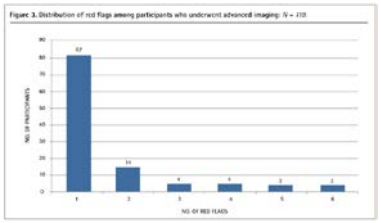
| | | | | **Box 1. The a priori criteria for ordering bone scan, MRI, or CT in a patient presenting with spinal pain of nontraumatic origin:** *Any 1 of these red flags prompted 1 or more advanced imaging techniques in 110 patients.*<br><br>Relevant history<br>• Cancer<br>• Recent infection or risk of tuberculosis<br>• Intravenous drug abuse<br>• HIV infection or immunosuppressed state<br>• Diabetes mellitus<br>• Age >65 y<br>• Previous spinal surgery<br>• Surgical intervention or procedure near the spinal region of interest<br>Relevant symptoms<br>• Unexplained weight loss<br>• Anorexia<br>• Bowel or bladder incontinence<br>• Symptoms of neurogenic claudication<br>• Fever or chills<br>Relevant physical examination findings<br>• Objective muscle weakness or wasting<br>• Absent reflexes or hyperreflexia<br>• Dermatomal sensory loss<br>• Sensation is lost below a specific spinal level<br>• Pyramidal tract signs<br>Suspected spondylitis (inflammatory back pain)<br>• Back or buttock pain with at least 1 of the following:<br>-morning stiffness lasting longer than 1 h;<br>-enthesitis;<br>-uveitis;<br>-dactylitis;<br>-psoriasis;<br>-Crohn disease or ulcerative colitis;<br>-excellent response to nonsteroidal anti-inflammatory drugs;<br>-family history of spondyloarthropathy;<br>-positive test results for human leukocyte antigen B27; or<br>-elevated erythrocyte sedimentation rate or C-reactive protein level<br><br>CT—computed tomography, MRI—magnetic resonance imaging.<br><br>  | | |

**References:**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2. Ferrari, R. (2016). "Imaging studies in patients with spinal pain: Practice audit evaluation of Choosing Wisely Canada recommendations." Canadian Family Physician 62(3): e129-137
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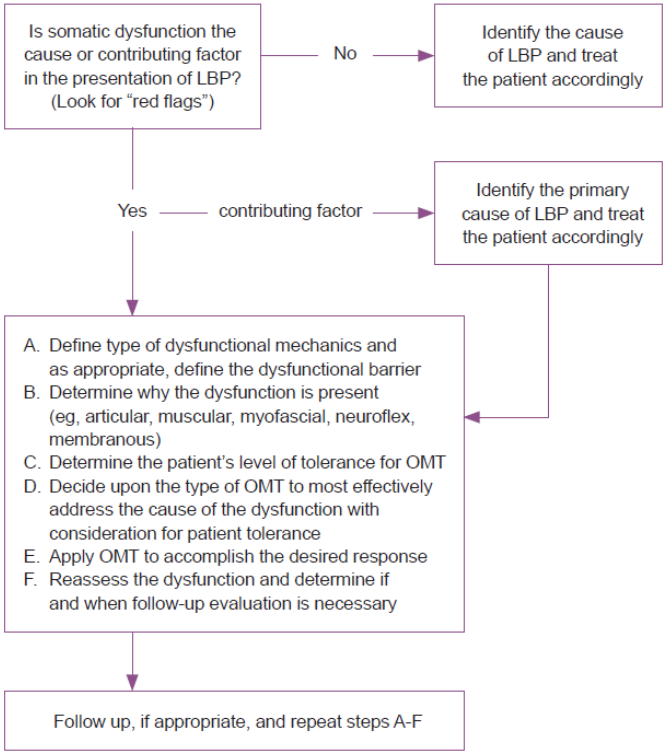
**Question #2. What validated risk assessment tool (i.e., OMSPQ, STarT Back, DRAM) is the most accurate in identifying people with low back pain at risk of poor outcomes or delayed improvement?**

**Guideline Recommendations:**

The **Institute for Clinical Systems Improvement 2016** guideline on Pain: assessment, non-opioid treatment approaches and opioid management states to use validated tools to assess and document the patient's functional status, quality-of-life and pain intensity **(Level of evidence not included).**

The United Kingdom's **National Institute for Health and Care Excellence (NICE) 2016** guideline states to consider using risk stratification (for example, the STarT Back risk assessment tool) at first point of contact with a healthcare professional for each new episode of low back pain with or without sciatica to inform shared decision making about stratified management. Based on risk stratification, consider: (1) simpler and less intensive support for people with low back pain with or without sciatica likely to improve quickly and have a good outcome (for example, reassurance, advice to keep active and guidance on self-management) and (2) more complex and intensive support for people with low back pain with or without sciatica at higher risk of a poor outcome (for example, exercise programmes with or without manual therapy or using a psychological approach) **(Level of evidence not included).**

**American Osteopathic Association 2016** guideline included following algorithm that includes recommendations for defining dysfunction and determining why the dysfunction is present. No validated tool was recommended in recommendation **(Level of evidence not included).**




The **Institute for Clinical Systems Improvement 2012** guideline on low back pain, adult acute and subacute stated to conduct an evaluation by collecting history and physical examination, documenting presence/absence of "red flags", conduct functional assessment using Oswestry Disability Questionnaire or other scale, conduct pain assessment using visual analog or other pain scale, recommends against imaging (not recommended for non-specific low back pain) and to reevaluate as needed. Reevaluation of low back pain should include the following: (1) Pain reassessed with a repeat Visual Analog Scale and Oswestry Disability; (2) Questionnaire; (3) Sensory changes; (4) Strength changes; (5) Job and activity associations considered and noted; and (6) Presence or absence of red flags and psychosocial indicators confirmed. **(Level of evidence not included).**

**American Physical Therapy Association in 2012** stated clinicians should use validated self-report questionnaires, such as the Oswestry Disability Index and the Roland-Morris Disability Questionnaire. American Physical Therapy Association states the tools are useful for identifying a patient's baseline status relative to pain, function, and disability and for monitoring a chance in a patient's status throughout the course of treatment **(Recommendation based on strong evidence).**

The **American College of Physicians and American Pain Society 2007** guideline recommended that clinicians should conduct a focused history and physical examination to help place patients with low back pain into 1 of 3 broad categories: nonspecific low back pain, back pain potentially associated with radiculopathy or spinal stenosis, or back pain potentially

associated with another specific spinal cause. The history should include assessment of psychosocial risk factors, which predict risk for chronic disabling back pain **(strong recommendation, moderate-quality evidence).**

**References:**


7. (2016). "American Osteopathic Association Guidelines for Osteopathic Manipulative Treatment (OMT) for Patients With Low Back Pain." Journal of the American Osteopathic Association **116**(8): 536-549.
8. Bernstein, I. A., et al. (2017). "Low back pain and sciatica: summary of NICE guidance." BMJ 356.
9. Chou, R., et al. (2007). "Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society." Annals of Internal Medicine **147**(7): 478-491.
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11. Goertz M., et al., (2012). Low back pain, adult acute and subacute. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI). Nov. 91 p.
12. Hooten M., et al., (2016). Pain: assessment, non-opioid treatment approaches and opioid management. Institute for Clinical Systems Improvement. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI). Sep. 160 p.


**Primary Literature:**

| **PICO Question:** What validated risk assessment tool (i.e., OMSPQ, STarT Back, DRAM) is the most accurate in identifying people with low back pain at risk of poor outcomes or delayed improvement? (literature in last 10 years) | | | | | | Lower Quality Rating if: ☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)* ☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)* ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)* |
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| **Modality:** STarT Back Tool; **Outcome:** Identifying patients at risk of poor outcomes | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 6 # of Systematic Reviews: 1 # of RCTs: 1 # of Non-Randomized Studies: 4** | | | | | | |
| Karran, E.L., et al, 2017, *BMC Medicine* | To evaluate the performance of low back pain (LBP) screening instruments for determining risk of poor outcomes in adults with LBP of less than 3 months duration | Systematic review with meta-analysis | 18 studies investigating seven instruments. Studies were eligible if they involved adults (aged 18 or over) with 'recent onset' LBP (i.e. acute LBP (0–6 weeks) or subacute LBP (6 weeks to 3 months)), with or without leg pain. | **Five studies investigated the STarT Back Tool: performance for discriminating pain outcomes at follow-up was 'non-informative' (pooled AUC = 0.59 (0.55–0.63), n = 1153) and 'acceptable' for discriminating disability outcomes (pooled AUC = 0.74 (0.66–0.82), n = 821).**<br><br>Discrimination of pain outcomes:<br>The five studies investigating the SBT used pain as an outcome measure. All authors provided raw data for statistical analysis or followed guidance for analysis of their recent onset data. **Consistent classification of 'poor outcome' allowed pooling of AUC values (pooled AUC = 0.59 (0.55–0.63). Discriminative performance was 'non-informative'. There was no evidence of** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies | |

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| | | | | **statistical heterogeneity (I2 = 0.00%, P = 0.47).**<br><br><u>Discrimination of disability outcomes:</u><br>Three SBT studies included disability as an outcome measure. 'Poor outcome' (in disability terms) was defined consistently. **The pooled AUC value of 0.74 (0.66–0.82) indicated 'acceptable' discrimination. There was substantial statistical heterogeneity (I2 = 80.95%, P = 0.005).** To explore the source of heterogeneity, two studies that did not have overlapping confidence intervals were separately removed. **Heterogeneity was no longer significant in both analyses (P > 0.05), with impact on the AUC values.**<br>  | | <u>Increase Quality Rating if:</u><br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☒ Moderate<br>☐ Low<br>☐ Very Low |
| Wideman, T.H., et al., 2012, *Pain* | To compare the responsiveness of the STarT Back Tool to its corresponding full-length measures, and evaluate its ability to detect clinically meaningful improvement | RCT; Participants were recruited across 10 general practices in England. Patients were mailed a recruitment package providing information about the trial, an invitation to schedule an initial assessment, and baseline self-report questionnaires. Eligible participants were randomized to either control or intervention groups. All participants received an initial 30-minute physiotherapy evaluation and a brief education and advice intervention. Additional treatments for Control participants were left to the discretion of their physiotherapist, as this arm was designed to represent treatment as usual. Additional treatments for Intervention participants were provided according to their baseline risk stratification as determined by the STarT Back | 300 people; 76 were considered high-risk | **Results revealed that STarT Change was significantly correlated (P < 0.05) with all reference standard variables (Pearson coefficients ranged from .485 to .674).** When compared to its reference standards, STarT Change and Disability Change were equal in having the strongest correlations with Global Change (Pearson coefficient = -.582); STarT Change (Pearson coefficient = .637) was second to Disability Change (Pearson coefficient = .645) in having the strongest correlations with Pain Severity Change; STarT Change (Pearson coefficient = .674) had the strongest correlation with Disability Change. | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☒ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important | |

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| | | screening tool: low-risk patients were not provided with any additional care; medium-risk patients were provided with physiotherapy to address their pain-related symptoms and physical function; and high-risk patients were referred for psychologically informed physiotherapy interventions, which addressed both physical and psychosocial barriers to recovery. Data collection, for all participants, was conducted via postal questionnaire prior to treatment and 4 months later. | | | | |
| Toh, I., et al., 2017, *Journal of Orthopaedic & Sports Physical Therapy* | To compare the predictive validity of 3 STarT Back Screening Tool (SBT) measures (SBT overall, psychosocial, and categorical scores) with future pain intensity in patients receiving physical therapy for low back pain (LBP) | Prospective cohort study; Patients with LBP receiving physical therapy completed the SBT at initial (baseline) evaluation and were evaluated 12 weeks later for their pain intensity. Multivariable proportional odds regression was used to evaluate the associations of the various SBT measures with pain intensity at follow-up. At the first (baseline) physical therapy visit, patients completed the SBT, a 9-item questionnaire developed by Hill et al. The SBT overall score (ranging from 0 to 9) was determined by summing all positive items, while the SBT psychosocial subscale score (ranging from 0 to 5) was determined by summing the 5 items related to fear, anxiety, catastrophizing, depression, and bothersomeness. Based on the SBT overall and psychosocial scores, 3 risk categories (SBT categorical scores) were identified: (1) high risk<br>(both overall and psychosocial scores of 4 or greater, indicating a high level of psychosocial factors | 270 patients with LBP receiving physical therapy | Adjusting for covariates**, all SBT measures were positively and significantly associated with the odds of greater pain intensity at follow-up evaluation (P<.01). Adding SBT psychosocial scores to a covariate-only model improved its predictive accuracy (95% confidence interval: 0.01, 0.09), while improvements in prediction were smaller or negligible with the SBT overall and categorical scores.**<br><br>In mutually adjusted analyses, **SBT psychosocial scores added incremental predictive value over SBT overall scores in predicting future pain intensity (P = .03).** | Study Limitations =<br>☒ None<br>***Non-Randomized Studies***<br>☐ Failure to develop and apply appropriate eligibility criteria<br>☐ Flawed measurement of both exposure and outcome<br>☐ Failure to adequately control confounding<br>☐ Incomplete or inadequately short follow-up<br>☐ Differences in important prognostic factors at baseline | |

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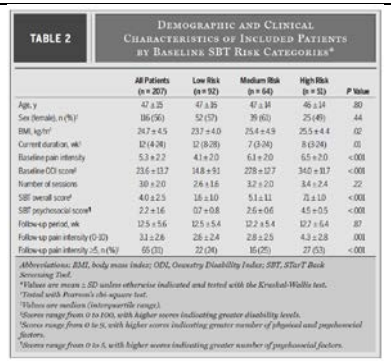
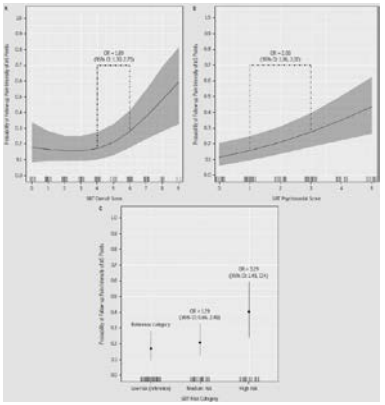
| | | with or without the presence of physical factors), (2) medium risk (overall score of 4 or greater and psychosocial subscale score less than 4, indicating a moderate level of psychosocial factors), and (3) low risk (overall score of 3 or less, indicating the presence of only a few physical and psychosocial factors). Multivariable proportional odds regression was used to evaluate the associations of the various SBT measures with pain intensity at follow-up. | | **TABLE 2** Demographic and Clinical Characteristics of Included Patients by Baseline SBT Risk Categories*<br>  <br>  | | |
| Riis, A., et al., 2017, *BMC Musculoskeletal Disorders* | To investigate STarT's ability to predict a 30% improvement in the Roland Morris Disability Questionnaire (RMDQ) score | Ancillary analysis of RCT; An inclusion criterion was age 18 to 65 years of age. Exclusion criteria were pregnancy, fractures, and signs of underlying pathology. Patient-reported STarT score and the Roland Morris Disability Questionnaire were administered at baseline and again after 4, 8, and 52 weeks. | 475 patients from original study | 441 (92.8%) patients provided information regarding STarT. Baseline and eight-week RMDQ data were available for 304 (64.0%) patients. After 8 weeks, 61 (65.6%) in the low-risk group, 67 (54.9%) in the medium-risk group, and 33 (37.1%) in the high-risk group had achieved a 30% improvement in the RMDQ score. **After 8 weeks, high-risk patients were at 61% (95% CI: 20-125%, P < 0.001) higher risk of not achieving a 30% improvement in the RMDQ score compared with patients in either the low-risk group or the medium-risk group.** | Study Limitations =<br>☐ None<br>***Non-Randomized Studies***<br>☐ Failure to develop and apply appropriate eligibility criteria<br>☐ Flawed measurement of both exposure and outcome<br>☒ Failure to adequately control confounding<br>☐ Incomplete or inadequately short follow-up<br>☐ Differences in important prognostic factors at baseline | |

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| | | | |  <br>**Table 2** STarT Back Tool risk groups and 30% improvement in the Roland Morris Disability score<br>STarT Back cut-off: Low vs Medium/High; Low/Medium vs High<br>Follow-up: RR 95% CI *P*-value RR 95% CI *P*-value<br>4 weeks: 1.64 (1.26–2.15) < 0.001 1.71 (1.18–2.49) 0.002<br>8 weeks: 1.38 (1.13–1.70) 0.003 1.61 (1.20–2.15) < 0.001<br>52 weeks: 1.21 (1.02–1.43) 0.040 1.36 (1.08–1.72) 0.003<br>*Note:* Relative risk (RR) of not achieving a clinically relevant improvement in function (30% improvement in the Roland Morris Disability score). The higher RR comparing Low/Medium vs High is equivalent to more desirable functional outcomes for the 'Low/Medium group' | | |
| George, S.Z., and J.M. Beneciuk, 2015, *BMC Musculoskeletal Disorders* | To: 1) describe LBP recovery rates at 6 months following 4 weeks of physical therapy; 2) identify psychological factors predictive of 6 month recovery status; and 3) identify psychological factors that co-occur with 6 month recovery status | Secondary analysis of a prospective cohort study; Patients were administered the STarT Back Screening Tool (SBT), individual psychological measures, a numerical pain rating scale (NPRS) and Roland Morris Disability Questionnaire (RMDQ) at intake, 4-week, and 6-month assessments. LBP recovery was operationally defined based on meeting NPRS= 0/10 and RMDQ<=2 criterion at 6-month follow-up assessment. Recovery groups were then compared for differences on all variables at intake and on individual psychological measures at 6-months. Discriminant function analysis (DFA) identified which descriptive variables were predictive of recovery status. | 111 patients | The 6-month recovery rate was 14/111 (12.6%) for the combined NPRS and RMDQ criterion. **Non-recovered patients were associated with SBT risk status (p = 0.004), higher intake pain intensity (p = .008) and higher depressive symptoms (p < .001) scores compared to recovered patients.** The overall accuracy for intake classification using DFA was 87.2% with SBT risk status, pain intensity, and depressive symptoms all making unique contributions. At 6-months, non-recovered patients had higher fear-avoidance, kinesiophobia, and depressive symptoms (p's < .001) compared to recovered patients. The overall accuracy for 6-month classification using DFA was 86.4% with fear-avoidance, kinesiophobia, and depressive symptoms all making unique contributions. | Study Limitations =<br>☒ None<br>***Non-Randomized Studies***<br>☐ Failure to develop and apply appropriate eligibility criteria<br>☐ Flawed measurement of both exposure and outcome<br>☐ Failure to adequately control confounding<br>☐ Incomplete or inadequately short follow-up<br>☐ Differences in important prognostic factors at baseline | |

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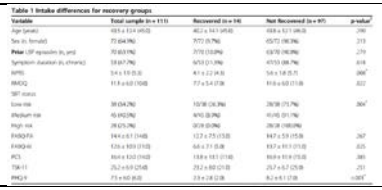
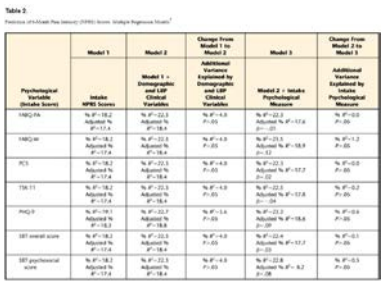
| | | | |  | | |
| Beneciuk, J.M., et al., 2013, *Physical Therapy* | To test the predictive validity of the STarT Back Screening Tool (SBT) in comparison with single-construct psychological measures for 6-month clinical outcomes | Observational, prospective cohort study; Patients receiving physical therapy for low back pain were administered the STarT Back Tool (SBT) and a battery of psychological measures (Fear-Avoidance Beliefs Questionnaire physical activity scale and work scale [FABQ-PA and FABQ-W, respectively], Pain Catastrophizing Scale [PCS], 11-item version of the Tampa Scale of Kinesiophobia [TSK-11], and 9-item Patient Health Questionnaire [PHQ-9]) at initial evaluation and 4 weeks later. Treatment was at the physical therapist's discretion. Clinical outcomes consisted of pain intensity and self-reported disability. Prediction of 6-month clinical outcomes was assessed for intake SBT and psychological measure scores using multiple regression models while controlling for other prognostic variables. In addition, the predictive capabilities of intake to 4-week changes in SBT and psychological measure scores for 6-month clinical outcomes were assessed. | 146 patients | Intake pain intensity scores (beta=.39 to .45) and disability scores (beta=.47 to .60) were the strongest predictors in all final regression models, explaining 22% and 24% and 43% and 48% of the variance for the respective clinical outcome at 6 months. Neither SBT nor psychological measure scores improved prediction of 6-month pain intensity. **The SBT overall scores (beta=.22) and SBT psychosocial scores (beta=.25) added to the prediction of disability at 6 months.** Four-week changes in TSK-11 scores (beta=-.18) were predictive of pain intensity at 6 months. Four-week changes in FABQ-PA scores (beta=-.21), TSK-11 scores (beta=-.20) and SBT overall scores (beta=-.18) were predictive of disability at 6 months.<br>  | Study Limitations =<br>☐ None<br>***Non-Randomized Studies***<br>☐ Failure to develop and apply appropriate eligibility criteria<br>☐ Flawed measurement of both exposure and outcome<br>☐ Failure to adequately control confounding<br>☒ Incomplete or inadequately short follow-up<br>☐ Differences in important prognostic factors at baseline | |

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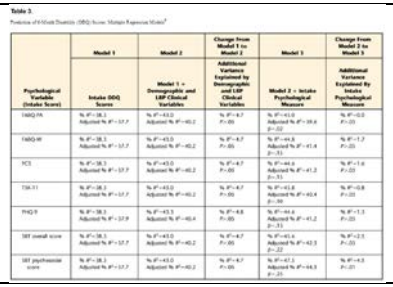
| | | | |  | | |

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1. Beneciuk, J. M., et al. (2013). "The STarT back screening tool and individual psychological measures: evaluation of prognostic capabilities for low back pain clinical outcomes in outpatient physical therapy settings." Physical Therapy 93(3): 321-333.
2. George, S. Z. and J. M. Beneciuk (2015). "Psychological predictors of recovery from low back pain: a prospective study." BMC Musculoskeletal Disorders 16: 49.
3. Karran, E. L., et al. (2017). "Can screening instruments accurately determine poor outcome risk in adults with recent onset low back pain? A systematic review and meta-analysis." BMC Medicine 15(1): 13.
4. Riis, A., et al. (2017). "Predictive ability of the start back tool: an ancillary analysis of a low back pain trial from Danish general practice." BMC Musculoskeletal Disorders 18(1): 360.
5. Toh, I., et al. (2017). "Evaluation of the STarT Back Screening Tool for Prediction of Low Back Pain Intensity in an Outpatient Physical Therapy Setting." Journal of Orthopaedic & Sports Physical Therapy 47(4): 261-267.
6. Wideman, T. H., et al. (2012). "Comparing the responsiveness of a brief, multidimensional risk screening tool for back pain to its unidimensional reference standards: the whole is greater than the sum of its parts." Pain 153(11): 2182-2191.


**PICO Question:** What validated risk assessment tool (i.e., OMSPQ, STarT Back, DRAM) is the most accurate in identifying people with low back pain at risk of poor outcomes or delayed improvement? (literature in last 10 years)

**Modality:** Modified STarT Back Tool; **Outcome:** Identifying patients at risk of poor outcomes

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
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| **Total # of Studies: 2 # of Diagnostic Studies: 2** | | | | | |
| Hill, J.C., et al, 2016, *BMJ Open* | To investigate whether a modified STarT Back Tool predicted outcome with a broader group of musculoskeletal patients, and assessed the consequences of using existing risk-group cut-points across different pain regions | Secondary analysis of prospective data from 2 cohorts (1) outpatient musculoskeletal physiotherapy services (PhysioDirect trial) and (2) musculoskeletal primary-secondary care interface services (SAMBA study). The original STarT Back Tool includes nine items of which five concern psychosocial factors (fear, catastrophising, anxiety, depression and bothersomeness). The PhysioDirect trial and SAMBA study included the STarT Back Tool's psychosocial items within their baseline questionnaires. These items were used without modification as they were | PhysioDirect trial n=1887 and SAMBA study n=1082 patients with back, neck, upper limb, lower limb or multisite pain with a completed modified STarT Back Tool (baseline) and 6-month physical health outcome | Area under the receiving operator curve (AUCs) tested discriminative abilities of the tool's baseline score for identifying poor 6-month outcome (SF-36 lower tertile Physical Component Score). Risk-group cut-points were tested using sensitivity and specificity for identifying poor outcome using (1) Youden's J statistic and (2) a clinically determined rule that specificity should not fall below 0.7 (false-positive rate <30%). RESULTS: In PhysioDirect and SAMBA, poor 6-month physical health was 18.5% and 28.2%, respectively. **Modified STarT Back Tool score AUCs for predicting outcome in back pain were 0.72 and 0.79 and multisite pain 0.83 and 0.82 in PhysioDirect and** | Study Limitations =<br>☐ None<br>***Diagnostic Studies***<br>☐ Patients not enrolled in consecutive or random manner<br>☐ Case-control study<br>☒ No independent, blind comparison between index test and reference test<br>☒ Not all patients received reference test<br>☐ Reference test not likely to correctly classify target condition<br>☒ Failure to include all patients in analysis |

Lower Quality Rating if:

☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness*

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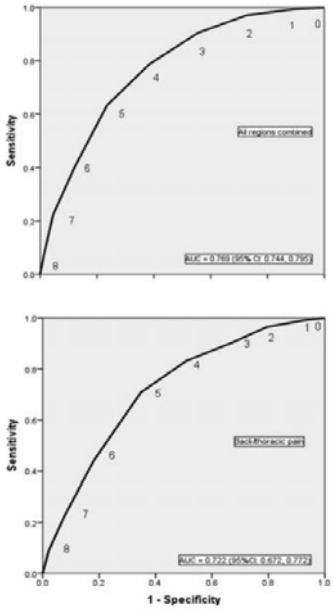
| | | developed from generic tools and are not specific to low back pain. However, the four further items of the original STarT Back Tool that capture three physical factors (referred pain from the back down the leg, comorbid pain in the neck and shoulder, and physical function with walking and dressing items) are specific to low back pain and therefore these items in their original form needed to be replaced by similar items that were applicable for all musculoskeletal patients. The STarT Back Tool's two 'function' items (walking and dressing) were replaced by items from the generic EQ-5D ('I have some problems in walking about', Y/N and 'I have some problems washing or dressing myself', Y/N), and used item 7 from the SF-12 ('How much bodily pain have you had?' with positive responses defined as 'extremely' or 'very severe') instead of the original STarT Back Tool item for comorbid pain in the neck or shoulder. It was not possible to replace 'referred pain from the back down the leg' with an item that was suitable for all musculoskeletal pain and so this construct of the 'spread of pain' was omitted from the modified tool. | | **SAMBA, respectively.** Differences between pain region AUCs were non-significant. Optimal cut-points to discriminate low-risk and medium-risk/high-risk groups depended on pain region and clinical services.   | | *of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |
| Mehling, W.E., et al., 2015, *European Journal of Pain* | To determine Start-Back tool's bio-psycho-social risk factors for chronic pain using a questionnaire | Prospective Cohort Study; Secondary analysis of dataset from Prognosis of Pain (Pop) study was used in the analysis. Patients with LBP of less than 30 days answered a questionnaire with 6 items identical and 3 items analogous to the 9-item STarT-Back. Participants were followed up at 6 months and 2 years. STarT-Back rules were applied to classify participant's risk | 605 primary care patients with low back pain of less than 30 days | **The proportion of patients with chronic pain at follow-up was considerably lower (6 months: 22%; 2 years: 25%) than in the STarT-Back validation cohort (40%) of patients with pain of any duration. The probability of developing chronic pain given a high-risk designation by items similar to the STarT-Back increased the pre-test probability to 31% and 35%. Likelihood ratios were close to 1.** | Study Limitations =<br>☐ None<br>***Diagnostic Studies***<br>☒ Patients not enrolled in consecutive or random manner<br>☐ Case-control study<br>☒ No independent, blind comparison between index test and reference test<br>☒ Not all patients received reference test | |

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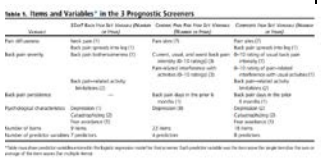
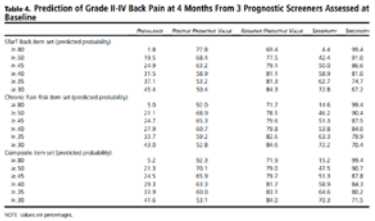
| | | of chronic LBP, and the performance of the screening items in predicting outcomes was assessed using likelihood ratios. The following six study items were identical with STarT-Back items: bothersomeness of pain (#1), presence of pain radiating below the knee (#2), additional pain in neck or shoulders (#3), getting dressed more slowly (#5), walking only short distances due to LBP (#6), and whether the pain is felt to be terrible and never going to get better (#8). The three remaining STarT-Back items (numbers 4, 7 and 9) were analogous to items with corresponding face validity taken from established questionnaires for the same psychological constructs of fear avoidance (#4), catastrophizingrumination (#7), and depression (#9). Items 4, 7 and 9 were continuous variables (range 0–10; anchored `never' and `always'), according to the STarT-Back website's information (the website includes a key for comparing the `yes/no' screening tool version with a STarT-Back Clinical Measurement Tool version that uses a 0–10 scale for the same items. The time frame was the duration from onset (<4 weeks; mean 17 ± 8 days; median 14 days) or the past week, comparable to the past 2 weeks assessment in the STarT-Back. | |  | ☐ Reference test not likely to correctly classify target condition<br>☐ Failure to include all patients in analysis | |

**References:**


1. Hill, J. C., et al. (2016). "Does a modified STarT Back Tool predict outcome with a broader group of musculoskeletal patients than back pain? A secondary analysis of cohort data." BMJ Open 6(10): e012445.
2. Mehling, W. E., et al. (2015). "Can a back pain screening tool help classify patients with acute pain into risk levels for chronic pain?" Eur J Pain 19(3): 439-446.

**PICO Question:** What validated risk assessment tool (i.e., OMSPQ, STarT Back, DRAM) is the most accurate in identifying people with low back pain at risk of poor outcomes or delayed improvement? (literature in last 10 years)

**Modality:** STarT Back and Chronic Pain Risk and Composite Item Set; **Outcome:** Identifying patients at risk of poor outcomes

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Non-Randomized Studies: 1** | | | | | |
| Von Korff, M., et al., 2014, *Journal of Pain* | To evaluate and compare item sets similar to those used in these 2 validated prognostic methods (STarT Back and Chronic Pain Risk), in terms of prediction of unfavorable back pain outcomes among patients initiating a new episode of back pain care | Prospective Study; Compared alternative prognostic item sets based on STarT Back and Chronic Pain Risk screeners in a cohort of patients initiating primary care for back pain. The STarT Back item set was brief and relied on binary responses, whereas the Chronic Pain Risk item set employed scaled responses and assessed pain persistence and diffuse pain. Patients were assessed soon after their initial visit and were reassessed 4 months later. Items sets based on STarT Back and Chronic Pain Risk prognostic screeners, as well as a combination of items from both, were used to predict Chronic Pain Grade II-IV back pain at 4 months.<br>  | 571 patients | **The area under the receiver operating characteristic curve estimates (95% confidence intervals) were .79 (.74-.83) for items based on the STarT Back, .80 (.75-.83) for items based on Chronic Pain Risk, and .81 (.77-.85) for a composite item set.** Differences in prediction were modest. Items from 2 prognostic screeners, and both combined, achieved acceptable and similar prediction of unfavorable back pain outcomes.<br>  | Study Limitations =<br>☐ None<br>***Diagnostic Studies***<br>☒ Patients not enrolled in consecutive or random manner<br>☐ Case-control study<br>☐ No independent, blind comparison between index test and reference test<br>☒ Not all patients received reference test<br>☐ Reference test not likely to correctly classify target condition<br>☒ Failure to include all patients in analysis |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☒ Low
☐ Very Low

**References:**

1. Von Korff, M., et al. (2014). "Comparison of back pain prognostic risk stratification item sets." Journal of Pain 15(1): 81-89.

| **PICO Question:** What validated risk assessment tool (i.e., OMSPQ, STarT Back, DRAM) is the most accurate in identifying people with low back pain at risk of poor outcomes or delayed improvement? (literature in last 10 years) | | | | | | |
|---|---|---|---|---|---|---|
| **Modality:** Orebro Musculoskeletal Pain Questionnaire; **Outcome:** Identifying patients at risk of poor outcomes | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | | |
| Karran, E.L., et al, 2017, *BMC Medicine* | To evaluate the performance of low back pain (LBP) screening instruments for determining risk of poor outcomes in adults with LBP of less than 3 months duration | Systematic review with meta-analysis | 18 studies investigating seven instruments. Studies were eligible if they involved adults (aged 18 or over) with 'recent onset' LBP (i.e. acute LBP (0–6 weeks) or subacute LBP (6 weeks to 3 months)), with or without leg pain. | **Seven studies investigated the Orebro Musculoskeletal Pain Screening Questionnaire: performance was 'poor' for discriminating pain outcomes (pooled AUC = 0.69 (0.62–0.76), n = 360), 'acceptable' for disability outcomes (pooled AUC = 0.75 (0.69–0.82), n = 512), and 'excellent' for absenteeism outcomes (pooled AUC = 0.83 (0.75–0.90), n = 243).**<br><br>Discrimination of pain outcomes:<br>Four of the seven studies investigating the OMPSQ included pain as an outcome measure. **Consistent classification of 'poor outcome' was achieved, allowing pooling of all AUC values (pooled AUC = 0.69 (0.62–0.76); Discriminative performance was 'poor'.** Statistical heterogeneity was moderate but not statistically significant (I2 = 40.95%, P = 0.17).<br><br>Discrimination of disability outcomes:<br>Five OMPSQ studies included disability as an outcome measure. Three studies classified 'poor outcome' as ≥ 30% disability, one used ≥ 20% and one used ≥ 40%. Despite different definitions, the results were pooled and post-hoc sensitivity analysis confirmed this to be acceptable. **Discriminative performance was 'acceptable' (pooled AUC = 0.75 (0.69–0.82)).** There was no evidence of statistical heterogeneity (I2 = 0.00%, P = 0.64). | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies | Lower Quality Rating if:<br>☐ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*<br><br>☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☒ Moderate<br>☐ Low<br>☐ Very Low |

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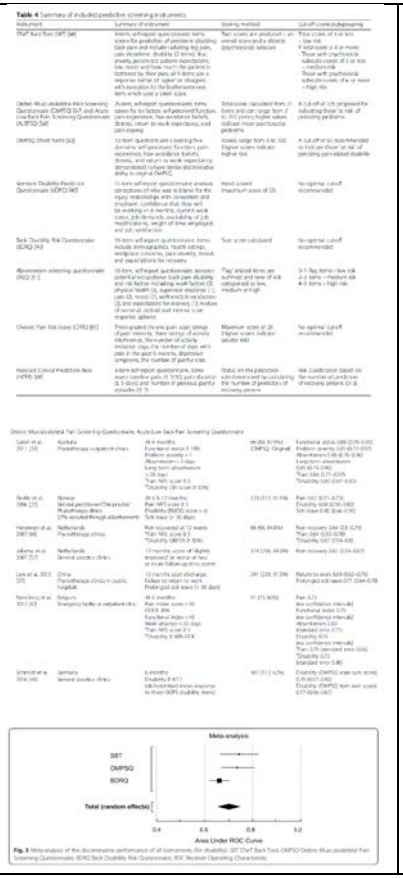
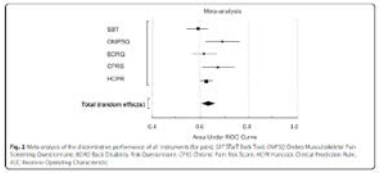
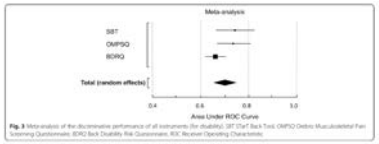
| | | | |  | | |

**References:**


1. Karran, E. L., et al. (2017). "Can screening instruments accurately determine poor outcome risk in adults with recent onset low back pain? A systematic review and meta-analysis." BMC Medicine 15(1): 13.

| **PICO Question:** What validated risk assessment tool (i.e., OMSPQ, STarT Back, DRAM) is the most accurate in identifying people with low back pain at risk of poor outcomes or delayed improvement? (literature in last 10 years) | | | | | | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☒ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*<br><br>☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |
|---|---|---|---|---|---|---|
| **Modality:** STarT Back Tool vs. Orebro Musculoskeletal Pain Questionnaire; **Outcome:** Identifying patients at risk of poor outcomes | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 2 # of Systematic Reviews: 1 # of Non-Randomized Studies: 1** | | | | | | |
| Karran, E.L., et al, 2017, *BMC Medicine* | To evaluate the performance of low back pain (LBP) screening instruments for determining risk of poor outcomes in adults with LBP of less than 3 months duration | Systematic review with meta-analysis | 18 studies investigating seven instruments. Studies were eligible if they involved adults (aged 18 or over) with 'recent onset' LBP (i.e. acute LBP (0–6 weeks) or subacute LBP (6 weeks to 3 months)), with or without leg pain. | SBT discriminating pain outcomes at follow-up was 'non-informative' (pooled AUC = 0.59 (0.55-0.63), n = 1153) and 'acceptable' for discriminating disability outcomes (pooled AUC = 0.74 (0.66-0.82), n=821).<br><br>OMPSQ was 'poor' for discriminating pain outcomes (pooled AUC = 0.69 (0.62-0.76), n = 360), 'acceptable' for disability outcomes (pooled AUC = 0.75 (0.69-0.82), n = 512), and 'excellent' for absenteeism outcomes pooled AUC = 0.83 (0.75-0.90), n = 243).<br><br>  <br>  | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies | |
| Forsbrand, M., et al., 2017, *BMC Musculoskeletal Disorders* | To compare the concurrent validity of the SBT and the short form of the OMPSQ including | Cross-Sectional Study; Patients who applied for physiotherapy by direct access at 35 primary care centers in south Sweden, with acute or subacute back and/or neck pain, aged 18-67 years, who were not currently on sick leave or had been | 329 patients | **The statistical correlation for SBT and OMPSQ-short total scores was moderately strong (0.62, p < 0.01).** In subgroup analyses, the correlations were 0.69 (p < 0.01) for males and 0.57 (p < 0.01) for females. The correlations were lower among older age groups, especially | Study Limitations =<br>☒ None<br>***Non-Randomized Studies***<br>☐ Failure to develop and apply appropriate eligibility criteria<br>☐ Flawed measurement of both exposure and outcome | |

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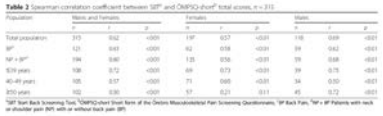
| | psychometric properties and clinical utility in a primary care setting | on sick leave less than 60 days were asked to complete the SBT and OMPSQ-short questionnaire (n = 329). Researchers used the Spearman's rank correlations to study correlations, cross tabulation and Cohen's kappa to analyze agreement of patient classification. Clinical utility was described as clinician scoring miscalculations and misclassifications of total and/or subscale scores. | | females over 50 years (0.21, p = 0.11). Classification to high or low risk for long-term pain and disability had moderate agreement (kappa = 0.42**). The SBT classified 53.7% as high risk and 46.3% as low risk while the ÖMPSQ-short classified 36.5% as high risk and 63.5% as low risk. Observed classification agreement was 70.2%. Thus, 29.8% was allocated in disagreement.** The disagreement observed (29.8%) was significantly skewed towards the high risk group with a higher proportion of patients allocated to the SBT high risk group (53.7%) than to the ÖMPSQ-short high risk group (36.5%). The SBT had fewer miscalculations (13/315) than the OMPSQ-short (54/315).<br>  | ☐ Failure to adequately control confounding<br>☐ Incomplete or inadequately short follow-up<br>☐ Differences in important prognostic factors at baseline | |


**References:**

1. Karran, E. L., et al. (2017). "Can screening instruments accurately determine poor outcome risk in adults with recent onset low back pain? A systematic review and meta-analysis." BMC Medicine 15(1): 13.
2. Forsbrand, M., et al. (2017). "Comparison of the Swedish STarT Back Screening Tool and the Short Form of the Orebro Musculoskeletal Pain Screening Questionnaire in patients with acute or subacute back and neck pain." BMC Musculoskeletal Disorders 18(1): 89


**PICO Question:** What validated risk assessment tool (i.e., OMSPQ, STarT Back, DRAM) is the most accurate in identifying people with low back pain at risk of poor outcomes or delayed improvement? (literature in last 10 years)

**Modality:** Predicting the Inception of Chronic Pain Tool (PICKUP); **Outcome:** Identifying patients at risk of poor outcomes

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Non-Randomized Studies: 1** | | | | | |
| Traeger, A.C., et al., 2016, *PLoS Medicine* | To develop and validate a prognostic model to estimate the risk of chronic low back pain | Validation Study; Data from patients with acute LBP attending primary care in Australia were used to develop and externally validate the model. The primary outcome was chronic LBP (ongoing pain at 3 mo.).<br><br><u>PICKUP Questions include:</u> | 2.758 patients | In all, 30% of the development sample and 19% of the external validation sample developed chronic LBP**. In the external validation sample, the primary model (PICKUP) discriminated between those who did and did not develop chronic LBP with acceptable performance (area under** | Study Limitations =<br>☐ None<br>***Non-Randomized Studies***<br>☐ Failure to develop and apply appropriate eligibility criteria<br>☐ Flawed measurement of both exposure and outcome |

<u>Lower Quality Rating if:</u>
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*When studies include few patients and*

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|---|---|---|---|---|---|---|
| | | "How much low back pain have you had during the past week?" 1 = none, 2 = very mild, 3 = mild, 4 = moderate, 5 = severe, 6 = very severe; Leg = "Do you have leg pain?" 0 = no, 1 = yes; Comp = "Is your back pain compensable, e.g., through worker's compensation or third party insurance?" 0 = no, 1 = yes; Depress = "How much have you been bothered by feeling depressed in the past week (0–10 scale)?" 0 = not at all, 10 = extremely; Risk = "In your view, how large is the risk that your current pain may become persistent (0–10 scale)?" 0 = none, 10 = extreme. | | **the receiver operating characteristic curve 0.66 [95% CI 0.63 to 0.69]).** | ☒ Failure to adequately control confounding<br>☐ Incomplete or inadequately short follow-up<br>☐ Differences in important prognostic factors at baseline | *few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br><u>Increase Quality Rating if:</u><br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |

**References:**

1. Traeger, A. C., et al. (2016). "Estimating the Risk of Chronic Pain: Development and Validation of a Prognostic Model (PICKUP) for Patients with Acute Low Back Pain." PLoS Medicine 13(5): e1002019.

| **PICO Question:** What validated risk assessment tool (i.e., OMSPQ, STarT Back, DRAM) is the most accurate in identifying people with low back pain at risk of poor outcomes or delayed improvement? (literature in last 10 years) | | | | | | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*<br><br>☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)* |
|---|---|---|---|---|---|---|
| **Modality:** STarT Back Tool vs. Orebro Musculoskeletal Pain Questionnaire vs. Predicting the Inception of Chronic Pain Tool; **Outcome:** Identifying patients at risk of poor outcomes | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 1 # of Non-Randomized Studies: 1** | | | | | | |
| Karran, E.L., et al., 2017, *Journal of Pain* | To compare the performance of the short-form Orebro Musculoskeletal Pain Screening Questionnaire, the Predicting the Inception of Chronic Pain | Longitudinal Cohort Study; Potential study participants were identified from screening the referrals of all patients placed in Spinal Outpatient Clinic booking queues. These patients were contacted via telephone to check inclusion criteria, provide study information, and confirm verbal consent. Measurement and data collection | 195 patients | Eighty-four percent reported 'poor outcome' at follow-up. **The area under the receiver operating characteristic curve (95% confidence interval) was .66 (.54–.78) for the Orebro Musculoskeletal Pain Screening Questionnaire, .61 (.49–.73) for the Predicting the Inception of Chronic Pain Tool, and .69 (.51–.80) for the STarT Back Tool.** | Study Limitations =<br>☒ None<br>***Non-Randomized Studies***<br>☐ Failure to develop and apply appropriate eligibility criteria<br>☐ Flawed measurement of both exposure and outcome<br>☐ Failure to adequately control confounding | |

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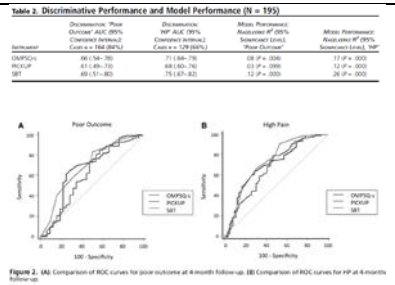
| | Tool, and the STarT Back Tool | were achieved via self-completion of mailed questionnaires. At study inception, participants were mailed information sheets and consent forms for signing. They were requested to complete baseline screening questionnaires (3 instruments) and pain and disability numeric rating scale (NRS) scores. Follow-up questionnaires and outcome measures were mailed 4 months after baseline screening. | |  | ☐ Incomplete or inadequately short follow-up<br>☐ Differences in important prognostic factors at baseline | ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☐ Low<br>☒ Very Low |

**References:**


1. Karran, E. L., et al. (2017). "The Value of Prognostic Screening for Patients With Low Back Pain in Secondary Care." Journal of Pain 18(6): 673-686.


**PICO Question:** What validated risk assessment tool (i.e., OMSPQ, STarT Back, DRAM) is the most accurate in identifying people with low back pain at risk of poor outcomes or delayed improvement? (literature in last 10 years)

**Modality:** Vermont Disability Prediction Questionnaire; **Outcome:** Identifying patients at risk of poor outcomes

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | |
| Karran, E.L., et al, 2017, *BMC Medicine* | To evaluate the performance of low back pain (LBP) screening instruments for determining risk of poor outcomes in adults with LBP of less than 3 months duration | Systematic review with meta-analysis | 18 studies investigating seven instruments. Studies were eligible if they involved adults (aged 18 or over) with 'recent onset' LBP (i.e. acute LBP (0–6 weeks) or subacute LBP (6 weeks to 3 months)), with or without leg pain. | Two studies investigated the Vermont Disability Prediction Questionnaire and four further instruments were investigated in single studies only.<br><br>These studies of prognostic screening indicated the potential utility of the VDPQ to predict return to work at 3 months post low back injury. **The initial validation study revealed 'outstanding' discriminative performance (AUC = 0.92, no confidence intervals obtained) and the subsequent study suggested it was 'acceptable' (AUC = 0.78; no confidence intervals obtained).** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias

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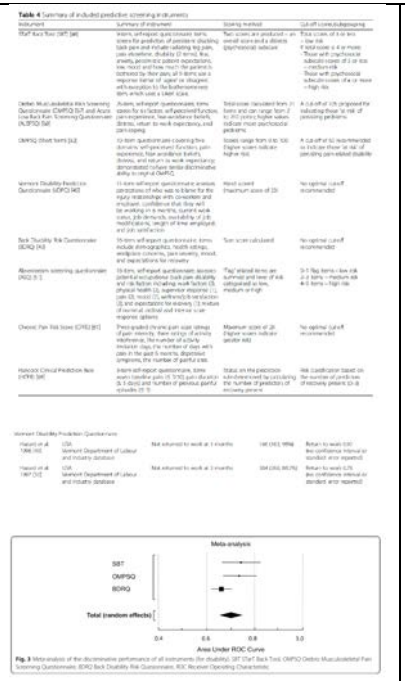
|---|---|---|---|---|---|---|
| | | | |  | | *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |

**References:**


1. Karran, E. L., et al. (2017). "Can screening instruments accurately determine poor outcome risk in adults with recent onset low back pain? A systematic review and meta-analysis." BMC Medicine 15(1): 13.


| **PICO Question:** What validated risk assessment tool (i.e., OMSPQ, STarT Back, DRAM) is the most accurate in identifying people with low back pain at risk of poor outcomes or delayed improvement? (literature in last 10 years) | | | | | | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* |
|---|---|---|---|---|---|---|
| **Modality:** Absenteeism Screening Questionnaire; **Outcome:** Identifying patients at risk of poor outcomes | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | | |
| Karran, E.L., et al, 2017, *BMC Medicine* | To evaluate the performance of low back pain (LBP) screening instruments for determining risk of poor outcomes in adults with LBP of | Systematic review with meta-analysis | 18 studies investigating seven instruments. Studies were eligible if they involved adults (aged 18 or over) with 'recent onset' LBP (i.e. acute LBP (0–6 weeks) or subacute LBP (6 | **One study investigated the Absenteeism Screening Questionnaire.** This study suggested 'acceptable' discrimination of long-term absenteeism (>182 cumulative days) at 12-month follow-up using the ASQ (AUC = 0.73; no confidence intervals obtained). | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was | |

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| | less than 3 months duration | | weeks to 3 months)), with or without leg pain. |  | not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies | ☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |

**References:**


1. Karran, E. L., et al. (2017). "Can screening instruments accurately determine poor outcome risk in adults with recent onset low back pain? A systematic review and meta-analysis." BMC Medicine 15(1): 13.


| **PICO Question:** What validated risk assessment tool (i.e., OMSPQ, STarT Back, DRAM) is the most accurate in identifying people with low back pain at risk of poor outcomes or delayed improvement? (literature in last 10 years) | | | | | | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*<br><br>☐ Studies are imprecise (*When studies include few patients and few events and thus have wide* |
|---|---|---|---|---|---|---|
| **Modality:** Chronic Pain Risk Score; **Outcome:** Identifying patients at risk of poor outcomes | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | | |
| Karran, E.L., et al, 2017, *BMC Medicine* | To evaluate the performance of low back pain (LBP) screening instruments for determining risk of poor outcomes in adults with LBP of less than 3 | Systematic review with meta-analysis | 18 studies investigating seven instruments. Studies were eligible if they involved adults (aged 18 or over) with 'recent onset' LBP (i.e. acute LBP (0–6 weeks) or subacute LBP (6 weeks to 3 months)), with or without leg pain. | **One study investigated the Chronic Pain Risk Score.**<br><br>Pain grades 3 & 4 0.67 (0.59-0.72) | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality | |

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| | months duration | | |  | ☒ Methods and/or results were inconsistent across studies | *confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |

**References:**


1. Karran, E. L., et al. (2017). "Can screening instruments accurately determine poor outcome risk in adults with recent onset low back pain? A systematic review and meta-analysis." BMC Medicine 15(1): 13.


| **PICO Question:** What validated risk assessment tool (i.e., OMSPQ, STarT Back, DRAM) is the most accurate in identifying people with low back pain at risk of poor outcomes or delayed improvement? (literature in last 10 years) | | | | | | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*<br><br>☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)* |
|---|---|---|---|---|---|---|
| **Modality:** Back Disability Risk Questionnaire; **Outcome:** Identifying patients at risk of poor outcomes | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | | |
| Karran, E.L., et al, 2017, *BMC Medicine* | To evaluate the performance of low back pain (LBP) screening instruments for determining risk of poor outcomes in adults with LBP of less than 3 months duration | Systematic review with meta-analysis | 18 studies investigating seven instruments. Studies were eligible if they involved adults (aged 18 or over) with 'recent onset' LBP (i.e. acute LBP (0–6 weeks) or subacute LBP (6 weeks to 3 months)), with or without leg pain. | **One study investigated the Back Disability Risk Questionnaire:**<br><br>Pain 0.61 (0.56-0.66)<br>Disability 0.66 (0.62-0.70) | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies | |

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| | | | |  | | ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |


**References:**

1. Karran, E. L., et al. (2017). "Can screening instruments accurately determine poor outcome risk in adults with recent onset low back pain? A systematic review and meta-analysis." BMC Medicine 15(1): 13.


| **PICO Question:** What validated risk assessment tool (i.e., OMSPQ, STarT Back, DRAM) is the most accurate in identifying people with low back pain at risk of poor outcomes or delayed improvement? (literature in last 10 years) | | | | | | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*<br><br>☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness* |
|---|---|---|---|---|---|---|
| **Modality:** Hancock Clinical Prediction Rule; **Outcome:** Identifying patients at risk of poor outcomes | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | | |
| Karran, E.L., et al, 2017, *BMC Medicine* | To evaluate the performance of low back pain (LBP) screening instruments for determining risk of poor outcomes in adults with LBP of less than 3 months duration | Systematic review with meta-analysis | 18 studies investigating seven instruments. Studies were eligible if they involved adults (aged 18 or over) with 'recent onset' LBP (i.e. acute LBP (0–6 weeks) or subacute LBP (6 weeks to 3 months)), with or without leg pain. | **One study investigated the Hancock Clinical Prediction Rule:**<br><br>Sustained recover 0.60 (0.56-0.64)<br>Pain 0.62 (0.60-0.65) | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies | |

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| | | | |  | | *of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |

**References:**


1. Karran, E. L., et al. (2017). "Can screening instruments accurately determine poor outcome risk in adults with recent onset low back pain? A systematic review and meta-analysis." BMC Medicine 15(1): 13.


**Assessment Tool Evidence Summary:**

| Assessment Tool | Pain AUC | Disability AUC | Absenteeism AUC |
|---|---|---|---|
| STarT Back Tool (SBT) | 0.59* (5 studies, n = 1153) | 0.74* (3 studies, n = 821) | |
| Modified SBT | 0.72 (1 study, n = 1887) and 0.79 (1 study, n = 1082) | | |
| Composite Item Set | 0.81 (1 study, n= 571) | | |
| Orebro Musculoskeletal Pain Questionnaire (OMPSQ) | 0.69* (4 studies, n = 360) | 0.75* (5 studies, n = 512) | 0.83* (3 studies, n = 280) |
| Predicting the Inception of Chronic Pain Tool (PICKUP) | 0.66 (1 study, n = 1,528) | | |
| Vermont Disability Prediction Questionnaire (VDPQ) | | | 0.92 and 0.78 (2 studies, n = 470) |

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|---|---|---|---|
| Absenteeism Screening Questionnaire (ASQ) | | | 0.73* (1 study, n = 535) |
| Chronic Pain Risk Score (CPRS) | 0.67* (1 study, n = 458) | | |
| Back Disability Risk Questionnaire (BDRQ) | 0.61* (1 study, n = 568) | 0.66* (1 study, n = 568) | |
| Hancock Clinical Prediction Rule (HCPR) | 0.62* (1 study, n = 956) | | |

*Pooled AUC from systematic review

**Question #3. What are the comparative harms and benefits of routine imaging vs. usual care in patients with acute or subacute low back pain?**

**Guideline Recommendations:**

The United Kingdom's **National Institute for Health and Care Excellence (NICE) 2016** guideline states to not routinely offer imaging in a non-specialist setting for people with low back pain with or without sciatica. Also, to explain to people with low back pain with or without sciatica that if they are being referred for specialist opinion, they may not need imaging. Providers should consider imaging in specialist settings of care (for example, a musculoskeletal interface clinic or hospital) for people with low back pain with or without sciatica only if the result is likely to change management **(Level of evidence not included**).

The **American College of Radiology 2015** guideline recommends that uncomplicated acute LBP and/or radiculopathy are benign, self-limited conditions that do not warrant any imaging studies. However, if there are persistent or progressive symptoms during or following 6 weeks of conservative management and the patient is a surgery or intervention candidate or diagnostic uncertainty remains, MRI of the lumbar spine has become the initial imaging modality of choice in evaluating complicated LBP and that patients with recurrent low back pain and history of prior surgical intervention should be evaluated with contrast-enhanced MRI. **(Level of evidence not included).**

The **Institute for Clinical Systems Improvement (ICSI) 2012** guideline on low back pain, adult acute and subacute recommends that clinicians should not recommend imaging (including computed tomography [CT], magnetic resonance imaging [MRI], and x-ray) for patients with non-specific low back pain **(Strong Recommendation, Moderate-Quality Evidence).** However, imaging may be considered for low back pain when fracture is suspected **(Strong Recommendation, Moderate-Quality Evidence),** and clinicians should not recommend imaging (including CT, MRI or x-ray) for patients in the first six weeks of radicular pain **(Strong Recommendation, Moderate-Quality Evidence).**

The **2012 Health Evidence Review Commission (HERC) Advanced Imaging for Low Back Pain** guideline recommends that clinicians should not routinely obtain imaging or other diagnostic tests in patients with nonspecific low back pain **(Strong recommendation, Moderate-Quality evidence)** and clinicians should evaluate patients with persistent low back pain and signs or symptoms of radiculopathy or spinal stenosis with MRI (preferred) or CT only if they are potential candidates for surgery or epidural steroid injection (for suspected radiculopathy) **(Strong recommendation, Moderate-Quality evidence).**

The **American College of Physicians and American Pain Society 2007** guideline recommended that clinicians should not routinely obtain imaging or other diagnostic tests in patients with nonspecific low back pain **(Strong recommendation, Moderate-Quality evidence)** and that clinicians should perform diagnostic imaging and testing for patients with low back pain when severe or progressive neurologic deficits are present or when serious underlying conditions are suspected on the basis of history and physical examination **(Strong recommendation, Moderate-Quality evidence).** They also recommend that clinicians should evaluate patients with persistent low back pain and signs or symptoms of radiculopathy or spinal stenosis with magnetic resonance imaging (preferred) or computed tomography only if they are potential candidates for surgery or epidural steroid injection (for suspected radiculopathy) **(Strong recommendation, Moderate-Quality evidence).**

**References:**


2. Bernstein, I. A., et al. (2017). "Low back pain and sciatica: summary of NICE guidance." BMJ 356.
3. Chou, R., et al. (2007). "Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society." Annals of Internal Medicine **147**(7): 478-491.
4. Goertz M., et al., (2012). Low back pain, adult acute and subacute. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI). Nov. 91 p.
5. Livingston, C., Little, A., King, V., Pettinari, C., Thielke, A., Vandegriff, S., & Gordon, C. (2012). State of Oregon Evidence-based Clinical Guidelines Project. Advanced imaging for low back pain: A clinical practice guideline based on the joint practice guideline of the American College of Physicians and the American Pain Society (Diagnosis and treatment of low back pain). Salem: Office for Oregon Health Policy & Research.
6. Patel, N. D., et al. (2016). "ACR Appropriateness Criteria Low Back Pain." J Am Coll Radiol 13(9): 1069-1078.


**Primary Literature:**

| **PICO Question:** What are the comparative harms and benefits of routine imaging vs. usual care in patients with acute or subacute low back pain? (literature in last 10 years) | | | | | | Lower Quality Rating if: ☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)* ☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)* |
|---|---|---|---|---|---|---|
| **Outcome:** Harms and Benefits (e.g. pain, disability) | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 5 # of Systematic Reviews: 1 # of RCTs: 2 # of Non-Randomized Studies: 2** | | | | | | |
| Haig, A. J., et al. (2007). *Journal of Bone & Joint Surgery - American Volume* | This study was performed to evaluate the relationships of magnetic resonance imaging measures and electrodiagnostic data with the clinical | Prospective Cohort Study. Persons between the ages of 55 and 85, including asymptomatic volunteers and persons referred for lumbar magnetic resonance imaging, underwent clinical examination, electrodiagnosis, and magnetic resonance imaging. The cohort was divided into three groups--no back pain, mechanical back pain, and clinical spinal stenosis--on the basis | 150 patients | **The examining physician's diagnosis of clinical spinal stenosis was significantly related to the neurological findings on examination ($p < 0.05$) and to the spine surgeon's diagnosis ($p < 0.001$)**. The diagnosis of clinical spinal stenosis was also significantly related to the presence of fibrillations on electrodiagnostic testing (p < or = 0.003), the minimum anteroposterior diameter of the spinal canal on the magnetic resonance images (p | Study Limitations = ☒ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☐ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up | |

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| | syndrome of spinal stenosis. | of the impression of the examining physician, for whom the results of the magnetic resonance imaging and electrodiagnostic testing were masked. A spine surgeon also reviewed both the imaging and clinical examination data. | | = 0.016), and the average of the two smallest spinal canal diameters (p = 0.008) on the images. **Measurements on magnetic resonance imaging did not differentiate subjects with clinical spinal stenosis from controls better than chance, whereas paraspinal mapping electrodiagnosis scores did.** | ☐ Differences in important prognostic factors at baseline | ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☒ Moderate<br>☐ Low<br>☐ Very Low |
| Ash, L. M., et al. (2008). *American Journal of Neuroradiology* | To assess the effect of knowledge of diagnostic findings on clinical outcome. | RCT. Patients with acute (<3 weeks) low back pain (LBP) and/or radiculopathy (150 LBP and 96 radiculopathy patients) were were randomized to either the unblinded group (MR imaging results provided within 48 hours) or the blinded group (both patient and physician blinded to MR imaging results.) After the initial MR imaging, patients followed 6 weeks of conservative management. Roland function, visual pain analog, absenteeism, Short Form (SF)-36 Health Status Survey, self-efficacy scores, and Fear Avoidance Questionnaire were completed at presentation; 2, 4, 6, and 8 weeks; and 6, 12, and 24 months. Improvement of Roland score by 50% or more and patient satisfaction assessed by Cherkin symptom satisfaction measure were considered a positive outcome. | 246 patients | **There was no statistical difference in the primary or secondary outcomes of the two groups at each interval.**<br><br>**Table 2: Comparison of unblinded and blinded patients at 6 weeks**<br><br>Variable \| Unblinded \| Blinded \| Unadjuste P<br>Mean Roland score \| 6.1 (SD = 5.48) \| 5.1 (SD = 5.50) \| .099<br>No. with 50% Roland score improvement (%) \| 55 (60.4%) \| 57 (67.1%) \| .397<br>Mean VPAS for average pain \| 3.5 (SD = 2.70) \| 2.96 (SD = 2.71) \| .179<br>No. with 50% VPAS improvement (%) \| 43 (48.3%) \| 44 (53.7%) \| .529<br>Mean no. of sick days \| 0.6 (SD = 2.2) \| 0.8 (SD = 2.3) \| .743<br>No. with 0 sick days (%) \| 12 (14.0%) \| 12 (15.0%) \| .677<br>Mean self-efficacy pain \| 72.2 (SD = 21.8) \| 72.5 (SD = 24.1) \| .639<br>Mean self-efficacy other \| 73.6 (SD = 19.2) \| 74.8 (SD = 21.3) \| .400<br>Mean FAQ physical activity \| 13.8 (SD = 5.4) \| 13.4 (SD = 6.3) \| .698<br>Mean FAQ work \| 12.1 (SD = 11.3) \| 10.8 (SD = 10.6) \| .457<br>Mean SF-36: PF \| 69.0 (SD = 22.3) \| 76.0 (SD = 24.7) \| .010<br>Mean SF-36: RP \| 60.5 (SD = 41.3) \| 70.2 (SD = 39.5) \| .112<br>Mean SF-36: BP \| 56.5 (SD = 22.7) \| 65.0 (SD = 24.4) \| .041<br>Mean SF-36: GH \| 77.5 (SD = 19.4) \| 80.7 (SD = 15.5) \| .360<br>Mean SF-36: VT \| 58.3 (SD = 21.4) \| 63.1 (SD = 20.0) \| .157<br>Mean SF-36: SF \| 85.3 (SD = 21.7) \| 86.0 (SD = 20.6) \| .886<br>Mean SF-36: RE \| 77.5 (SD = 36.7) \| 84.8 (SD = 29.8) \| .246<br>Mean SF-36: MH \| 69.4 (SD = 21.0) \| 78.7 (SD = 20.2) \| .001 | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☒ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | |

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| | | | | **Table 3: Comparison of unblinded and blinded patients at 1 year**<br>Variable \| Unblinded \| Blinded \| Unadjusted P<br>Mean Roland score \| 4.0 (SD = 5.3) \| 4.2 (SD = 5.3) \| .386<br>Mean VPAS for average pain \| 2.9 (SD = 2.4) \| 2.8 (SD = 2.8) \| .407<br>Mean VPAS for worst pain \| 4.5 (SD = 3.1) \| 3.9 (SD = 3.3) \| .221<br>Mean no. of sick days \| 0.27 (SD = 0.85) \| 0.34 (SD = 3.3) \| .493<br>Mean self-efficacy pain \| 72.0 (SD = 23.6) \| 73.9 (SD = 21.8) \| .749<br>Mean self-efficacy other \| 75.7 (SD = 21.6) \| 75.9 (SD = 9.9) \| .310<br>Mean FAQ physical activity \| 13.3 (SD = 7.0) \| 13.9 (SD = 6.5) \| .589<br>Mean FAQ work \| 11.2 (SD = 10.5) \| 11.7 (SD = 9.9) \| .770<br>Mean SF-36: PF \| 75.0 (SD = 25.4) \| 75.7 (SD = 24.2) \| .303<br>Mean SF-36: RP \| 72.5 (SD = 38.3) \| 73.5 (SD = 40.8) \| .507<br>Mean SF-36: BP \| 64.1 (SD = 26.5) \| 64.7 (SD = 26.8) \| .388<br>Mean SF-36: GH \| 70.2 (SD = 24.7) \| 75.2 (SD = 18.2) \| .161<br>Mean SF-36: VT \| 58.9 (SD = 22.1) \| 62.4 (SD = 21.7) \| .362<br>Mean SF-36: SF \| 85.9 (SD = 24.9) \| 86.7 (SD = 22.8) \| .380<br>Mean SF-36: RE \| 83.1 (SD = 33.1) \| 87.4 (SD = 28.0) \| .565<br>Mean SF-36: MH \| 74.3 (SD = 20.2) \| 81.0 (SD = 16.7) \| .032* | | |
| Cohen, S. P., et al. (2012). *Archives of Internal Medicine* | To determine whether magnetic resonance imaging (MRI) improves outcomes or affects decision making in patients with lumbosacral radiculopathy referred for ESI. | RCT. The treating physician in group 1 patients was blinded to the MRI results, while the physician for group 2 patients decided on treatment after reviewing the MRI findings. In group 1 subjects, an independent physician proposed a treatment plan after reviewing the MRI, which was compared with the treatment the patient received.<br><br>Group 1 subjects all received ESIs, with the type (eg, interlaminar or transforaminal) and level determined solely by history and physical examination findings (ie, the treating physician was blinded to the MRI). In group 2, the physician determined treatment based on clinical findings and imaging results. In these patients, the treating physician could elect not to perform an ESI if the MRI finding was noncorroborative. In this scenario, the patient exited the study because the alternative treatment (eg, surgical referral, | 132 patients | **Slightly lower leg pain scores were noted in the group 2 at 1 month compared with MRI-blinded patients in group 1 (mean scores, 3.6 vs 4.4) (P = .12). No differences were observed in pain scores or function at 3 months. Overall, the proportion of patients who experienced a positive outcome was similar at all time points (35.4% at 3 months in group 1 vs 40.7% in group 2). Among subjects in group 1 who received a different injection than that proposed by the independent physician, scores for both leg pain (4.8 vs 2.4) (P = .01) and function (38.7 vs 28.2) (P = .04) were inferior to patients whose injection correlated with imaging. Collectively, 6.8% of patients did not (group 2) or would not have (group 1) received an ESI after the MRI was reviewed.** | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☒ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | |

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| | | rehabilitation program) and follow-up could not be standardized. | | | | |
| Graves, J. M., et al. (2012). *Spine* | To evaluate the association of early imaging and health and disability status 1 year following acute low back injury, among a population-based sample of Washington State workers' compensation claimants. | Prospective cohort study. Washington State workers' compensation claimants with nonspecific LBP used administrative claims and interview data. Multivariable regression methods were used to estimate change in health outcome scores, the relative risk of disability at 1 year, and the rate of recovery 1 year after injury. | 1226 patients | Participants with early MRI differed significantly at baseline in pain, function, and psychosocial variables**. After adjusting for covariates, early imaging was not associated with substantial differences in 1-year health outcomes for sprains or radiculopathy.** For workers with mild/major sprain, early imaging was associated with a 2-fold increase in the likelihood of work disability benefits at 1 year (adjusted relative risk: 2.03, 95% confidence interval: 1.33-3.11). Early imaging was not associated with an increased risk of long-term disability for workers with radiculopathy (adjusted relative risk: 1.31, 95% confidence interval: 0.84-2.05). **For both groups, early MRI was associated with longer disability duration (P < 0.001).** | Study Limitations =<br>☒ None<br>***Non-Randomized Studies***<br>☐ Failure to develop and apply appropriate eligibility criteria<br>☐ Flawed measurement of both exposure and outcome<br>☐ Failure to adequately control confounding<br>☐ Incomplete or inadequately short follow-up<br>☐ Differences in important prognostic factors at baseline | |
| Steffens, D., et al. (2014). *European Journal of Pain* | To systematically review whether MRI findings of the lumbar spine predict future LBP in different samples with and without LBP. | Systematic Review | 12 studies. Six studies presented data on participants with current LBP; one included a sample with no current LBP, three included a sample with no history of LBP and two included mixed sample | **Due to the risk of bias of the included studies, no consistent associations between MRI findings and outcomes were identified.** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies | |

**References:**


1. Haig, A. J., et al. (2007). "Electromyographic and magnetic resonance imaging to predict lumbar stenosis, low-back pain, and no back symptoms." Journal of Bone & Joint Surgery - American Volume 89(2): 358-366.
2. Ash, L. M., et al. (2008). "Effects of diagnostic information, per se, on patient outcomes in acute radiculopathy and low back pain." Ajnr: American Journal of Neuroradiology 29(6): 1098-1103.
3. Cohen, S. P., et al. (2012). "Effect of MRI on treatment results or decision making in patients with lumbosacral radiculopathy referred for epidural steroid injections: a multicenter, randomized controlled trial.[Erratum appears in Arch Intern Med. 2012 Apr 23;172(8):673].
4. Graves, J. M., et al. (2012). "Early imaging for acute low back pain: one-year health and disability outcomes among Washington State workers." Spine 37(18): 1617-1627.
5. Steffens, D., et al. (2014). "Does magnetic resonance imaging predict future low back pain? A systematic review." European Journal of Pain 18(6): 755-765.

**Question #4: What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, anti-seizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications.**

**Guideline Recommendations:**

In **2017**, the **American College of Physicians** recommended that patients with chronic low back pain who have had an inadequate response to non-pharmacologic therapy, clinicians and patients should consider pharmacologic treatment with nonsteroidal anti-inflammatory drugs as first-line therapy, or tramadol or duloxetine as second-line therapy. Clinicians should only consider opioids as an option in patients who have failed the aforementioned treatments and only if the potential benefits outweigh the risks for individual patients and after a discussion of known risks and realistic benefits with patients. **(Weak recommendation, Moderate-quality Evidence)**

The **2017 HERC Low Back Pain Coverage for Corticosteroid Injections** guidance stated that:

- Epidural corticosteroid injections are not recommended for coverage for the treatment of low back pain with radiculopathy. **(Weak Recommendation)**
- Epidural corticosteroid injections are not recommended for coverage for the treatment of low back pain without radiculopathy. **(Strong Recommendation)**
- Corticosteroid injections ( including facet joint, medial branch, and sacroiliac joint) are not recommended for coverage for the treatment of low back pain. **(Strong Recommendation)**

The **2016 ICSI Non-Opioids Guideline** recommended that:

- Sedative hypnotics including benzodiazepines and carisoprodol should be rarely used and if so for short-term (<1 week) treatment of muscle spasms related to acute pain. Use of non-sedative hypnotic muscle relaxants are of low benefit, but if used, limit to less than four weeks. Do not use carisoprodol for pain.
- The first opioid prescription for acute pain should be no more than 20 low dose, short-acting opioids or three days of medication, whichever is less. The total dose for acute pain should not exceed 100 morphine milligram equivalents (MME). For patients presenting in acute pain, already on chronic opioids, opioid tolerant or on methadone, use the same pill and dose limits as for opioid-naïve patients.
- Avoid using opioids to treat patients with chronic pain.

The **UK's National Institute for Health and Care Excellence in 2016** recommended the following for pharmacological interventions:

- Consider oral non-steroidal anti-inflammatory drugs (NSAIDs) for managing low back pain, taking into account potential differences in gastrointestinal, liver and cardio-renal toxicity, and the person's risk factors, including age.
- When prescribing oral NSAIDs for low back pain, think about appropriate clinical assessment, ongoing monitoring of risk factors, and the use of gastroprotective treatment.
- Prescribe oral NSAIDs for low back pain at the lowest effective dose for the shortest possible period of time.
- Consider weak opioids (with or without paracetamol) for managing acute low back pain only if an NSAID is contraindicated, not tolerated or has been ineffective.

- Do not offer paracetamol alone for managing low back pain.
- Do not routinely offer opioids for managing acute low back pain (see recommendation 1.2.20).
- Do not offer opioids for managing chronic low back pain.
- Do not offer selective serotonin reuptake inhibitors, serotonin–norepinephrine reuptake inhibitors or tricyclic antidepressants for managing low back pain.
- Do not offer anticonvulsants for managing low back pain.
- Do not offer spinal injections for managing low back pain.
- Consider epidural injections of local anaesthetic and steroid in people with acute and severe sciatica.
- Do not use epidural injections for neurogenic claudication in people who have central spinal canal stenosis.

The **2014 Health Evidence Review Commission (HERC) Lower Back Pain: Pharmacological Interventions** guideline recommends:
Acute low back pain

- Initial pharmacologic therapy should be acetaminophen or non-steroidal anti-inflammatory medications (NSAIDS) and/or skeletal muscle relaxants.
- Second line agents include benzodiazepines and opioids.

Chronic low back pain (>1 month)

- First line: acetaminophen or NSAIDS, tricyclic antidepressants
- Second line: benzodiazepines and opioids
- Skeletal muscle relaxants should not be covered for chronic low back pain

Given the risk profile of opiates and benzodiazepines, there should be a risk assessment prior to initiating therapy, and clear documentation of functional benefit should be required for ongoing prescription coverage.

Systemic steroids are not recommended for coverage for low back pain.

The **Institute for Clinical Systems Improvement 2012** guideline on low back pain, adult acute and subacute stated the following:

- Non-steroidal anti-inflammatory drugs (NSAIDs) may be used for short-term pain relief in patients with acute and subacute low back pain **(Weak Recommendation, Moderate Quality Evidence).**
- Muscle relaxants may be used as an option in treating acute low back pain. However, possible side effects should be considered **(Weak Recommendation, Moderate Quality Evidence).**
- Cautious and responsible use of opioids may be considered for those carefully selected patients with severe acute pain not controlled with acetaminophen and NSAIDs, at a minimum effective dose, for a limited period of time, usually less than one to two weeks **(Strong Recommendation, Low Quality Evidence).**
- Epidural steroid injections may be used for acute low back pain with a radicular component to assist with short-term pain relief **(Weak Recommendation, Moderate Quality Evidence).**

The **2009 American Pain Society Guideline** Recommended that patients with persistent nonradicular low back pain, facet joint corticosteroid injection, prolotherapy, and intradiscal corticosteroid injection are not recommended (strong recommendation, moderate-quality evidence). There is insufficient evidence to adequately evaluate benefits of local injections, botulinum toxin injection, epidural steroid injection, intradiscal electrothermal therapy (IDET), therapeutic medial branch block, radiofrequency denervation, sacroiliac joint steroid injection, or intrathecal therapy with opioids or other medications for nonradicular low back pain.

The **2007 American College of Physicians and American Pain** Society Guideline recommended that for patients with low back pain, clinicians should consider the use of medications with proven benefits in conjunction with back care information and self-care. Clinicians should assess severity of baseline pain and functional deficits, potential benefits, risks, and relative lack of long-term efficacy and safety data before initiating therapy **(strong recommendation, moderate-quality evidence).** For most patients, first-line medication options are acetaminophen or nonsteroidal anti-inflammatory drugs.

**References**:


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8. Chou, R., et al. (2007). "Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society." Annals of Internal Medicine **147**(7): 478-491.
9. Goertz M., et al., (2012). Low back pain, adult acute and subacute. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI). Nov. 91 p.
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11. Qaseem, A., et al. (2017). "Noninvasive treatments for acute, subacute, and chronic low back pain: A clinical practice guideline from the American college of physicians." Annals of Internal Medicine 166(7): 514-530.
12. Hooten M., et al., (2016). Pain: assessment, non-opioid treatment approaches and opioid management. Institute for Clinical Systems Improvement. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI).
13. Chou, R., et al. (2009). "Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society." Spine (Phila Pa 1976) 34(10): 1066-1077**.**


***Agency for Healthcare Research and Quality 2016 Comparative Effectiveness Review:***

For acute or subacute low back pain, NSAIDs, opioids (buprenorphine patch), and skeletal muscle relaxants were associated with small effects on pain versus placebo, and NSAIDs were associated with small effects on function. Acetaminophen and systemic corticosteroids were associated with no beneficial effects versus placebo. Head-to-head comparisons were limited but indicated no clear differences between acetaminophen versus NSAIDs or between different NSAIDs.

**Summary of evidence for pharmacological therapies versus placebo for acute low back pain**

| Drug | Pain: Magnitude of Effect | Pain: Evidence | Pain: SOE | Function: Magnitude of Effect | Function: Evidence | Function: SOE |
|---|---|---|---|---|---|---|
| Acetaminophen | No effect | 1 RCT | Low | No effect | 1 RCT | Low |
| NSAIDs | Small (pain intensity); no effect (pain relief) | 1 SR (4 RCTs) | Moderate | Small | 2 RCTs | Low |
| Opioids (buprenorphine patch) | Small | 2 RCTs | Low | No evidence | -- | -- |
| Skeletal muscle relaxants | Pain relief: RR, 1.72 (95% CI, 1.32 to 2.22) at 5–7 days | 1 SR (3 RCTs) + 1 RCT | Moderate | No evidence | -- | -- |
| Benzodiazepines | Unable to estimate | 2 RCTs | Insufficient | Unable to estimate | 2 RCTs | Insufficient |
| Antiseizure medications | No evidence | -- | -- | No evidence | -- | -- |
| Systemic corticosteroids | No effect | 2 RCTs | Low | No effect | 2 RCTs | Low |

**Summary of evidence for pharmacological therapies versus active comparators for acute low back pain**

| Drug | Pain: Magnitude of Effect | Pain: Evidence | Pain: SOE | Function: Magnitude of Effect | Function : | Function : SOE |
|---|---|---|---|---|---|---|
| Acetaminophen vs. NSAID | Unable to estimate | 1 RCT | Insufficient | Unable to estimate | 1 RCT | Insufficient |
| NSAID vs. NSAID | No difference | 6 RCTs | Moderate | -- | -- | -- |
| Opioid vs. NSAID | Unable to estimate (inconsistent) | 3 RCTs | Insufficient | No difference | 1 RCT | Insufficient |
| Long-acting opioid vs. long-acting opioid | No clear difference | 4 RCTs | Moderate | No clear difference | 4 RCTs | Moderate |
| Long-acting opioid vs. short-acting opioid | No clear difference* | 6 RCTs | Low | -- | -- | -- |
| Benzodiazepine (diazepam) vs. skeletal muscle relaxant | No difference | 1 RCT | Low | -- | -- | -- |
| Skeletal muscle relaxant vs. skeletal muscle relaxant | No clear difference | 1 SR (2 RCTs) | Low | -- | -- | -- |

CI = confidence interval; NSAID = nonsteroidal anti-inflammatory drug; RCT = randomized controlled trial; RR = relative risk; SOE = strength of evidence; SR = systematic review; SSRI = selective serotonin reuptake inhibitor.

**Summary of evidence for pharmacological therapies versus placebo for radicular low back pain**

| Drug | Pain: Magnitude of | Pain: Evidence | Pain: SOE | Function: Magnitude of Effect | Function: Evidence | Function: SOE |
|---|---|---|---|---|---|---|
| NSAIDs | Small | 1 SR (2 RCTs) | Low | -- | -- | -- |
| Benzodiazepines: diazepam | RR, 0.5 (95% CI, 0.3 to | 1 RCT | Low | No effect | 1 RCT | Low |
| Systemic corticosteroids | No effect | 5 RCTs | Moderate | No effect | 5 RCTs | Moderate |
| Gabapentin/pregabalin | Unable to estimate | 5 RCTs | Insufficient | Unable to estimate | 5 RCTs | Insufficient |

CI = confidence interval; NSAID = nonsteroidal anti-inflammatory drug; RCT = randomized controlled trial; RR = relative risk; SOE = strength of evidence; SR = systematic review

**Detailed evidence tables for pharmacologic treatments**

| Key Question | Intervention | Outcome | Strength of Evidence | Conclusion |
|---|---|---|---|---|
| **Pharmacological therapies** | Acetaminophen | Acetaminophen vs. placebo, acute LBP: Pain and function | Low | One good-quality trial found no difference between acetaminophen vs. placebo in pain intensity or function through 3 weeks. |
| | | Acetaminophen vs. NSAID, acute LBP: Pain and global improvement | Insufficient | A systematic review found no difference between acetaminophen vs. NSAIDs in pain intensity (3 trials; pooled SMD, 0.21; 95% CI, −0.02 to 0.43) or likelihood of experiencing global improvement (3 trials; RR, 0.81; 95% CI, 0.58 to 1.14) at ≤3 weeks, although estimates favored NSAIDs. |
| | | Acetaminophen vs. placebo, chronic LBP | Insufficient | No study evaluated acetaminophen vs. placebo. |
| | | Acetaminophen vs. NSAID, chronic LBP | Insufficient | There was insufficient evidence from 1 trial to determine effects of acetaminophen vs. NSAIDs. |
| | | Acetaminophen vs. other interventions, acute LBP | Insufficient | There was insufficient evidence from 4 trials to determine effects of acetaminophen vs. other interventions. |
| | | Acetaminophen vs. placebo: Adverse events (serious adverse events) | Moderate | One trial found no difference between scheduled acetaminophen, as- needed acetaminophen, or placebo in risk of serious adverse events (~1% in each group). |
| | | Acetaminophen vs. NSAIDs: Adverse events | Moderate | A systematic review found that acetaminophen was associated with lower risk of side effects vs. NSAIDs. |
| | | Acetaminophen vs placebo, NSAID, or other intervention, radicular LBP | Insufficient | No study evaluated acetaminophen for radicular low back pain. |

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| **Pharmacological therapies** | NSAIDs | NSAIDs vs. placebo, acute LBP: Pain and function | Moderate for pain, low for function | A systematic review found NSAIDs to be associated with greater improvement in pain intensity vs. placebo (4 studies; WMD, −8.39; 95% CI, −12.68 to −4.10; chi-square, 3.47; p >0.1), but 4 trials found no clear effects on the likelihood of achieving significant pain relief. One subsequent trial also found lower pain intensity after the first dose vs. placebo. One trial found NSAIDs to be associated with better function vs. placebo. |
| | | NSAIDs vs. placebo, chronic LBP: Pain and function | Moderate for pain, low for function | A systematic review found NSAIDs to be associated with greater improvement in pain vs. placebo (4 trials; WMD, −12.40; 95% CI, −15.53 to −9.26; chi-square, 1.82; p >0.5); 2 trials found NSAIDs to be associated with greater improvement in function. |
| | | NSAIDs vs. placebo, radicular LBP: Pain | Low | A systematic review found no difference in pain intensity between NSAIDs vs. placebo (2 trials; WMD, −0.16; 95% CI, −11.92 to 11.59; chi-square, 7.25; p <0.01). |
| | | NSAID plus another intervention vs. other intervention alone | Insufficient | There was insufficient evidence from 2 trials of an NSAID plus another intervention vs. the other intervention alone to determine effectiveness. |
| | | NSAIDs vs. interventions other than acetaminophen and opioids | Insufficient | There was insufficient evidence from 2 trials to determine the effects of NSAIDs vs. interventions other than acetaminophen and opioids. |
| | | NSAID vs. NSAID, acute or chronic LBP: Pain | Moderate | A systematic review found that most trials of 1 NSAID vs. another found no differences in pain relief in patients with acute LBP (15 of 21 trials) or chronic LBP (6 of 6 trials). |
| | | NSAIDs vs. placebo: Adverse events | Moderate | A systematic review found NSAIDs to be associated with more side effects vs. placebo (10 trials; RR, 1.35; 95% CI, 1.09 to 1.68). |
| | | COX-2-selective NSAIDs vs. nonselective NSAIDs: Adverse events | Moderate | COX-2-selective NSAIDs were associated with lower risk of side effects vs. nonselective NSAIDs (4 trials; RR, 0.83; 95% CI, 0.70 to 0.99). |
| | | Opioids vs. placebo, chronic LBP: Pain and function | Moderate | A systematic review found opioids to be associated with greater short-term improvement vs. placebo in pain scores (6 trials; SMD, −0.43; 95% CI, −0.52 to −0.33; I2 = 0.0%, for a mean difference of ~1 point on a 0–10 pain scale) and function (4 trials; SMD, −0.26; 95% CI, −0.37 to −0.15; I2 = 0.0%, for a mean difference of ~1 point on the RDQ); 3 additional trials reported results consistent with the systematic review. |

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| **Pharmacological therapies** | Opioids, tramadol, and tapentadol | Tramadol vs. placebo, chronic LBP: Pain and function | Moderate | A systematic review found tramadol to be associated with greater short-term pain relief vs. placebo (5 trials; SMD, −0.55; 95% CI, −0.66 to −0.44; I2 = 86%, for a mean difference of 1 point or less on a 0–10 pain scale) and function (5 trials; SMD, −0.18; 95% CI, −0.29 to −0.07; I2 = 0%, for a mean difference of ~1 point on the RDQ); 2 trials not included in the systematic review reported results consistent with the systematic review findings. |
| | | Buprenorphine patch vs. placebo, subacute or chronic LBP: Pain and function | Low for pain, insufficient for function | A systematic review included 2 trials that found buprenorphine patches to be associated with greater short-term improvement in pain vs. placebo patches; effects on function showed no clear effect or were unclearly reported. |
| | | Opioids vs. NSAIDs, chronic LBP: Pain relief, function | Insufficient | Three trials reported inconsistent effects of opioids vs. NSAIDs for pain relief; 1 trial found no difference in function. |
| | | Opioids vs. acetaminophen, acute LBP: Days to return to work, pain | Insufficient | One trial found no significant differences between opioids vs. acetaminophen in days to return to work; pain was not reported. |
| | | Long acting opioids vs. long-acting opioids: Pain and function | Moderate | Four trials found no clear differences among different long-acting opioids in pain or function. |
| | | LongL-acting opioids vs. short-acting opioids: Pain | Low | Six trials found no clear differences between long-acting vs. short- acting opioids in pain relief. Although some trials found long-acting opioids to be associated with greater pain relief, patients randomized to long-acting opioids also received higher doses of opioids. |
| | | Opioids vs. placebo: Adverse events | Moderate | Short-term use of opioids was associated with higher risk vs. placebo of nausea, dizziness, constipation, vomiting, somnolence, and dry mouth; risks of opioids were higher in trials that did not use an enriched enrollment and withdrawal design. |
| | Skeletal muscle relaxants | SMRs vs. placebo, acute LBP: Pain | Moderate | A systematic review found SMRs to be superior to placebo for short- term pain relief (≥2-point or 30% improvement on a 0–10 VAS pain scale) after 2 to 4 days (4 trials; RR, 1.25; 95% CI, 1.12 to 1.41; I2 = 0%) and 5 to 7 days (3 trials; RR, 1.72; 95% CI, 1.32 to 2.22; I2 = 0%); a more recent large (n = 562) trial was consistent with the systematic review. |
| | | SMR plus NSAID vs. NSAID alone, acute LBP: Pain | Low | A systematic review found no difference between an SMR plus an NSAID vs. the NSAID alone in the likelihood of experiencing pain relief, although the estimate favored combination therapy (2 trials; RR, 1.56; 95% CI, 0.92 to 2.70; I2 = 84%); 1 other trial (n = 197) also reported results that favored combination therapy. |

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| | | SMR vs. placebo, chronic LBP: Pain | Insufficient | Evidence from 3 placebo-controlled trials was insufficient to determine effects due to imprecision and inconsistent results. |

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| **Pharmacologic al therapies** | Skeletal muscle relaxants | SMR vs. SMR, acute or chronic LBP: Pain | Low | Three trials in a systematic review found no differences in any outcome among different SMRs for acute or chronic low back pain. |
| | | SMR vs. placebo, acute LBP: Adverse events | Moderate | A systematic review found skeletal muscle relaxants for acute LBP to be associated with increased risk of any adverse event vs. placebo (8 trials; RR, 1.50; 95% CI, 1.14 to 1.98) and increased risk of central nervous system events, primarily sedation (8 trials; RR, 2.04; 95% CI, 1.23 to 3.37; I2 = 50%); 1 additional placebo-controlled trial was consistent with these findings. |
| | Benzodiazepines | Benzodiazepines vs. placebo, acute LBP: Pain and function | Insufficient | There was insufficient evidence from 2 trials with inconsistent results to determine effectiveness of benzodiazepines vs. placebo. |
| | | Tetrazepam vs. placebo, chronic LBP: Pain, overall improvement | Low | A systematic review included 2 trials that found tetrazepam to be associated with lower likelihood of no improvement in pain at 5–7 days (RR, 0.82; 95% CI, 0.72 to 0.94) and at 10–14 days (RR, 0.71;<br>95% CI, 0.54 to 0.93) vs. placebo, and lower likelihood of no overall improvement at 10–14 days (RR, 0.63; 95% CI, 0.42 to 0.97). |
| | | Diazepam vs. placebo, acute or subacute radicular pain: Pain and function | Low | One trial found no difference between diazepam 5 mg twice daily for 5 days vs. placebo in function at 1 week through 1 year or in other outcomes, including analgesic use, return to work, or likelihood of surgery through 1 year of followup. Diazepam was associated with lower likelihood of experiencing ≥50% improvement in pain at 1 week (41% vs. 79%; RR, 0.5; 95% CI, 0.3 to 0.8). |
| | | Benzodiazepines vs. SMRs, chronic LBP: Pain and function | Insufficient | There was insufficient evidence from 2 trials with inconsistent results to determine effects of benzodiazepines vs. SMRs. |
| | | Diazepam vs. cyclobenzaprine, chronic LBP: Muscle spasms | Low | One trial found no difference between diazepam vs. cyclobenzaprine in outcomes related to muscle spasm. |
| | | Benzodiazepines vs. placebo: Adverse events | Low | A systematic review found that central nervous system adverse events such as somnolence, fatigue, and lightheadedness were reported more frequently with benzodiazepines vs. placebo, although harms were not reported well; no trial was designed to evaluate risks with long-term use of benzodiazepines such as addiction, abuse, or overdose. |

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| **Pharmacologic al therapies** | Antidepressants | Tricyclic antidepressants or SSRIs vs. placebo, chronic LBP: Pain and function | Moderate for pain, low for function | A systematic review found no differences in pain between tricyclic antidepressants vs. placebo (4 trials; SMD, −0.10; 95% CI, −0.51 to 0.31; I2 = 32%) or SSRIs vs. placebo (3 trials; SMD, 0.11; 95% CI, −0.17 to 0.39; I2 = 0%); there was also no difference between antidepressants vs. placebo in function (2 trials; SMD, −0.06; 95% CI, −0.40 to 0.29; I2 = 0%). |
| | | Duloxetine vs. placebo, chronic LBP: Pain and function | Moderate | Three trials found duloxetine to be associated with lower pain intensity (differences, 0.58 to 0.74 on a 0 to 10 scale) and better function (differences, 0.58 to 0.74 on the Brief Pain Inventory- Interference scale) vs. placebo. |
| | | Duloxetine vs. tricyclic antidepressants | Insufficient | No study compared duloxetine vs. a tricyclic antidepressant. |
| | | Antidepressants vs. placebo: Adverse events, serious adverse events | Moderate | Antidepressants were associated with higher risk of any adverse events compared with placebo, with no difference in risk of serious adverse events. |
| **Pharmacologic al therapies** | Antiseizure medications | Antiseizure medications, acute nonradicular LBP | Insufficient | No trial evaluated antiseizure medications for acute nonradicular LBP. |
| | | Gabapentin vs. placebo, chronic nonradicular LBP | Insufficient | One trial found no difference between gabapentin (up to 3600 mg/ day) vs. placebo but did not meet inclusion criteria because it was published only as an abstract. |
| | | Gabapentin vs. placebo, chronic radicular LBP: Pain and function | Insufficient | There was insufficient evidence from 3 poor-quality trials with inconsistent findings to determine effects of gabapentin vs. placebo. |
| | | Topiramate vs. placebo, chronic radicular or mixed radicular and nonradicular LBP: Pain | Insufficient | Two trials reported inconsistent results for effects of topiramate vs. placebo. |
| | | Pregabalin vs. placebo, chronic radicular LBP: Pain and function | Insufficient | Two trials reported inconsistent effects of pregabalin vs. placebo for pain or function. |
| | | Pregabalin vs. amitriptyline: Pain | Insufficient | There was insufficient evidence from 1 poor-quality trial to determine effects of pregabalin vs. amitriptyline. |

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| | | Pregabalin plus transdermal buprenorphine vs. transdermal buprenorphine, chronic nonradicular LBP: Pain | Insufficient | One small trial found that the addition of pregabalin 300 mg/day to transdermal buprenorphine was associated with substantially lower pain scores than transdermal buprenorphine alone at 3 weeks (difference, ~26 points on a 0 to 100 scale; p <0.05), but the estimate was very imprecise |

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| **Pharmacologic al therapies** | Antiseizure medications | Pregabalin plus another analgesic vs. the other analgesic alone: Pain | Insufficient | One trial found pregabalin (mean, 2.1 mg/kg/day) plus celecoxib to be associated with lower pain scores than celecoxib alone (difference, 11 points on a 0–100 scale; p = 0.001) after 4 weeks, and 1 trial found no effects of adding pregabalin (titrated to 300 mg/day) to tapentadol prolonged release vs. tapentadol prolonged release alone on pain or the SF-12 after 8 weeks. |
| | | Gabapentin vs. placebo: Adverse events | Low | Two trials of gabapentin vs. placebo reported no clear differences in risk of adverse events. |
| | | Topiramate vs. placebo: Withdrawal due to adverse events, sedation, diarrhea | Insufficient | Two trials of topiramate vs. placebo reported inconsistent effects on risk of withdrawal due to adverse events; 1 of the trials found topiramate to be associated with higher risk of sedation and diarrhea. |
| | | Pregabalin vs. placebo: Withdrawal due to adverse events, somnolence, dizziness | Insufficient | Two trials of pregabalin vs. placebo reported inconsistent effects on risk of withdrawal due to adverse events, somnolence, and dizziness; 1 of the trials used an enrichment/withdrawal design |
| | Corticosteroids | Systemic corticosteroids vs. placebo, acute nonradicular LBP: Pain and function | Low | Two trials found no differences between a single intramuscular injection or a 5-day course of systemic corticosteroids vs. placebo for pain or function. |
| | | Systemic corticosteroids vs. placebo, radicular LBP: Pain and function | Moderate | Five trials consistently found no differences between systemic corticosteroids (administered as a single bolus or as a short taper) vs. placebo in pain or function for acute or unspecified-duration LBP; 1 trial found no effect on need for spine surgery. |
| | | Systemic corticosteroids vs. placebo, spinal stenosis: Pain and function | Low | One trial found no differences through 12 weeks of followup between a 3-week course of prednisone vs. placebo in pain intensity, the RDQ, or any SF-36 subscale. |
| | | Systemic corticosteroids: Adverse events | Low | Trials of systemic corticosteroids did not report serious adverse events, including hyperglycemia requiring medical treatment, but adverse events were not reported well in some trials. |

**References:**

1. Chou, R., Deyo, R., Friedly, J., Skelly, A., Hashimoto, R., Weimer, M., . . . Brodt, E. (2016). AHRQ Comparative Effectiveness Reviews Noninvasive Treatments for Low Back Pain. Rockville (MD): Agency for Healthcare Research and Quality (US).

**Primary literature published since the 2016 AHRQ comparative effectiveness review:**

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|---|---|---|---|---|---|---|
| **PICO Question:** What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, antiseizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications. | | | | | | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect<br>*(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*<br><br>☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias<br>*(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |
| **Modality:** Epidural Injections<br>**Outcome:** Pain Reduction | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 4 # of Systematic Reviews: 1 # of RCTs: 3 # of Non-Randomized Studies: 0<br># of Diagnostic Studies: 0** | | | | | | |
| Chou, R., et al. (2015). *Annals of Internal Medicine* | To review evidence on the benefits and harms of epidural corticosteroid injections in adults with radicular low back pain or spinal stenosis of any duration. | Systematic Review. | 30 placebo-controlled trials evaluated epidural corticosteroid injections for radiculopathy, and 8 trials were done for spinal stenosis. Patients with acute, subacute, and chronic pain were included in the studies. | **Radiculopathy:** Epidural corticosteroid injections were associated with greater immediate reduction in pain intensity compared with placebo interventions (6 trials; WMD on a scale of 0 to 100, -7.55 [95% CI, -11.4 to -3.74]; I2 = 30%; strength of evidence [SOE], moderate) but differences were smaller and not statistically significant at longer follow-up.<br><br>Epidural corticosteroid injections and placebo interventions did not differ in the likelihood of a successful outcome for pain<br><br>Epidural corticosteroid injections were associated with lower short-term risk for surgery than placebo interventions (8 trials; RR, 0.62 [CI, 0.41 to 0.92]; I2 =0%; SOE, low). There was no difference in risk for long-term surgery (14 trials; RR, 0.97 [CI, 0.75 to 1.25]; I2 = 23%; SOE, moderate)<br><br>**Spinal Stenosis:** small, non–statistically significant effects on pain intensity (WMD, 0.62 to 3.73 points) at short- and intermediate-term follow-up (SOE, low to moderate). There were no differences in likelihood of experiencing a successful pain outcome at any time point. | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☐ Methods and/or results were inconsistent across studies | |

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| Chun, E. H. and H. S. Park (2015). *Pain Physician* | To compare the effects of a high-volume injectate with those of a low-volume injectate using the same dose of dexamethasone for 2 groups in lumbar TFESI. | RCT. Patients were randomized to receive lumbar transforaminal epidural dexamethasone injections with either a low-volume injectate (3 mL, N = 30) or a high-volume injectate (8 mL, N = 32). The primary outcome measures for this study were the incidence of the patients achieving meaningful pain relief and a reduction on the Visual Analogue Scale (VAS, range 0-100) at 4 weeks after the procedure. The definition of "meaningful pain relief" was >= 50% from baseline. The secondary outcomes included the Roland-Morris Disability Questionnaire (RMDQ, range 0-24) score and adverse effects. The outcomes were assessed 4 weeks after the procedure. | 60 patients, 12 patients were acute or subacute. | In the DL8 group, the incidence of achieving meaningful pain relief was higher compared with DL3 group (19, 59.4% vs. 9, 30%, P = 0.024). Both groups demonstrated a significant improvement in their VAS and RMDQ scores (P < 0.05). The VAS of the high-volume injectate group (DL8) was significantly lower than that of the low-volume injectate group (DL3) (33.3 +/- 25 vs. 46.3 +/- 25, P = 0.036). | Study Limitations =<br>☒ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | |
| Cohen, S. P., et al. (2015). *BMJ* | To evaluate whether an epidural steroid injection or gabapentin is a better treatment for lumbosacral radiculopathy. | RCT. Participants received either epidural steroid injection plus placebo pills or sham injection plus gabapentin. A positive outcome was defined as a >= 2 point decrease in leg pain coupled with a positive global perceived effect. All patients had one month follow-up visits; patients whose condition improved remained blinded for their three month visit. | 145 patients, 26 had subacute pain. | **There were no significant differences for the primary outcome measure at one month** (mean pain score 3.3 (SD 2.6) and mean change from baseline -2.2 (SD 2.4) in epidural steroid injection group versus 3.7 (SD 2.6) and -1.7 (SD 2.6) in gabapentin group; adjusted difference 0.4, 95% confidence interval -0.3 to 1.2; P=0.25)**. No statistical difference at three month**s (mean pain score 3.4 (SD 2.7) and mean change from baseline -2.0 (SD 2.6) versus 3.7 (SD 2.8) and -1.6 (SD 2.7), respectively; adjusted difference 0.3, -0.5 to 1.2; P=0.43).<br><br>Among secondary outcomes, one month after treatment those who received epidural steroid injection had greater reductions in worst leg pain (-3.0, SD 2.8) than those treated with gabapentin (-2.0, SD 2.9; P=0.04) and were more likely to experience a positive successful outcome (66% v 46%; number needed to treat=5.0, | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☒ Difference in important prognostic factors at baseline | |

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| | | | | 95% confidence interval 2.8 to 27.0; P=0.02). At three months, there were no significant differences between treatments. | | |
| Denis, I., et al. (2015). *Pain Medicine* | To compare equivalent doses of a nonparticulate (dexamethasone) with a particulate (betamethasone) corticosteroid in lumbar transforaminal epidural steroid injections (TFESIs) in terms of pain, function, and complications. | RCT. Patients presenting with debilitating radicular pain were randomized in a double-blind controlled trial to receive a lumbar transforaminal injection of either dexamethasone 7.5 mg (n=29) or betamethasone 6.0 mg (n=27).The primary outcome was pain reduction on a visual analog scale (VAS) at 3 months. Secondary outcomes were functional improvement, as measured by the Oswestry Disability Index (ODI), and number and type of complications | 56 patients | **No differences on the VAS, analyzed either as a continuous (P=0.209) or categorical variable (>=50% (P=0.058) or >=75% (P=0.865) improvement) were found between the two groups at 3 months.** | Study Limitations =<br>☒ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | |


**References:**

1. Chou, R., et al. (2015). "Epidural Corticosteroid Injections for Radiculopathy and Spinal Stenosis: A Systematic Review and Meta-analysis." Annals of Internal Medicine 163(5): 373-381.
2. Chun, E. H. and H. S. Park (2015). "Effect of High-Volume Injectate in Lumbar Transforaminal Epidural Steroid Injections: A Randomized, Active Control Trial." Pain Physician 18(6): 519-525.
3. Cohen, S. P., et al. (2015). "Epidural steroid injections compared with gabapentin for lumbosacral radicular pain: multicenter randomized double blind comparative efficacy study." BMJ 350: h1748.
4. Denis, I., et al. (2015). "Randomized Double-Blind Controlled Trial Comparing the Effectiveness of Lumbar Transforaminal Epidural Injections of Particulate and Nonparticulate Corticosteroids for Lumbosacral Radicular Pain." Pain Medicine 16(9): 1697-1708


**PICO Question:** What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, antiseizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications.

**Modality:** Epidural Injections
**Outcome:** Function

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
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| **Total # of Studies: 4 # of Systematic Reviews: 1 # of RCTs: 3 # of Non-Randomized Studies: 0 # of Diagnostic Studies: 0** | | | | | |
| Chou, R., et al. (2015). *Annals of Internal Medicine* | To review evidence on the benefits and harms of epidural corticosteroid | Systematic Review. | 30 placebo-controlled trials evaluated epidural corticosteroid injections for radiculopathy, and 8 trials were done for spinal stenosis. Patients | **Radiculopathy:** For immediate functional improvement, effects favored epidural corticosteroids, but the difference was not statistically significant (4 trials; SMD, -0.75 [CI, -1.62 to 0.11 ]; SOE, low). | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*When studies include few patients and*

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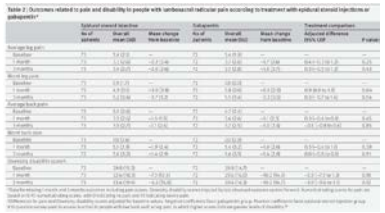
| | injections in adults with radicular low back pain or spinal stenosis of any duration. | | with acute, subacute, and chronic pain were included in the studies | **Spinal Stenosis:** There were no differences in functional improvement or likelihood of experiencing a successful pain, function, or composite outcome at any time point, although estimates were based on few trials (SOE low, except for short-term function [moderate]). | ☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☐ Methods and/or results were inconsistent across studies | *few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias<br>*(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br><u>Increase Quality Rating if:</u><br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |
| Chun, E. H. and H. S. Park (2015). *Pain Physician* | To compare the effects of a high-volume injectate with those of a low-volume injectate using the same dose of dexamethasone for 2 groups in lumbar TFESI. | RCT. Patients were randomized to receive lumbar transforaminal epidural dexamethasone injections with either a low-volume injectate (3 mL, N = 30) or a high-volume injectate (8 mL, N = 32). The primary outcome measures for this study were the incidence of the patients achieving meaningful pain relief and a reduction on the Visual Analogue Scale (VAS, range 0-100) at 4 weeks after the procedure. The definition of "meaningful pain relief" was >= 50% from baseline. The secondary outcomes included the Roland-Morris Disability Questionnaire (RMDQ, range 0-24) score and adverse effects. The outcomes were assessed 4 weeks after the procedure. | 60 patients, 12 of which had acute or subacute pain | Both groups demonstrated a significant improvement in their VAS and RMDQ scores ($P < 0.05$).<br><br>**There was no significant difference in the RMDQ score between the 2 groups.** | Study Limitations =<br>☒ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | |
| Cohen, S. P., et al. (2015). *BMJ* | To evaluate whether an epidural steroid injection or gabapentin is a better treatment for lumbosacral radiculopathy. | RCT. Participants received either epidural steroid injection plus placebo pills or sham injection plus gabapentin. A positive outcome was defined as a >= 2 point decrease in leg pain coupled with a positive global perceived effect. All patients had one month follow-up visits; patients whose condition improved remained blinded for their three month visit. | 145 patients, 26 of which had subacute pain. | No statistically significant difference in Oswestry disability score between the two groups.<br>  | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☒ Difference in important prognostic factors at baseline | |

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| Denis, I., et al. (2015). *Pain Medicine* | To compare equivalent doses of a nonparticulate (dexamethasone) with a particulate (betamethasone) corticosteroid in lumbar transforaminal epidural steroid injections (TFESIs) in terms of pain, function, and complications. | RCT. Patients presenting with debilitating radicular pain were randomized in a double-blind controlled trial to receive a lumbar transforaminal injection of either dexamethasone 7.5 mg (n=29) or betamethasone 6.0 mg (n=27).The primary outcome was pain reduction on a visual analog scale (VAS) at 3 months. Secondary outcomes were functional improvement, as measured by the Oswestry Disability Index (ODI), and number and type of complications | 56 patients | **No differences in ODI (P=0.181) were found between the two groups at 3 months.**<br><br>**At 6 months, improvement of ODI score was at the limit of statistical significance in favor of dexamethasone (P=0.050). Multivariate regression analysis, adjusting for potential confounding variables, showed that differences on the ODI became statistically significant at the 6 month follow-up, also in favor of dexamethasone (adjusted P=0.003).** | Study Limitations =<br>☒ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | |


**References:**

1. Chou, R., et al. (2015). "Epidural Corticosteroid Injections for Radiculopathy and Spinal Stenosis: A Systematic Review and Meta-analysis." Annals of Internal Medicine 163(5): 373-381.
2. Chun, E. H. and H. S. Park (2015). "Effect of High-Volume Injectate in Lumbar Transforaminal Epidural Steroid Injections: A Randomized, Active Control Trial." Pain Physician 18(6): 519-525.
3. Cohen, S. P., et al. (2015). "Epidural steroid injections compared with gabapentin for lumbosacral radicular pain: multicenter randomized double blind comparative efficacy study." BMJ 350: h1748.
4. Denis, I., et al. (2015). "Randomized Double-Blind Controlled Trial Comparing the Effectiveness of Lumbar Transforaminal Epidural Injections of Particulate and Nonparticulate Corticosteroids for Lumbosacral Radicular Pain." Pain Medicine 16(9): 1697-1708.


**PICO Question:** What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, antiseizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications.

**Modality:** Epidural Injections
**Outcome:** Surgery Risk Reduction

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
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| **Total # of Studies: 1 # of Systematic Reviews: 1 # of RCTs: 0 # of Non-Randomized Studies: 0 # of Diagnostic Studies: 0** | | | | | |
| Bicket, M. C., et al. (2015). *Spine Journal: Official Journal of the North American Spine Society* | To determine whether epidural steroid injections (ESI) have a surgery-sparing effect in patients with spinal pain. | Systematic Review. | 26 studies. Studies included both acute and subacute pain patients. | **ESI demonstrated a trend to reduce the need for surgery for short-term** (<1 year) outcomes (risk ratio, 0.68; 95% confidence interval, 0.41-1.13; p=.14) **but not long-term (>=1 year) outcomes** (0.95, 0.77-1.19, p=0.68) | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was |

Lower Quality Rating if:
☐ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

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| | | | | **Although fewer patients demonstrated a need for surgery in the ESI group** (18.2% [199 out of 1,096]) **in comparison with the non-ESI group** (20.3% [234 out of 1,155]), **the difference did not reach statistical significance for the entire cohort** (RR, 0.92; 95% CI, 0.76–1.11; I2512%; p=0.37). | not appraised or studies were of low quality<br>☐ Methods and/or results were inconsistent across studies | ☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |

**References:**

1. Bicket, M. C., et al. (2015). "Epidural injections in prevention of surgery for spinal pain: systematic review and meta-analysis of randomized controlled trials." Spine Journal: Official Journal of the North American Spine Society 15(2): 348-362.

**PICO Question:** What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, antiseizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications.

**Modality:** Epidural Injections
**Outcome:** Harm

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | Lower Quality Rating if: ☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*<br><br>☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness* |
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| **Total # of Studies: 4 # of Systematic Reviews: 1# of RCTs: 3 # of Non-Randomized Studies: 0<br># of Diagnostic Studies: 0** | | | | | | |
| Chou, R., et al. (2015). *Annals of Internal Medicine* | To review evidence on the benefits and harms of epidural corticosteroid injections in adults with radicular low back pain or spinal stenosis of any duration. | Systematic Review. | 30 placebo-controlled trials evaluated epidural corticosteroid injections for radiculopathy, and 8 trials were done for spinal stenosis. Patients with acute, subacute, and chronic pain were included in the studies | **In 30 placebo-controlled trials (2912 participants in total) of epidural corticosteroid injections for radiculopathy, 1 serious adverse event (a case of retroperitoneal hematoma in a patient receiving anticoagulation) was reported. Methods for assessing harms were not well reported, and harms data were sparse. Thirteen trials did not report harms at all or reported no harms** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☐ Methods and/or results were inconsistent across studies | |

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| Chun, E. H. and H. S. Park (2015). *Pain Physician* | To compare the effects of a high-volume injectate with those of a low-volume injectate using the same dose of dexamethasone for 2 groups in lumbar TFESI. | RCT. Patients were randomized to receive lumbar transforaminal epidural dexamethasone injections with either a low-volume injectate (3 mL, N = 30) or a high-volume injectate (8 mL, N = 32). The primary outcome measures for this study were the incidence of the patients achieving meaningful pain relief and a reduction on the Visual Analogue Scale (VAS, range 0-100) at 4 weeks after the procedure. The definition of "meaningful pain relief" was >= 50% from baseline. The secondary outcomes included the Roland-Morris Disability Questionnaire (RMDQ, range 0-24) score and adverse effects. The outcomes were assessed 4 weeks after the procedure. | 60 patients, 12 of which had acute or subacute pain | No severe adverse events were reported in this study. | Study Limitations =<br>☒ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | *of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☒ Moderate<br>☐ Low<br>☐ Very Low |
| Cohen, S. P., et al. (2015). *BMJ* | To evaluate whether an epidural steroid injection or gabapentin is a better treatment for lumbosacral radiculopathy. | RCT. Participants received either epidural steroid injection plus placebo pills or sham injection plus gabapentin. A positive outcome was defined as a >= 2 point decrease in leg pain coupled with a positive global perceived effect. All patients had one month follow-up visits; patients whose condition improved remained blinded for their three month visit. | 145 patients, 26 of which had subacute pain. | The proportion of patients reporting one or more adverse events from the injection was 8% (n=6) in the epidural steroid injection group and lO% (n=7) in the gabapentin group (P=0.75). The proportion of patients reporting one or more adverse events from drug treatment was 42% (n=30) in the epidural steroid injection group and 51%(n=37) in the gabapentin group (P=0.24) | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☒ Difference in important prognostic factors at baseline | |
| Denis, I., et al. (2015). *Pain Medicine* | To compare equivalent doses of a nonparticulate (dexamethasone) with a particulate (betamethasone) | RCT. Patients presenting with debilitating radicular pain were randomized in a double-blind controlled trial to receive a lumbar transforaminal injection of either dexamethasone 7.5 mg (n=29) or betamethasone 6.0 mg | 56 patients | **Complications were almost exclusively reported at 1 month follow-up with none noted at 6 months.** The majority were minor and short-lived (a few minutes, a few days) after the injection. The most serious complication was postdural | Study Limitations =<br>☒ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit | |

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| | corticosteroid in lumbar transforaminal epidural steroid injections (TFESIs) in terms of pain, function, and complications. | (n=27).The primary outcome was pain reduction on a visual analog scale (VAS) at 3 months. Secondary outcomes were functional improvement, as measured by the Oswestry Disability Index (ODI), and number and type of complications | | puncture headache in a patient with severe transforaminal stenosis. This complication was related to the technique rather than a side-effect of corticosteroid use. It was resolved completely with a blood patch. The frequency of complications remained low (1.9-11 .3%). | ☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | |


**References:**

1. Chou, R., et al. (2015). "Epidural Corticosteroid Injections for Radiculopathy and Spinal Stenosis: A Systematic Review and Meta-analysis." Annals of Internal Medicine 163(5): 373-381.
2. Chun, E. H. and H. S. Park (2015). "Effect of High-Volume Injectate in Lumbar Transforaminal Epidural Steroid Injections: A Randomized, Active Control Trial." Pain Physician 18(6): 519-525.
3. Cohen, S. P., et al. (2015). "Epidural steroid injections compared with gabapentin for lumbosacral radicular pain: multicenter randomized double blind comparative efficacy study." BMJ 350: h1748.
4. Denis, I., et al. (2015). "Randomized Double-Blind Controlled Trial Comparing the Effectiveness of Lumbar Transforaminal Epidural Injections of Particulate and Nonparticulate Corticosteroids for Lumbosacral Radicular Pain." Pain Medicine 16(9): 1697-1708.
5. Miller, T., et al. (2015). "Patients with refractory back pain treated in the emergency department: is immediate interlaminar epidural steroid injection superior to hospital admission and standard medical pain management?" Pain Physician 18(2): E171-176 .


**PICO Question:** What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, antiseizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications.

**Modality:** Corticosteroid ( IV or oral)
**Outcome:** Pain Reduction

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 3 # of Systematic Reviews: 1 # of RCTs: 2 # of Non-Randomized Studies: 0 # of Diagnostic Studies: 0** | | | | | |
| Balakrishnamoorthy, R., et al. (2015). *Emergency Medicine Journal* | To assess the effect of a single dose of intravenous dexamethasone in addition to routine treatment on visual analogue scale (VAS) pain scores at 24 h in emergency department (ED) patients with low back pain with | RCT. Adult ED patients with LBPR, received either the intervention was 8 mg of intravenous dexamethasone (or placebo) in addition to current routine care. The primary outcome was the change in VAS pain scores between presentation and 24 h. Secondary outcomes included VAS pain scores at 6 weeks, ED length of stay (EDLOS), straight leg raise (SLR) angles and Oswestry functional scores. | 58 adult ED patients with LBPR, conducted in one tertiary and one urban ED. | **Patients treated with dexamethasone had a 1.86 point** (95% CI 0.31 to 3.42, P=0.019) **greater reduction in VAS pain scores at 24 h than placebo** (dexamethasone: -2.63 (95% CI -3.63 to -1.63) versus placebo: -0.77 (95% CI -2.04 to 0.51)**). At 6 weeks, both groups had similar significant and sustained decrease in VAS scores compared with baseline.**<br><br>Patients receiving dexamethasone had a significantly shorter ED LOS (median: 3.5 h | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☒ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:

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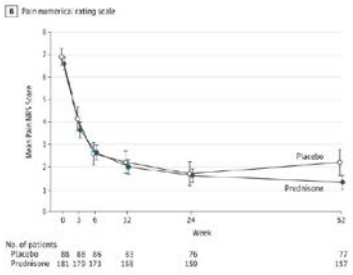
| | radiculopathy (LBPR). | | | vs 18.8 h, P=0.049) and improved SLR angle at discharge (14.7degree, P=0.040). | | ☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |
| Goldberg, H., et al. (2015). *JAMA* | To determine if oral prednisone is more effective than placebo in improving function and pain among patients with acute sciatica. | RCT. Participants were randomly assigned in a 2:1 ratio to receive a tapering 15-day course of oral prednisone (5 days each of 60 mg, 40 mg, and 20 mg; total cumulative dose=600 mg; n=181) or matching placebo (n=88). The primary outcome was Oswestry Disability Index (ODI) change at 3 weeks; secondary outcomes were ODI change at 1 year, change in lower extremity pain (measured on a 0-10 scale; higher scores indicate more pain), spine surgery, and Short Form 36 Health Survey (SF-36) Physical Component Summary (PCS) and Mental Component Summary (MCS) scores (0-100 scale; higher scores better). | 269 patients with radicular pain for 3 months or less, an Oswestry Disability Index (ODI) score of 30 or higher (range, 0-100; higher scores indicate greater dysfunction), and a herniated disk confirmed by magnetic resonance imaging were eligible. | **Compared with the placebo group, the prednisone group showed an adjusted mean 0.3-point** (95% CI, -0.4 to 1.0; P=.34) **greater reduction in pain at 3 weeks and a mean 0.6-point** (95% CI, -0.2 to 1.3; P=.15) greater reduction at 52 weeks. **Not statistically significant**<br><br>There were no differences in surgery rates at 52-week follow-up.<br>  <br> | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☒ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☒ Difference in important prognostic factors at baseline | |
| Vekaria, R., et al. (2016). *European Spine Journal* | To determine if intra-articular facet joint injections with active drug are more effective in reducing back pain and back pain-related disability than a sham procedure or a placebo/inactive injection. Secondly, to determine if intra-articular facet | Systematic Review. | 6 studies with 434 participants with acute, subacute, and chronic pain. | There was high heterogeneity between the trials and the authors were not able to perform a meta-analysis.<br><br>Injection vs sham injection: **None of the trials reported significant differences in pain or disability between groups at their pre-specified primary outcome**.<br><br>Injection vs conservative treatment: **Only two of the trials report any significant between-group differences in pain (mean difference -1.0, 95% CI -2.0 to -0.1) and (P = 0.032)** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies | |

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| | joint injections with active drug or placebo/inactive injection are more effective in reducing back pain and back pain-related disability than conservative treatment. | | | | | |


**References:**

1. Balakrishnamoorthy, R., et al. (2015). "Does a single dose of intravenous dexamethasone reduce Symptoms in Emergency department patients with low Back pain and Radiculopathy (SEBRA)? A double-blind randomised controlled trial." Emergency Medicine Journal 32(7): 525-530.
2. Goldberg, H., et al. (2015). "Oral steroids for acute radiculopathy due to a herniated lumbar disk: a randomized clinical trial." JAMA 313(19): 1915-1923.
3. Vekaria, R., et al. (2016). "Intra-articular facet joint injections for low back pain: a systematic review." European Spine Journal 25(4): 1266-1281.


**PICO Question:** What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, antiseizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications.

**Modality:** Corticosteroid ( IV or oral)
**Outcome:** Function

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 3 # of Systematic Reviews: 1 # of RCTs: 2 # of Non-Randomized Studies: 0 # of Diagnostic Studies: 0** | | | | | |
| Balakrishnamoorthy, R., et al. (2015). *Emergency Medicine Journal* | To assess the effect of a single dose of intravenous dexamethasone in addition to routine treatment on visual analogue scale (VAS) pain scores at 24 h in emergency department (ED) patients with low back pain with | RCT. Adult ED patients with LBPR, received either the intervention was 8 mg of intravenous dexamethasone (or placebo) in addition to current routine care. The primary outcome was the change in VAS pain scores between presentation and 24 h. Secondary outcomes included VAS pain scores at 6 weeks, ED length of stay (EDLOS), straight leg raise (SLR) angles and Oswestry functional scores. | 58 adult ED patients with LBPR, conducted in one tertiary and one urban ED. | **There was not a statistically significant difference in Oswestry scores between the dexamethasone and placebo group. There was also no statistical difference between groups in ability to return to their normal activities by 6 weeks.** | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☒ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

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| | radiculopathy (LBPR). | | | | | Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |
| Goldberg, H., et al. (2015). *JAMA* | To determine if oral prednisone is more effective than placebo in improving function and pain among patients with acute sciatica. | RCT. Participants were randomly assigned in a 2:1 ratio to receive a tapering 15-day course of oral prednisone (5 days each of 60 mg, 40 mg, and 20 mg; total cumulative dose=600 mg; n=181) or matching placebo (n=88). The primary outcome was Oswestry Disability Index (ODI) change at 3 weeks; secondary outcomes were ODI change at 1 year, change in lower extremity pain (measured on a 0-10 scale; higher scores indicate more pain), spine surgery, and Short Form 36 Health Survey (SF-36) Physical Component Summary (PCS) and Mental Component Summary (MCS) scores (0-100 scale; higher scores better). | 269 patients with radicular pain for 3 months or less, an Oswestry Disability Index (ODI) score of 30 or higher (range, 0-100; higher scores indicate greater dysfunction), and a herniated disk confirmed by magnetic resonance imaging were eligible. | **The prednisone-treated group showed an adjusted mean 6.4-point (95% CI, 1.9-10.9; P=.006) greater improvement in ODI scores at 3 weeks than the placebo group and a mean 7.4-point (95% CI, 2.2-12.5; P=.005) greater improvement at 52 weeks.** | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☒ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☒ Difference in important prognostic factors at baseline | |
| Vekaria, R., et al. (2016). *European Spine Journal* | To determine if intra-articular facet joint injections with active drug are more effective in reducing back pain and back pain-related disability than a sham procedure or a placebo/inactive injection. Secondly, to determine if intra-articular facet joint injections with active drug or placebo/inactive injection are | Systematic Review. | 6 studies with 434 participants with acute, subacute, or chronic pain. | There was high heterogeneity between the trials and the authors were not able to perform a meta-analysis.<br><br>Injection vs sham injection: **None of the trials reported significant differences in pain or disability between groups at their pre-specified primary outcome**.<br><br>Injection vs conservative treatment: **Of the three trials, two report no significant changes and one reports a significant improvement over time (P=0.013)** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies | |

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| | more effective in reducing back pain and back pain-related disability than conservative treatment. | | | | | |


**References:**

1. Balakrishnamoorthy, R., et al. (2015). "Does a single dose of intravenous dexamethasone reduce Symptoms in Emergency department patients with low Back pain and Radiculopathy (SEBRA)? A double-blind randomised controlled trial." Emergency Medicine Journal 32(7): 525-530.
2. Goldberg, H., et al. (2015). "Oral steroids for acute radiculopathy due to a herniated lumbar disk: a randomized clinical trial." JAMA 313(19): 1915-1923.
3. Vekaria, R., et al. (2016). "Intra-articular facet joint injections for low back pain: a systematic review." European Spine Journal 25(4): 1266-1281.


**PICO Question:** What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, antiseizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications.

**Modality:** Corticosteroid ( IV or oral)
**Outcome:** Harm

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 2 # of Systematic Reviews: 0 # of RCTs: 2 # of Non-Randomized Studies:** Click here to enter text. **# of Diagnostic Studies:** Click here to enter text. | | | | | |
| Balakrishnamoorthy, R., et al. (2015). *Emergency Medicine Journal* | To assess the effect of a single dose of intravenous dexamethasone in addition to routine treatment on visual analogue scale (VAS) pain scores at 24 h in emergency department (ED) patients with low back pain with radiculopathy (LBPR). | RCT. Adult ED patients with LBPR, received either the intervention was 8 mg of intravenous dexamethasone (or placebo) in addition to current routine care. The primary outcome was the change in VAS pain scores between presentation and 24 h. Secondary outcomes included VAS pain scores at 6 weeks, ED length of stay (EDLOS), straight leg raise (SLR) angles and Oswestry functional scores. | 58 adult ED patients with LBPR, conducted in one tertiary and one urban ED. | **Incidence of adverse effect reporting between groups was similar (18% vs 15%). One patient receiving dexamethasone reported a dexamethasone-specific adverse event directly after the intravenous bolus; peri-anal itching. All the adverse effects were mild (eg, nausea, mild headache, light-headedness), transi-ent and none required treatment.** | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☒ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient

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|---|---|---|---|---|---|---|
| Goldberg, H., et al. (2015). *JAMA* | To determine if oral prednisone is more effective than placebo in improving function and pain among patients with acute sciatica. | RCT. Participants were randomly assigned in a 2:1 ratio to receive a tapering 15-day course of oral prednisone (5 days each of 60 mg, 40 mg, and 20 mg; total cumulative dose=600 mg; n=181) or matching placebo (n=88). The primary outcome was Oswestry Disability Index (ODI) change at 3 weeks; secondary outcomes were ODI change at 1 year, change in lower extremity pain (measured on a 0-10 scale; higher scores indicate more pain), spine surgery, and Short Form 36 Health Survey (SF-36) Physical Component Summary (PCS) and Mental Component Summary (MCS) scores (0-100 scale; higher scores better). | 269 patients with radicular pain for 3 months or less, an Oswestry Disability Index (ODI) score of 30 or higher (range, 0-100; higher scores indicate greater dysfunction), and a herniated disk confirmed by magnetic resonance imaging were eligible. | **By the 3-week visit, 88 participants (49.2%) in the prednisone group reported at least 1 adverse event compared with 21 (23.9%) randomized to placebo (P < .001).** The majority (82.1%) of these were minor, expected adverse effects commonly associated with short courses of prednisone, such as insomnia, nervousness, and increased appetite.<br><br>By the 52-week visit, 208 participants (77-3%) reported a total of 723 adverse events; there were no significant differences in the mean number of adverse events per person in the active- and placebo-treated groups (2.70 vs 2.69; P = .98) or in the proportion of participants in each group reporting at least 1 adverse event (80.1% vs 71.6%; P = .12).<br><br>Overall, 5 serious adverse events occurred over the 52-week follow-up period, 3 in the prednisone group (appendectomy, suicide attempt, and deep venous thrombosis) and 2 in the placebo group (upper gastroin-testinal tract hemorrhage and partial nephrectomy for renal cell carcinoma); none was judged to be likely due to the study medication. | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☒ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☒ Difference in important prognostic factors at baseline | ☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |

**References:**


1. Balakrishnamoorthy, R., et al. (2015). "Does a single dose of intravenous dexamethasone reduce Symptoms in Emergency department patients with low Back pain and Radiculopathy (SEBRA)? A double-blind randomised controlled trial." Emergency Medicine Journal 32(7): 525-530.
2. Goldberg, H., et al. (2015). "Oral steroids for acute radiculopathy due to a herniated lumbar disk: a randomized clinical trial." JAMA 313(19): 1915-1923.


| **PICO Question:** What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, antiseizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications. | | | | | | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in* |
|---|---|---|---|---|---|---|
| **Modality:** Corticosteroid ( IV or oral)<br>**Outcome:** Surgery Risk Reduction | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 1 # of Systematic Reviews: 0 # of RCTs: 1 # of Non-Randomized Studies:** Click here to enter text.<br>**# of Diagnostic Studies:** Click here to enter text. | | | | | | |

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| Goldberg, H., et al. (2015). *JAMA* | To determine if oral prednisone is more effective than placebo in improving function and pain among patients with acute sciatica. | RCT. Participants were randomly assigned in a 2:1 ratio to receive a tapering 15-day course of oral prednisone (5 days each of 60 mg, 40 mg, and 20 mg; total cumulative dose=600 mg; n=181) or matching placebo (n=88). The primary outcome was Oswestry Disability Index (ODI) change at 3 weeks; secondary outcomes were ODI change at 1 year, change in lower extremity pain (measured on a 0-10 scale; higher scores indicate more pain), spine surgery, and Short Form 36 Health Survey (SF-36) Physical Component Summary (PCS) and Mental Component Summary (MCS) scores (0-100 scale; higher scores better). | 269 patients with radicular pain for 3 months or less, an Oswestry Disability Index (ODI) score of 30 or higher (range, 0-100; higher scores indicate greater dysfunction), and a herniated disk confirmed by magnetic resonance imaging were eligible. | **There were no differences in surgery rates at 52-week follow-up.** | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☒ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☒ Difference in important prognostic factors at baseline | *regard to population, intervention, comparison, or outcome)*<br><br>☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☐ Low<br>☒ Very Low |

**References:**

1. Goldberg, H., et al. (2015). "Oral steroids for acute radiculopathy due to a herniated lumbar disk: a randomized clinical trial." JAMA 313(19): 1915-1923.

| **PICO Question:** What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, antiseizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications. | | | | | | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in* |
|---|---|---|---|---|---|---|
| **Modality:** NSAID combinations<br>**Outcome:** Pain Reduction | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 2 # of Systematic Reviews: 0 # of RCTs: 2 # of Non-Randomized Studies: 0<br># of Diagnostic Studies: 0** | | | | | | |

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| Friedman, B. W., et al. (2017). *Annals of Emergency Medicine* | To compare pain and functional outcomes 1 week and 3 months after ED discharge among patients randomized to a 1-week course of naproxen+diazepam versus naproxen+placebo. | RCT. Patients were eligible for enrollment immediately before discharge from an ED if they had a score greater than 5 on the Roland-Morris Disability Questionnaire, a validated 24-item inventory of functional impairment caused by low back pain. Higher scores on the questionnaire indicate greater functional disability. The primary outcome in the trial was improvement in the score between ED discharge and 1 week later. Secondary outcomes included pain intensity 1 week and 3 months after ED discharge, as measured on a 4-point descriptive scale (severe, moderate, mild, and none). All patients were given 20 tablets of naproxen 500 mg, to be taken twice a day as needed for low back pain. Additionally, patients were randomized to receive either 28 tablets of diazepam 5 mg or identical placebo, to be received as 1 or 2 tablets every 12 hours as needed for low back pain. All patients received a standardized 10-minute low back pain educational session before discharge. | 114 patients with acute, nontraumatic, nonradicular low back pain of no more than a duration of 2 weeks. | At 1-week follow-up, 18 of 57 diazepam patients (32%; 95% CI 21% to 45%) reported moderate or severe low back pain versus 12 of 55 placebo patients (22%; 95% CI 13% to 35%). At 3-month follow-up, 6 of 50 diazepam patients (12%; 95% CI 5% to 24%) reported moderate or severe low back pain versus 5 of 53 placebo patients (9%; 95% CI 4% to 21%).<br><br>By 3 months after the ED visit, most patients had recovered completely. **Similar to the findings at 1-week follow-up, differences in 3-month pain or functional outcomes between groups were neither clinically nor statistically significant.** | Study Limitations =<br>☒ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | *regard to population, intervention, comparison, or outcome)*<br><br>☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br><u>Increase Quality Rating if:</u><br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |
| Gottlieb, M. and A. Njie (2016). *CJEM Canadian Journal of Emergency Medical Care* | To compare functional outcomes at one week and three months after emergency department (ED) presentation for acute low back pain among patients prescribed naproxen plus one | RCT. Patients were stratified into one of three groups using block randomization based upon the results of their baseline scores on the RMDQ. All participants received twenty 500-mg tablets of naproxen with instructions to use one tablet every 12 hours. Each of the participants also received 60 identical-appearing tablets of one of the following | 323 patients | At the 7-day follow up, There were no statistically significant differences in degree of back pain in the preceding 24 hours, frequency of back pain during the preceding 24 hours, or return to normal activities.<br><br>At the 3-month follow up, most patients had fully recovered, but approximately 24% of participants in each of the groups still reported moderate or severe low back | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☒ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U | |

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| | of the following: (1) oxycodone/acetaminophen; (2) cyclobenzaprine; or (3) placebo. | medications to be taken as one or two tablets every eight hours as needed: (1) oxycodone 5 mg with acetaminophen 325 mg; (2) cyclobenzaprine 5 mg; or (3) placebo. Research personnel also provided all participants with a IO-minute educational intervention on non-pharmacologic approaches to low back pain. Patients were followed via telephone at one week and three months after hospital discharge. | | pain and the continued use of medications for the back pain. | ☐ Difference in important prognostic factors at baseline | |


**References:**

2. Friedman, B. W., et al. (2017). "Diazepam Is No Better Than Placebo When Added to Naproxen for Acute Low Back Pain." Annals of Emergency Medicine 70(2): 169-176.e161.
3. Gottlieb, M. and A. Njie (2016). "Comparison of naproxen with cyclobenzaprine, oxycodone-acetaminophen, and placebo for the treatment of acute low back pain." CJEM Canadian Journal of Emergency Medical Care 18(6): 491-494.


**PICO Question:** What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, antiseizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications.

**Modality:** NSAIDs
**Outcome:** Function

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 2 # of Systematic Reviews: 0 # of RCTs: 2 # of Non-Randomized Studies: 0 # of Diagnostic Studies: 0** | | | | | |
| Friedman, B. W., et al. (2017). *Annals of Emergency Medicine* | To compare pain and functional outcomes 1 week and 3 months after ED discharge among patients randomized to a 1-week course of naproxen+diazepam versus naproxen+placebo. | RCT. Patients presenting with acute, nontraumatic, nonradicular low back pain of no more than a duration of 2 weeks were eligible for enrollment immediately before discharge from an ED if they had a score greater than 5 on the Roland-Morris Disability Questionnaire, a validated 24-item inventory of functional impairment caused by low back pain. Higher scores on the questionnaire indicate greater functional disability. The primary outcome in the trial was | 114 patients | One week after the ED visit, patients randomized to diazepam improved by a mean of 11 (95% CI 9 to 13) Roland-Morris Disability Questionnaire points, whereas placebo patients improved by 11 (95% CI 8 to 13) for mean difference of 0.3: –2.8 to 3.5). **The between group difference achieved neither clinical nor statistical significance.** | Study Limitations =<br>☒ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

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|---|---|---|---|---|---|---|
| | | improvement in the score between ED discharge and 1 week later. Secondary outcomes included pain intensity 1 week and 3 months after ED discharge, as measured on a 4-point descriptive scale (severe, moderate, mild, and none). All patients were given 20 tablets of naproxen 500 mg, to be taken twice a day as needed for low back pain. Additionally, patients were randomized to receive either 28 tablets of diazepam 5 mg or identical placebo, to be received as 1 or 2 tablets every 12 hours as needed for low back pain. All patients received a standardized 10-minute low back pain educational session before discharge. | | | | <u>Increase Quality Rating if:</u><br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |
| Gottlieb, M. and A. Njie (2016). *CJEM Canadian Journal of Emergency Medical Care* | To compare functional outcomes at one week and three months after emergency department (ED) presentation for acute low back pain among patients prescribed naproxen plus one of the following: (1) oxycodone/acetaminophen; (2) cyclobenzaprine; or (3) placebo. | RCT. Patients were stratified into one of three groups using block randomization based upon the results of their baseline scores on the RMDQ. All participants received twenty 500-mg tablets of naproxen with instructions to use one tablet every 12 hours. Each of the participants also received 60 identical-appearing tablets of one of the following medications to be taken as one or two tablets every eight hours as needed: (1) oxycodone 5 mg with acetaminophen 325 mg; (2) cyclobenzaprine 5 mg; or (3) placebo. Research personnel also provided all participants with a IO-minute educational intervention on non-pharmacologic approaches to low back pain. Patients were followed via telephone at one | 323 patients | At the 7-day follow up, there was no significant difference in the primary outcome of improvement in the RDMQ scores.<br><br>At the 3-month follow up, most patients had fully recovered, but approximately 24% of participants in each of the groups still reported moderate or severe low back pain and the continued use of medications for the back pain. | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☒ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | |

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| | | week and three months after hospital discharge. | | **Table 1. Comparison of 7-day functional disability between oxycodone/acetaminophen, cyclobenzaprine, and placebo for acute low back pain**<br>Comparison Groups: Improvement in RMDQ between ED visit and 7-day follow up (98.3% CI)<br>Naproxen + oxycodone/acetaminophen: 11.1 (9.0 to 13.2)<br>Naproxen + cyclobenzaprine: 10.1 (7.9 to 12.3)<br>Naproxen + placebo: 9.8 (7.9 to 11.7)<br>RMDQ = Roland-Morris Disability Questionnaire; ED = emergency department; CI = confidence interval<br><br>**Table 2. Comparison of 3-month functional disability between oxycodone/acetaminophen, cyclobenzaprine, and placebo for acute low back pain**<br>Comparison Groups: Mean RMDQ score at 3-month follow up (95% CI)<br>Naproxen + oxycodone/acetaminophen: 4.6 (3.2 to 6.1)<br>Naproxen + cyclobenzaprine: 4.5 (3.0 to 5.9)<br>Naproxen + placebo: 3.8 (2.6 to 5.1)<br>RMDQ = Roland-Morris Disability Questionnaire; ED = emergency department; CI = confidence interval | | |


**References:**

1. Friedman, B. W., et al. (2017). "Diazepam Is No Better Than Placebo When Added to Naproxen for Acute Low Back Pain." Annals of Emergency Medicine 70(2): 169-176.e161.
2. Gottlieb, M. and A. Njie (2016). "Comparison of naproxen with cyclobenzaprine, oxycodone-acetaminophen, and placebo for the treatment of acute low back pain." CJEM Canadian Journal of Emergency Medical Care 18(6): 491-494.


**PICO Question:** What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, antiseizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications.

**Modality:** NSAID Combinations
**Outcome:** Harms

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 2# of Systematic Reviews: 0 # of RCTs: 2 # of Non-Randomized Studies: 0 # of Diagnostic Studies: 0** | | | | | |
| Friedman, B. W., et al. (2017). *Annals of Emergency Medicine* | To compare pain and functional outcomes 1 week and 3 months after ED discharge among patients randomized to a 1-week course of naproxen+diazepam versus | RCT. Patients presenting with acute, nontraumatic, nonradicular low back pain of no more than a duration of 2 weeks were eligible for enrollment immediately before discharge from an ED if they had a score greater than 5 on the Roland-Morris Disability Questionnaire, a validated 24-item inventory of functional impairment caused by low back pain. Higher scores on the questionnaire indicate | 114 patients | **Adverse events were relatively infrequent and comparable between the groups. There were no serious or unexpected adverse events.** | Study Limitations =<br>☒ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome) |

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| | naproxen+placebo. | greater functional disability. The primary outcome in the trial was improvement in the score between ED discharge and 1 week later. Secondary outcomes included pain intensity 1 week and 3 months after ED discharge, as measured on a 4-point descriptive scale (severe, moderate, mild, and none). All patients were given 20 tablets of naproxen 500 mg, to be taken twice a day as needed for low back pain. Additionally, patients were randomized to receive either 28 tablets of diazepam 5 mg or identical placebo, to be received as 1 or 2 tablets every 12 hours as needed for low back pain. All patients received a standardized 10-minute low back pain educational session before discharge. | | | ☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br><u>Increase Quality Rating if:</u><br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |
| Gottlieb, M. and A. Njie (2016). *CJEM Canadian Journal of Emergency Medical Care* | To compare functional outcomes at one week and three months after emergency department (ED) presentation for acute low back pain among patients prescribed naproxen plus one of the following: (1) oxycodone/acetaminophen; (2) cyclobenzaprine; or (3) placebo. | RCT. Patients were stratified into one of three groups using block randomization based upon the results of their baseline scores on the RMDQ. All participants received twenty 500-mg tablets of naproxen with instructions to use one tablet every 12 hours. Each of the participants also received 60 identical-appearing tablets of one of the following medications to be taken as one or two tablets every eight hours as needed: (1) oxycodone 5 mg with acetaminophen 325 mg; (2) cyclobenzaprine 5 mg; or (3) placebo. Research personnel also provided all participants with a IO-minute educational intervention on non-pharmacologic approaches to low back pain. Patients were followed via telephone at one week and three months after hospital discharge. | 323 patients | Adverse events were more common among both the oxycodone/acetaminophen group [difference: 19% (95% CI = 7% to 31 %), number needed to harm: 5.3 (95% CI = 3 to 14)] and cyclobenzaprine group [difference: 13% (95% CI = 1 % to 25%), number needed to harm: 7.8 (95% CI =4 to 129)] compared to placebo. The most common side effects included drowsiness, dizziness, stomach irritation, and nausea or vomiting. | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☒ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | |

**References:**

1. Friedman, B. W., et al. (2017). "Diazepam Is No Better Than Placebo When Added to Naproxen for Acute Low Back Pain." Annals of Emergency Medicine 70(2): 169-176.e161.
2. Gottlieb, M. and A. Njie (2016). "Comparison of naproxen with cyclobenzaprine, oxycodone-acetaminophen, and placebo for the treatment of acute low back pain." CJEM Canadian Journal of Emergency Medical Care 18(6): 491-494.

**PICO Question:** What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, antiseizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications.

**Modality:** Ketoprofen
**Outcome:** Pain Reduction

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 0 # of RCTs: 1 # of Non-Randomized Studies: 0 # of Diagnostic Studies: 0** | | | | | |
| Serinken, M., et al. (2016). *American Journal of Emergency Medicine* | The aim of this study was to reveal the effect of ketoprofen gel in patients presenting with mechanical low back pain to the ED. | RCT. Patients received intravenous dexketoprofen additional to study drugs. After dexketoprofen, 2 g of 2.5% ketoprofen gel or placebo was administered to the site with pain and tenderness. Pain relief at 15 and 30minuteswasmeasured by visual analog scale scores. | 140 patients. | The mean pain reduction in ketoprofen (27±13mm) and placebo (28±13) groups at 15 minutes was similar. However, the mean pain reduction at 30minuteswas 52±18 and 37±17, respectively.<br><br>**Although there was no difference considering the pain reduction at 15 minutes between 2 groups** (mean difference, 0.5 mm; 95% CI, −4 to 5 P=0.80), **ketoprofen gel was better than placebo at 30 minutes** (mean difference,16 mm; 95% CI, 10-21 P=0.000).<br><br>Table 2<br>Comparison of pain improvements between 2 groups at 15 and 30 minutes<br>Variable / Placebo vs ketoprofen / P<br>Differences from baseline to 15 min, mean (95% CI) 0.5 (−4 to 5) .8<br>Differences from baseline to 30 min, mean (95% CI) 16 (10-21) .000 | Study Limitations =<br>☒ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☐ Low
☒ Very Low

**References**:

1. Serinken, M., et al. (2016). "Ketoprofen gel improves low back pain in addition to IV dexketoprofen: a randomized placebo-controlled trial." American Journal of Emergency Medicine 34(8): 1458-1461.

**PICO Question:** What are the comparative benefits and harms of different pharmacological therapies for acute or subacute low back pain? Includes NSAIDs, acetaminophen, opioids, muscle, relaxants, antiseizure medications, antidepressants, corticosteroids, and topical/patch-delivered medications.

**Modality:** Ketoprofen
**Outcome:** Harms

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 0 # of RCTs: 1 # of Non-Randomized Studies: 0 # of Diagnostic Studies: 0** | | | | | |
| Serinken, M., et al. (2016). *American Journal of Emergency Medicine* | The aim of this study was to reveal the effect of ketoprofen gel in patients presenting with mechanical low back pain to the ED. | RCT. Patients received intravenous dexketoprofen additional to study drugs. After dexketoprofen, 2 g of 2.5% ketoprofen gel or placebo was administered to the site with pain and tenderness. Pain relief at 15 and 30minuteswasmeasured by visual analog scale scores. | 140 patients. | Ten patients (14%) in the placebo group and 2 patients (3%) in the ketoprofen gel group needed rescue drug (P=.35). One patient in the placebo group stated nausea; and 1 patient in the ketoprofen gel group, vertigo. | Study Limitations =<br>☒ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☐ Low
☒ Very Low

**References:**

1. Serinken, M., et al. (2016). "Ketoprofen gel improves low back pain in addition to IV dexketoprofen: a randomized placebo-controlled trial." American Journal of Emergency Medicine 34(8): 1458-1461.

**Question #5. What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers?**

**Guideline Recommendations:**

The **2018 Institute for Clinical Systems Improvement (ICSI) – Low Back Pain, Adult Acute and Subacute** guidelines recommended the following:

| Topic | Recommendation | Quality of Evidence (For GRADE Recommendations) | Strength of Recommendation (For GRADE Recommendations) | Relevant Resources |
|---|---|---|---|---|
| Education | All patients should receive appropriate education on the treatment and recovery expectations for acute and subacute low back pain. | Quality of Evidence: Moderate-High | Strong Recommendation | *Traeger, 2015 (Systematic Review and Meta-Analysis)* |
| Heat | Heat may be used for pain relief for acute and subacute low back pain. | Quality of Evidence: Moderate | Weak Recommendation | *Chou, 2016 (Comparative Effectiveness Review)* |
| Cold | Cold therapy may be used for pain relief. | N/A (Consensus Recommendation) | | *Chou, 2016 (Comparative Effectiveness Review)* |
| Activity | Clinicians should advise patients with acute and subacute low back pain to stay active and continue activities of daily living within the limits permitted by their symptoms. | Quality of Evidence: Moderate | Strong Recommendation | *Dahm 2010 (Systematic Review); McIntosh 2011 (Systematic Review)* |
| Spinal Manipulation | Spinal manipulation should be considered in early intervention for acute and subacute low back pain. | Quality of Evidence: Low-Moderate | Strong Recommendation | *Paige, 2017 (Systematic Review and Meta-Analysis); Chou, 2016 (Comparative Effectiveness Review)* |
| Acupuncture | Acupuncture should be considered for subacute low back pain. | Quality of Evidence: Low | Weak Recommendation | *Chou, 2016 (Comparative Effectiveness Review)* |

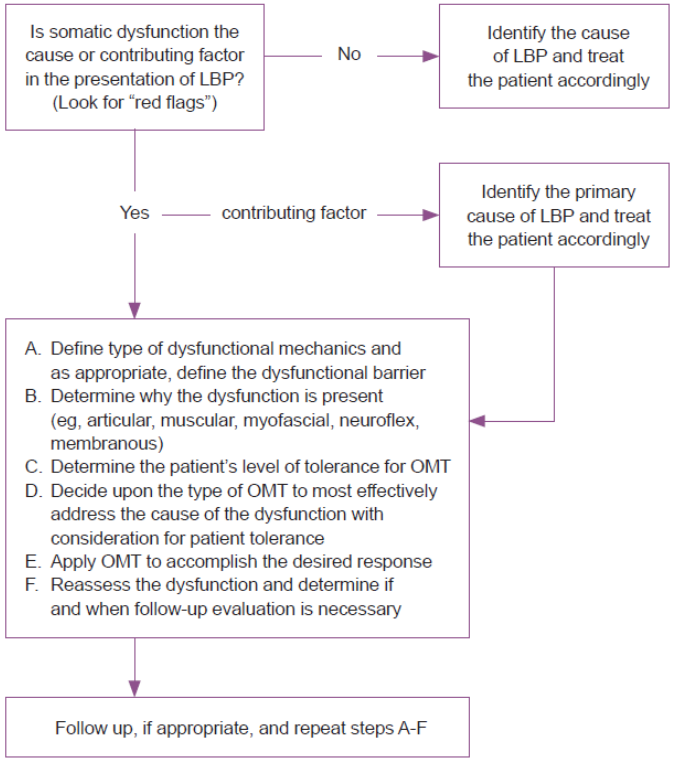
In **2017**, the **American College of Physicians** recommended that given that most patients with acute or subacute low back pain improve over time regardless of treatment, clinicians and patients should select nonpharmacologic treatment with superficial heat **(moderate-quality evidence)**, massage, acupuncture, or spinal manipulation **(low-quality evidence)**. If pharmacologic treatment is desired, clinicians and patients should select nonsteroidal anti-inflammatory drugs or skeletal muscle relaxants **(moderate-quality evidence)**. **(Grade: strong recommendation)**

The **UK's National Institute for Health and Care Excellence** in **2017** recommended the following for Non-pharmacological interventions:

- Self-management: Provide people with advice and information, tailored to their needs and capabilities, to help them self-manage their low back pain with or without sciatica, at all steps of the treatment pathway. Include: information on the nature of low back pain and sciatica encouragement to continue with normal activities.
- Exercise: Consider a group exercise programme (biomechanical, aerobic, mind–body or a combination of approaches) within the NHS for people with a specific episode or flare-up of low back pain with or without sciatica. Take people's specific needs, preferences and capabilities into account when choosing the type of exercise.
- Orthotics: Do not offer belts or corsets for managing low back pain with or without sciatica. Do not offer foot orthotics for managing low back pain with or without sciatica. Do not offer rocker sole shoes for managing low back pain with or without sciatica.
- Manual therapies: Do not offer traction for managing low back pain with or without sciatica. Consider manual therapy (spinal manipulation, mobilisation or soft tissue techniques such as massage) for managing low back pain with or without sciatica, but only as part of a treatment package including exercise, with or without psychological therapy.
- Acupuncture: Do not offer acupuncture for managing low back pain with or without sciatica.
- Electrotherapies: Do not offer ultrasound for managing low back pain with or without sciatica. Do not offer percutaneous electrical nerve simulation (PENS) for managing low back pain with or without sciatica. Do not offer transcutaneous electrical nerve simulation (TENS) for managing low back pain with or without sciatica. Do not offer interferential therapy for managing low back pain with or without sciatica.
- Psychological therapy: Consider psychological therapies using a cognitive behavioural approach for managing low back pain with or without sciatica but only as part of a treatment package including exercise, with or without manual therapy (spinal manipulation, mobilisation or soft tissue techniques such as massage).
- Combined physical and psychological programmes: Consider a combined physical and psychological programme, incorporating a cognitive behavioural approach (preferably in a group context that takes into account a person's specific needs and capabilities), for people with persistent low back pain or sciatica: when they have significant psychosocial obstacles to recovery (for example, avoiding normal activities based on inappropriate beliefs about their condition) or when previous treatments have not been effective.
- Return-to-work programmes: Promote and facilitate return to work or normal activities of daily living for people with low back pain with or without sciatica.

**(Level of evidence not included)**

**American Osteopathic Association 2016** guideline included following algorithm that includes recommendations for osteopathic manipulative treatment (OMT) **(Level of evidence not included).**




The **2014 Health Evidence Review Commission (HERC) Lower Back Pain: Non-Pharmacological/Non-Invasive Interventions** guideline recommends self-care for pain </= 4 weeks and for those who do not improve with self-care, spinal manipulation is recommended for coverage. For pain > 4 weeks duration acupuncture, cognitive-behavioral therapy, exercise therapy, intensive interdisciplinary rehabilitation, massage therapy, progressive relaxation, spinal manipulation and yoga (viniyoga) are commented for coverage. Continuous or intermittent traction and transcutaneous electrical nerve stimulation are not recommended for coverage. **(Level of evidence not provided)**

The **Institute for Clinical Systems Improvement 2012** guideline on low back pain, adult acute and subacute stated the following:

Core Treatment Plan:

- Clinicians should educate patients as an adjunct to other treatment. No standardized form of education is suggested **[Strong Recommendation, Moderate Quality Evidence]**.
- Heat should be used for pain relief **[Strong Recommendation, Moderate Quality Evidence]**.
- Cold therapy is not recommended for low back pain **[Weak Recommendation, Low Quality Evidence]**.

- Clinicians should advise patients with acute and subacute low back pain to stay active and continue activities of daily living within the limits permitted by their symptoms **[Strong Recommendation, Moderate Quality Evidence]**.
- Exercise should be recommended to reduce the recurrence of low back pain. However, no specific exercise is preferred **[Strong Recommendation, Moderate Quality Evidence]**.
- Clinicians should not recommend bed rest for patients with low back pain **[Strong Recommendation, Moderate Quality Evidence]**.
- Clinicians should not prescribe or recommend traction for the treatment of acute low back pain **[Weak Recommendation, Low Quality Evidence]**.

Early Acute Phase Treatment Considerations:

- Spinal manipulative therapy should be considered in the early intervention of low back pain **[Strong Recommendation, Moderate Quality Evidence]**.
- At this point evidence is not sufficient to strongly recommend the clinical prediction rule. However, studies are currently underway which may add further support. Therefore, the work group suggests consideration of the clinical prediction rule in the category of early low back pain patients **[Weak Recommendation, Low Quality Evidence]**.

Subacute Phase Treatment:

- Delayed-recovery risk assessment is not fully developed; however, much progress has been made and it is recommended that the clinician use one or more approaches to identify a patient who is at risk and intervene with specific interventions **[Weak Recommendation, Low Quality Evidence]**.
- Exercise is recommended in the treatment of subacute low back pain **[Strong Recommendation, Moderate Quality Evidence]**.
- Spinal manipulative therapy should be considered in the early intervention of low back pain **[Strong Recommendation, Moderate Quality Evidence]**.
- Clinicians should consider cognitive behavioral therapy in the treatment of subacute low back pain **[Weak Recommendation, Moderate Quality Evidence]**.
- Acupuncture may be used as an adjunct treatment for subacute low back pain **[Weak Recommendation, Low Quality Evidence]**.

The **2012 American Physical Therapy Association** recommended the following:

- MANUAL THERAPY: Clinicians should consider utilizing thrust manipulative procedures to reduce pain and disability in patients with mobility deficits and acute low back and back-related buttock or thigh pain. Thrust manipulative and nonthrust mobilization procedures can also be used to improve spine and hip mobility and reduce pain and disability in patients with subacute and chronic low back and back-related lower extremity pain. **(Recommendation based on strong evidence.)**
- TRUNK COORDINATION, STRENGTHENING, AND ENDURANCE EXERCISES: Clinicians should consider utilizing trunk coordination, strengthening, and endurance exercises to reduce low back pain and disability in patients with subacute and chronic low back pain with movement coordination impairments and in patients post lumbar microdiscectomy. **(Recommendation based on strong evidence.)**
- CENTRALIZATION AND DIRECTIONAL PREFERENCE EXERCISES AND PROCEDURES: Clinicians should consider utilizing repeated movements, exercises, or procedures to promote centralization to reduce symptoms in patients with acute low back pain with related (referred) lower extremity pain. Clinicians should consider using repeated exercises in a specific direction determined by treatment response to improve mobility and reduce symptoms in patients with acute, subacute, or chronic low back pain with mobility deficits. **(Recommendation based on strong evidence.)**
- LOWER-QUARTER NERVE MOBILIZATION PROCEDURES: Clinicians should consider utilizing lower-quarter nerve mobilization procedures to reduce pain and disability in patients with subacute and chronic low back pain and radiating pain. **(Recommendation based on weak evidence.)**

- TRACTION: There is conflicting evidence for the efficacy of intermittent lumbar traction for patients with low back pain. There is preliminary evidence that a subgroup of patients with signs of nerve root compression along with peripheralization of symptoms or a positive crossed straight leg raise will benefit from intermittent lumbar traction in the prone position. There is moderate evidence that clinicians should not utilize intermittent or static lumbar traction for reducing symptoms in patients with acute or subacute, nonradicular low back pain or patients with chronic low back pain. **(Recommendation based on conflicting evidence.)**
- PATIENT EDUCATION AND COUNSELING: Clinicians should not utilize patient education and counseling strategies that either directly or indirectly increase the perceived threat or fear associated with low back pain, such as education and counseling strategies that (1) promote extended bed-rest or (2) provide in-depth, pathoanatomical explanations for the specific cause of the patient's low back pain. Patient education and counseling strategies for patients with low back pain should emphasize (1) the promotion of the understanding of the anatomical/structural strength inherent in the human spine, (2) the neuroscience that explains pain perception, (3) the overall favorable prognosis of low back pain, (4) the use of active pain coping strategies that decrease fear and catastrophizing, (5) the early resumption of normal or vocational activities, even when still experiencing pain, and (6) the importance of improvement in activity levels, not just pain relief. **(Recommendation based on moderate evidence.)**

In **2007, the American College of Physicians and American Pain Society** recommended for patients who do not improve with selfcare options, clinicians should consider the addition of nonpharmacologic therapy with proven benefits—for acute low back pain, spinal manipulation; for chronic or subacute low back pain, intensive interdisciplinary rehabilitation, exercise therapy, acupuncture, massage therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation **(weak recommendation, moderate-quality evidence)**.

References:


1. (2016). "American Osteopathic Association Guidelines for Osteopathic Manipulative Treatment (OMT) for Patients With Low Back Pain." Journal of the American Osteopathic Association **116**(8): 536-549.
2. Bernstein, I. A., et al. (2017). "Low back pain and sciatica: summary of NICE guidance." BMJ 356.
3. Chou, R., et al. (2007). "Diagnosis and treatment of low back pain: a joint clinical practice guideline from the American College of Physicians and the American Pain Society." Annals of Internal Medicine **147**(7): 478-491.
4. Delitto, A., et al. (2012). "Low Back Pain: Clinical Practice Guidelines Linked to the International Classification of Functioning, Disability, and Health from the Orthopaedic Section of the American Physical Therapy Association." The Journal of orthopaedic and sports physical therapy **42**(4): A1-57.
5. Goertz M., et al., (2012). Low back pain, adult acute and subacute. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI). Nov. 91 p.
6. Health Evidence Review Commission (HERC) . (2014). Lower Back Pain: Non-Pharmacological/Non-Invasive Interventions. Retrieved from http://www.oregon.gov/oha/HPA/CSI-HERC/EvidenceBasedReports/Low-Back-Pain-Non-Pharmacologic-Non-Invasive-Interventions-11-13-14.pdf
7. Institute for Clinical Systems Improvement (ISCI). (2018). Low Back Pain, Adult Acute and Subacute. Retrieved from https://www.icsi.org/_asset/3v2nvw/LBP-03.18.pdf
8. Qaseem, A., et al. (2017). "Noninvasive treatments for acute, subacute, and chronic low back pain: A clinical practice guideline from the American college of physicians." Annals of Internal Medicine **166**(7): 514-530.

**Primary Literature:**

***Agency for Healthcare Research and Quality 2016 Comparative Effectiveness Review:***

Evidence on the effectiveness of nonpharmacological therapies for acute low back pain was limited. There was limited evidence that spinal manipulation, heat, massage, and low-level laser therapy are associated with some beneficial effects versus a sham therapy, no intervention, or usual care. Effects on pain or function were moderate for exercise, massage, and heat, and otherwise small.

**Summary of evidence for nonpharmacological treatments versus sham, no treatment, or usual care for acute or subacute low back pain**

| Intervention | Pain: Magnitude of Effect | Pain: Evidence | Pain: SOE | Function: Magnitude of Effect | Function: Evidence | Function: SOE |
|---|---|---|---|---|---|---|
| Exercise vs. usual care | Moderate | 1 SR (3 RCTs) + 3 RCTs | Low | Moderate | 1 SR (3 RCTs) + 3 RCTs | Low |
| Acupuncture vs. sham | Small | 2 RCTs | Low | No effect | 5 RCTs | Low |
| Massage vs. sham | Moderate | 1 SR (2 RCTs) | Low | Moderate | 1 SR (2 RCTs) | Low |
| Massage vs. usual care | Small to no effect | 2 RCTs | Low | Small to no effect | 2 RCTs | Low |
| Spinal manipulation vs. sham | Small | 2 RCTs | Low | No effect | 1 SR (3 RCTs) | Low |
| Heat wrap vs. placebo | Moderate | 1 SR (2 RCTs) + 2 RCTs | Moderate | Moderate | 1 SR (2 RCTs) | Moderate |
| Low-level laser therapy plus NSAID vs. sham plus NSAID | Moderate | 1 RCT | Low | Small | 1 RCT | Low |
| Lumbar supports vs. no lumbar supports or inactive treatment | Unable to determine | 5 RCTs | Insufficient | Unable to determine | 5 RCTs | Insufficient |

NSAID = nonsteroidal anti-inflammatory drug; RCT = randomized controlled trial; SOE = strength of evidence; SR = systematic review.

**Detailed evidence tables for nonpharmacological treatments**

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| **Nonpharmacological noninvasive therapies** | Exercise | Exercise vs. no exercise, chronic LBP: Pain and function | Moderate | A systematic review found exercise to be associated with greater pain relief vs. no exercise (19 trials; WMD, 10 on a 0 to 100 scale; 95% CI, 1.31 to 19.09), although the effect on function was small and not statistically significant (17 trials; WMD, 3.00 on a 0 to 100 scale; 95% CI, −0.53 to 6.48). Results from a more recent systematic review using more restrictive criteria and from additional trials not included in the systematic reviews were generally consistent with these findings. |

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| | | MCE vs. minimal intervention, chronic LBP: Pain and function | Low | A systematic review included 2 trials that found MCE to be associated with lower pain scores in the short term (WMD, −12.48 on a 0 to 100 scale; 95% CI, −19.04 to −5.93), intermediate term (WMD, −10.18; 95% CI, −16.64 to −3.72), and long term (WMD, −13.32; 95% CI, −19.75 to −6.90) vs. a minimal intervention. MCE was also associated with better function at short term (3 trials; WMD, −9.00 on 0 to 100 scale; 95% CI, −15.28 to −2.73), intermediate term (2 trials; WMD, −5.62; 95% CI, −10.46 to −0.77), and long term (2 trials; WMD, −6.64; 95% CI, −11.72 to −1.57). |
| | | Exercise vs. usual care, nonacute LBP: Work disability | Moderate | A systematic review found no clear effects of exercise therapy versus usual care on likelihood of short- or intermediate-term (~6 months) disability, but exercise was associated with lower likelihood of work disability at long term (~12 months) followup (10 comparisons in 8 trials; OR, 0.66; 95% CI, 0.48 to 0.92). |
| | | Exercise vs. usual care, radicular LBP: Pain and function | Low | Three trials not included in the systematic reviews found effects that favored exercise vs. usual care or no exercise in pain and function, although effects were small. |
| | | MCE vs. general exercise, chronic LBP: Pain and function | Low | A systematic review found MCE to be associated with lower pain intensity at short term (6 trials; WMD, −7.80 on 0 to 100 scale; 95% CI, −10.95 to −4.65) and intermediate term (3 trials; WMD, −6.06; 95% CI, −10.94 to −1.18) vs. general exercise, but effects were smaller and no longer statistically significant at long term (4 trials; WMD, −3.10; 95% CI, −7.03 to 0.83). MCE was also associated with better function in the short term (6 trials; WMD, −4.65 on 0 to 100 scale; 95% CI, −6.20 to −3.11) and long term (3 trials; WMD, −4.72; 95% CI, −8.81 to −0.63). One of 2 subsequent trials found no effect on pain, although effects on function were consistent with the systematic review. |
| | | Exercise vs. exercise, acute or chronic LBP | Moderate | For comparisons involving other types of exercise techniques, there were no clear differences in >20 head-to-head trials of patients with acute or chronic LBP. |

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|---|---|---|---|---|
| **Nonpharmacological noninvasive therapies** | Exercise | Exercise: Adverse events | Low | Harms were poorly reported in trials of exercise. When reported, harms were typically related to muscle soreness and increased pain, or no harms were reported; no serious harms were reported. |

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| | Pilates | Pilates vs. usual care plus physical activity, chronic LBP: Pain and function | Low | A systematic review included 7 trials that found Pilates to be associated with small (mean difference, −1.6 to −4.1 points) or no clear effects on pain at the end of treatment vs. usual care plus physical activity and no clear effects on function. |
| | | Pilates vs. other exercise, chronic LBP: Pain and function | Low | Three trials found no clear differences between Pilates vs. other types of exercise in pain or function. |
| | Tai chi | Tai chi vs. wait list or no tai chi, chronic LBP: Pain and function | Low | Two trials found tai chi to be associated with improved pain-related outcomes vs. wait list or no tai chi (mean differences, 0.9 and 1.3 on a 0 to 10 scale); 1 trial also found tai chi to be associated with better function (mean difference, 2.6 on the RDQ; 95% CI, 1.1 to 3.7). |
| | | Tai chi vs. other exercise, chronic LBP: Pain | Low | One trial found tai chi to be associated with lower pain intensity vs. backward walking or jogging through 6 months (mean differences, −0.7 and −0.8), but there were no differences vs. swimming. |
| | | Tai chi: Adverse events | Low | One trial of tai chi reported a small temporary increase in back pain symptoms, and 1 trial reported no harms. |
| | Yoga | Yoga vs. usual care, chronic LBP: Pain and function | Low | One trial found Iyengar yoga to be associated with lower pain scores (24 vs. 37 on a 0–100 VAS; p <0.001) and better function (18 vs. 21 on the 0 to 100 ODI; p <0.01, on a 0 to 100 scale) vs. usual care at 24 weeks. |
| | | Yoga vs. exercise, chronic LBP: Pain and function | Low | A systematic review found yoga to be associated with lower pain intensity and better function vs. exercise in most trials, although effects were small and differences were not always statistically significant (5 trials). |
| | | Yoga vs. education, chronic LBP: Pain and function | Moderate | Yoga was associated with lower short-term pain intensity vs. education (5 trials; SMD, −0.45; 95% CI, −0.63 to −0.26; I2 = 0%), but effects were smaller and not statistically significant at long term followup (4 trials; SMD, −0.28; 95% CI, −0.58 to −0.02; I2 = 47%);<br>yoga was also associated with better function at short-term (5 trials; SMD, 0.45; 95% CI, −0.65 to −0.25; I2 = 8%) and long-term followup<br>(4 trials; SMD, 0.39; 95% CI, −0.66 to −0.11; I2 = 40%). |
| | | Yoga: Adverse events | Low | Reporting of harms was suboptimal, but adverse events, when reported, were almost all classified as mild to moderate. |

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| **Nonpharmacological noninvasive therapies** | Psychological therapies | Progressive relaxation vs. wait-list control, chronic LBP: Pain and function | Low | A systematic review found progressive relaxation superior to wait-list control for post-treatment pain intensity (3 trials; mean difference, −19.77 on 0 to 100 VAS; 95% CI, −34 to −5.20; I2 = 57%) and functional status (3 trials; SMD, −0.88; 95% CI, −1.36 to −0.39; I2 = 0%) |
| | | EMG biofeedback, chronic LBP: Pain and function | Low | A systematic review found EMG biofeedback to be associated with lower pain intensity at the end of treatment (3 trials; SMD, −0.80; 95% CI, −1.32 to −0.28; I2 = 0%), with no clear effect on function (3 trials). |
| | | Operant therapy, chronic LBP: Pain and function | Low | A systematic review found operant therapy to be associated with lower pain intensity at the end of treatment (3 trials; SMD, −0.43; 95% CI, −0.75 to −0.1; I2 = 0%), with no clear effect on function (2 trials). |
| | | Cognitive therapy vs. wait-list control, chronic LBP | Insufficient | There was insufficient evidence from 2 trials to determine effects of cognitive therapy vs. wait-list control due to inconsistency and imprecision. |
| | | Cognitive-behavioral and other combined therapy vs. wait-list control, chronic LBP: Pain and function | Low | A systematic review found cognitive-behavioral and other combined psychological therapy to be associated with greater improvements in post-treatment pain intensity compared with wait-list control (5 trials; SMD, −0.60; 95% CI, −0.97 to −0.22; I2 = 40%), but effects on function were smaller and not statistically significant (4 trials; SMD, −0.37; 95% CI, −0.87 to 0.13; I2 = 50%). |
| | | Psychological therapies vs. exercise or physical therapy, chronic LBP: Pain and function | Low | A systematic review found no clear differences between psychological therapies vs. exercise therapy in pain intensity (2 trials) or between psychological therapies plus physiotherapy vs. physiotherapy alone (6 trials) in pain or function, although 1 small subsequent trial found combination therapy to be associated with greater improvements in pain and function immediately after treatment. |
| | | Psychological therapies vs. psychological therapies: Pain and function | Moderate | Ten trials found no clear differences among different psychological therapies in pain or function. |
| | | Psychological therapies: Adverse events | Low | Harms were not well reported, but no included trial reported any adverse events associated with psychological therapies. |

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| **Nonpharmacological noninvasive therapies** | Multidisciplinary rehabilitation | Multidisciplinary rehabilitation vs. usual care, chronic LBP: Pain, function, return to work | Moderate | A systematic review found multidisciplinary rehabilitation, compared with usual care, to be associated with lower short-term pain intensity (9 trials; SMD, −0.55; 95% CI, −0.83 to −0.28; I2 = 72%, or ~1.4-point mean difference on a 0 to 10 point numeric rating scale) and disability (9 trials; SMD, −0.41; 95% CI, −0.62 to −0.19; I2 = 58%, or ~2.5-point mean difference on the RDQ); effects on long-term pain intensity and disability also favored multidisciplinary rehabilitation but were smaller (7 trials; SMD, −0.21; 95% CI, −0.37 to −0.04; I2 = 25% and 6 trials; SMD,−0.23; 95% CI, −0.40 to −0.06; I2 = 19%, respectively), with no difference in likelihood of return to work (7 trials; OR, 1.04; 95% CI, 0.73 to 1.47; I2 = 31%). |
| | | Multidisciplinary rehabilitation vs. no multidisciplinary rehabilitation, chronic LBP: Pain and function | Low | A systematic review found multidisciplinary rehabilitation, compared with no multidisciplinary rehabilitation, to be associated with lower short-term pain intensity (3 trials; SMD, −0.73; 95% CI, −1.22 to −0.24; I2 = 64%, or ~1.7-point mean difference on a 0 to 10 numeric rating scale) and disability (3 trials; pooled SMD, −0.49; 95% CI, −0.76 to −0.22; I2 = 0%, or ~2.9-point mean difference on the RDQ); there was insufficient evidence to assess effects on long-term outcomes. |
| | | Multidisciplinary rehabilitation vs. physical therapy, chronic LBP: Pain and function | Moderate | A systematic review found multidisciplinary rehabilitation, compared with nonmultidisciplinary physical therapy, to be associated with lower short-term pain intensity (12 trials; SMD, −0.30; 95% CI, −0.54 to −0.06; I2 = 80%, or an approximate 0.6-point mean difference on a 0 to 10 point numeric rating scale) and disability (13 trials; SMD, −0.39; 95% CI, −0.68 to −0.10; I2 = 88%, or an approximate 1.2-point mean difference on the RDQ); multidisciplinary rehabilitation was also associated with lower long-term pain intensity (9 trials; SMD, −0.51; 95% CI, −1.04 to 0.01; I2 = 92%) and function (10 trials; SMD, −0.68; 95% CI, −1.19 to −0.16; I2 = 94%) and greater likelihood for return to work (8 trials; OR, 1.87; 95% CI, 1.39 to 2.53; I2 = 0%). |
| | | Multidisciplinary rehabilitation, acute LBP, radicular LBP | Insufficient | No study evaluated the effectiveness of multidisciplinary rehabilitation for acute LBP or for radicular LBP. |
| | | Multidisciplinary rehabilitation: Adverse events | Low | Harms were poorly reported in trials of multidisciplinary rehabilitation, although no serious harms were reported. |

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| **Nonpharmacological noninvasive therapies** | Acupuncture | Acupuncture vs. sham acupuncture, subacute LBP: Pain | Low | A systematic review found acupuncture to be associated with lower pain intensity vs. sham acupuncture using nonpenetrating needles (2 trials; mean difference, 9.38 on a 0 to 100 VAS; 95% CI, 1.76 to 17.0; I2 = 27%); 3 other trials reported effects consistent with these findings. One trial of sham acupuncture using penetrating needles to nonacupuncture points found no effect on pain. There were no clear effects on function in 5 trials. |
| | | Acupuncture vs. sham acupuncture, chronic LBP: Pain and function | Moderate | A systematic review found acupuncture to be associated with lower pain intensity vs. sham acupuncture (superficial needling at acupuncture or nonacupuncture points or nonpenetrating pressure at acupuncture points) immediately at the end of treatment (4 trials; WMD, −16.76; 95% CI, −33.3 to −0.19; I2 = 90%) and at up to 12 weeks (3 trials; WMD, −9.55; 95% CI, −16.5 to −2.58; I2 = 40%), but there were no differences in function. Four additional trials reported results consistent with these findings. |
| | | Acupuncture vs. no acupuncture, chronic LBP | Moderate | A systematic review found acupuncture to be associated with lower pain intensity (4 trials; SMD, −0.72; 95% CI, −0.94 to −0.49; I2 = 51%) and better function (3 trials; SMD, −0.94; 95% CI, −1.41 to −0.47; I2 = 78%) immediately after treatment vs. no acupuncture. Mean effects on pain ranged from 7 to 24 points on a 0 to 100 point scale; for function, 1 trial reported a difference of 8 points on a 0 to 100 scale and the other 2 trials showed small or no clear differences at long-term followup. |
| | | Acupuncture vs. NSAIDs, acute LBP: Overall improvement | Low | A systematic review found acupuncture to be associated with slightly greater likelihood of overall improvement vs. NSAIDs at the end of treatment (5 trials; RR, 1.11; 95% CI, 1.06 to 1.16; I2 = 0%). |
| | | Acupuncture vs. medications (NSAIDs, muscle relaxants and analgesics), chronic LBP: Pain and function | Low | A systematic review found acupuncture to be associated with better pain relief (3 trials; WMD, −10.56 on a 0 to 100 scale; 95% CI, −20.34 to −0.78; I 2 = 0%) and improvement in function (3 trials; SMD, −0.36; 95% CI, −0.67 to −0.04; I2 = 7%) immediately postintervention. |
| | | Acupuncture: Adverse events | Low | Harms of acupuncture were poorly reported in the trials, although no serious adverse events were reported. |
| | Massage | Massage vs. sham massage, acute LBP: Pain and function | Low | A systematic review included 2 trials that found massage to be associated with greater short-term (1 week) improvement in pain (SMD, −0.92; 95% CI, −1.35 to −0.48) and function (SMD, −1.76; 95% CI, −3.19 to −0.32) vs. sham therapy, but there was no difference in pain or function at 5 weeks in 1 trial. |

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| **Nonpharmacological noninvasive therapies** | Massage | Massage vs. usual care, chronic LBP: Pain and function | Low | One trial found no difference between foot reflexology vs. usual care in pain or function, and 1 trial found structural or relaxation massage to be associated with better function (mean, 2.5 to 2.9 points on the RDQ) vs. usual care at 10 weeks; effects were less pronounced at 52 weeks. |
| | | Massage vs. other interventions, subacute to chronic LBP: Pain and function | Moderate | A systematic review found massage to be associated with better effects on short-term pain in 7 of 9 trials (mean differences, −0.6 to −0.94 points on a 0 to 10 scale) and better effects on short-term function in 3 of 4 trials. |
| | | Massage plus another active intervention vs. the other intervention alone, subacute to chronic LBP: Pain and function | Low | A systematic review included 5 trials that generally found massage plus another intervention to be superior to the other intervention without massage for short-term pain, with effects somewhat stronger in trials in which massage was combined with exercise; few differences were observed for function or long-term pain.<br>Two subsequent trials of massage plus exercise reported findings generally consistent with these findings. |
| | | Massage vs. massage: Pain and function | Insufficient | Comparisons of different massage techniques were too heterogeneous and effects were too small from 6 trials to determine effects on pain and function. |
| | | Massage: Adverse events | Low | Harms were not well reported in trials of massage, although no serious adverse events were reported; 2 trials reported soreness during or shortly after the treatment. |
| | Spinal manipulation | Spinal manipulation, acute LBP: Pain and function | Low for function, insufficient for pain | Two trials (1 included in a systematic review) found spinal manipulation to be associated with better effects on function vs. sham manipulation (statistically significant in 1 trial); in 1 trial, effects on pain favored manipulation but were small and not statistically significant (mean difference, −0.50; 95% CI, −1.39 to 0.39). |
| | | Spinal manipulation vs. sham manipulation, chronic LBP: Pain and function | Low for pain, insufficient for function | A systematic review found spinal manipulation to be associated with small, statistically nonsignificant effects vs. sham manipulation on pain at 1 month (3 trials; WMD, −3.24; 95% CI, −13.62 to 7.15 on a 0 to 100 scale; I2 = 53%); 1 trial reported similar results for function (SMD, −0.45; 95% CI, −0.97 to 0.06); 1 trial not included in the systematic review reported generally consistent results. |

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| | | Spinal manipulation vs. inert treatment, acute LBP: Pain and function | Low | A systematic review found no differences between spinal manipulation vs. inert treatment in pain relief at 1 week (3 trials; WMD, 0.14 on a 0 to 10 scale; 95% CI, −0.69 to 0.96; I2 = 27%), although 1 trial found spinal manipulation to be associated with better long term pain relief (mean difference, −1.20 at 3 months; 95% CI, 2.11 to −0.29); there were no differences in function at 1 week (2 trials; SMD, −0.08; 95% CI, −0.37 to 0.21; I2 = 0%) or at 3 months (1 trial; SMD, −0.28; 95% CI, −0.59 to 0.02). |

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| **Nonpharmacological noninvasive therapies** | Spinal manipulation | Spinal manipulation vs. inert treatment, chronic LBP | Low | One trial with low risk of bias found spinal manipulation to be associated with greater improvement in the “main complaint” vs. an inert treatment (mean difference, 0.9 on a 0 to 10 scale; 95% CI, 0.1 to 1.7); results from 3 trials with high risk of bias and 3 additional trials not included in the systematic review were somewhat inconsistent, although some trials reported effects that favored manipulation. |
| | | Spinal manipulation vs. other active interventions, acute LBP: Pain and function | Moderate | A systematic review found no difference between spinal manipulation vs. other active interventions in pain relief at 1 week (3 trials; WMD, 0.06 on a 0 to 10 scale; 95% CI, −0.53 to 0.65; I2 = 0%), 1 month (3 trials; WMD, −0.15; 95% CI, −0.49 to 0.18; I2 = 0%), 3 to 6 months (2 trials; WMD, −0.20; 95% CI, −1.13 to 0.73; I2 = 81%), or 1 year (1 trial; mean difference, 0.40; 95% CI, −0.08 to 0.88). Findings were similar for function, with no differences observed at any timepoint. A subsequent trial of patients with acute or subacute LBP found that spinal manipulation was associated with moderate effects vs. usual care on pain and small effects on function at short-term followup, but effects were smaller and no longer statistically significant at 3 and 6 months. |

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| | | Spinal manipulation vs. other interventions, chronic LBP: Pain and function | Moderate | A systematic review found spinal manipulation to be associated with better short-term pain relief vs. other active interventions at 1 month (10 comparisons from 6 trials; WMD, −2.76 on a 0 to 100 scale; 95% CI, −5.19 to −0.32; I2 = 27%) and 6 months (7 comparisons from 4 trials; WMD, −3.07; 95% CI, −5.42 to −0.71; I2 = 0%), although the magnitude of effects was below the small/slight threshold. There was no difference at 12 months (3 trials; WMD, −0.76; 95% CI, −3.19 to 1.66; I2 = 0%). Manipulation was also associated with greater improvement in function vs. other active interventions at 1 month (10 comparisons from 6 trials; SMD, −0.17; 95% CI, −0.29 to −0.06; I2 = 3%); effects were smaller and no longer statistically significant at 6 and 12 months. Three trials not included in the systematic reviews reported results consistent with these findings. |
| | | Spinal manipulation plus exercise or advice vs. exercise or advice alone, acute LBP: Function | Low | Four trials in a systematic review found spinal manipulation plus either exercise or advice to be associated with greater improvement in function at 1 week (SMD, −0.41; 95% CI, −0.73 to −0.10; I2 = 18%) vs. exercise or advice alone, but there were no differences at 1 month (3 trials; SMD, −0.09; 95% CI, −0.39 to 0.21; I2 = 37%) or 3 months (2 trials; SMD, −0.22; 95% CI, −0.61 to 0.16; I2 = 41%). |

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| **Nonpharmacological noninvasive therapies** | Spinal manipulation | Spinal manipulation plus another active treatment, chronic LBP: Pain and function | Low | A systematic review found spinal manipulation plus another active treatment to be associated with greater pain relief at 1 month (3 trials; WMD, −5.88 on a 0 to 100 scale; 95% CI, −10.85 to −0.90; I2 = 0%), 3 months (2 trials; mean difference, −7.23; 95% CI, −11.72 to −2.74; I2 = 43%), and 12 months (2 trials; mean difference, −3.31; 95% CI, −6.60 to −0.02; I2 = 12%) vs. the other treatment alone. Combination therapy was also associated with better function at 1 month, (2 trials; SMD, −0.40; 95% CI, −0.73 to −0.07; I2 = 0%), 3 months (2 trials; SMD, −0.22; 95% CI, −0.38 to −0.06; I2 = 33%), and 12 months (2 trials; SMD, −0.21; 95% CI, −0.34 to −0.09; I2 = 0%). One trial not included in the systematic review reported results consistent with these findings. |
| | | Spinal manipulation plus home exercise and advice, radicular LBP | Low | One good-quality trial found spinal manipulation plus home exercise and advice to be associated with greater improvement in leg and back pain at 12 weeks vs. home exercise and advice alone (mean differences about 1 point on a 0 to 10 scale), but effects were smaller (0.3 to 0.7 points) and no longer statistically significant at 52 weeks. |

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| | | Spinal manipulation: Adverse events | Low | Harms were not reported well in most trials of spinal manipulation. No serious adverse events were reported, and most adverse events were related to muscle soreness or transient increases in pain. |
| | Ultrasound | Ultrasound vs. sham ultrasound, chronic LBP: Pain and function | Low for pain, insufficient for function | A systematic review found no difference between ultrasound vs. sham ultrasound in pain at the end of treatment (3 trials; mean difference, −7.12 on 0 to 100 scale; 95% CI, −18.0 to 3.75; I2 = 77%), and 2 trials found no effects on pain 4 weeks after the end of treatment. Evidence from 5 trials was too inconsistent to determine effects on function, although a larger good-quality trial found no effect on the RDQ. |
| | | Ultrasound vs. no ultrasound, chronic LBP: Pain and function | Low | A systematic review found no differences between ultrasound vs. no ultrasound in pain (2 trials; mean difference, −2.16; 95% CI, −4.66 to 0.34; I2 = 0%) or back-specific function (2 trials; mean difference, −0.41; 95% CI, −3.14 to 2.32), but estimates were imprecise. |
| | | Ultrasound plus exercise vs. exercise, chronic LBP: Pain and function | Insufficient | Evidence from 3 trials was insufficient to determine effects of ultrasound plus exercise vs. exercise alone on pain or function due to imprecision and methodological shortcomings. |
| | | Ultrasound plus exercise vs. exercise, radicular LBP: Back pain, leg pain | Insufficient | A small trial found no differences between ultrasound plus exercise vs. sham ultrasound plus exercise in back pain, leg pain, or the ODI after 3 weeks of therapy. |
| | | Ultrasound vs. other interventions | Insufficient | There was insufficient evidence from 3 small trials with methodological shortcomings to determine effects of ultrasound vs. other interventions. |

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| **Nonpharmacological noninvasive therapies** | Ultrasound | Ultrasound vs. other interventions, radiculopathy | Insufficient | There was insufficient evidence from 2 small trials with methodological shortcomings to determine effects of ultrasound vs. other interventions. |
| | | Ultrasound, acute nonradicular LBP | Insufficient | No study evaluated the effectiveness of ultrasound for acute nonradicular LBP. |
| | | Ultrasound vs. sham ultrasound: Adverse events | Low | One trial found no differences between ultrasound vs. sham ultrasound in risk of any adverse event (6.0% vs. 5.9%; RR, 1.03; 95% CI, 0.49 to 2.13) or serious adverse events (1.3% vs. 2.7%; RR, 0.48; 95% CI, 0.12 to 1.88). |
| | Transcutaneous electrical nerve stimulation | TENS vs. sham TENS, acute or subacute LBP: Pain and function | Insufficient | Evidence from single trials with methodological shortcomings was too limited to permit reliable conclusions regarding effectiveness. |

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| | | TENS vs. sham TENS, chronic LBP: Pain and function | Low | A systematic review found no differences between TENS vs. sham TENS in pain intensity (4 trials; WMD, −4.47 on a 0 to 100 scale; 95% CI, −12.84 to 3.89) or function (2 trials; WMD, −1.36 on a 0 to 100 scale; 95% CI, −4.38 to 1.66) at short-term followup; most trials found no effect on pain or function at the end of a course of treatment. |
| | | TENS vs. acupuncture, chronic LBP: Pain | Low | A systematic review found no differences between TENS vs. acupuncture for short- (4 trials; SMD, 0.15; 95% CI, −0.33 to 0.63) or long-term pain (2 trials; SMD, 0.32; 95% CI, −0.33 to 0.96). Evidence for TENS vs. other interventions was too limited to permit reliable conclusions. |
| | | TENS: Adverse events | Low | Evidence on harms associated with TENS was limited but suggests an increased risk of skin-site reactions without an increased risk of serious adverse events. |
| | Electrical muscle stimulation | EMS plus exercise vs. exercise, EMS vs. other interventions, acute or chronic LBP: Pain and function | Insufficient | There was insufficient evidence from 5 RCTs to determine effects of EMS plus exercise vs. exercise alone or vs. other interventions due to methodological limitations and imprecision. |
| | | EMS: Adverse events | Insufficient | There was insufficient evidence to determine harms of EMS. |
| | Percutaneous electrical nerve stimulation | PENS vs. sham PENS, PENS plus exercise vs. exercise, PENS vs. other interventions, chronic LBP (with or without radiculopathy) | Insufficient | There was insufficient evidence from 7 trials to determine effects of PENS vs. sham, PENS plus exercise vs. exercise alone, or PENS vs. other interventions due to methodological limitations, inconsistency, and imprecision. |
| | | PENS: Adverse events | Insufficient | Harms were poorly reported in trials of PENS. |

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| **Nonpharmacological noninvasive therapies** | Interferential therapy | IFT vs. other interventions, IFT plus another intervention vs. the other intervention, subacute to chronic LBP: Pain and function | Insufficient | There was insufficient evidence from 4 trials to determine effects of IFT vs. other interventions or IFT plus another intervention vs. the other intervention alone, due to methodological limitations and imprecision. |
| | | IFT: Adverse events | Insufficient | No study evaluated harms of IFT. |

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| | Superficial heat or cold | Heat wrap vs. placebo, acute or subacute LBP: Pain and function | Moderate | A systematic review found a heat wrap to be more effective than placebo for pain relief at 5 days (2 trials; mean difference, 1.06 on a 0 to 5 scale; 95% CI, 0.68 to 1.45) and disability at 4 days (mean difference, −2.10 on the RDQ; 95% CI, −3.19 to −1.01). Two subsequent trials also found a heat wrap to be associated with decreased pain intensity at 3 to 4 days (differences, 16 to 20 points on a 0 to 100 point VAS) or increased pain relief at 8 hours (difference, ~1.5 points on a 0 to 5 scale). Another trial found a heat wrap during emergency transport to be associated with substantially lower pain intensity vs, an unheated blanket on arrival to the hospital. |
| | | Heat plus exercise vs. exercise alone, acute LBP: Pain and function | Low | One higher quality trial found heat plus exercise to be associated with greater pain relief (mean difference, 1.40 on 0 to 10 scale; 95% CI, 0.69 to 2.11) and higher function (mean RDQ difference, −3.20; 95% CI, −5.42 to −0) vs. exercise without heat at day 7. |
| | | Heat plus NSAID vs. NSAID alone, acute LBP: Pain | Insufficient | One fair-quality trial found heat plus an NSAID to be associated with better pain scores versus an NSAID without heat at day 15 based on the McGill Pain Questionnaire (scoring methods unclear). |
| | | Heat vs. simple analgesics, acute or subacute LBP: Pain and function | Low | A systematic review included 1 trial that found heat to be more effective for pain relief than acetaminophen (mean difference, 0.90 on a 0 to 10 scale; 95% CI, 0.50 to 1.30) or ibuprofen (0.65; 95% CI, 0.25 to 1.05) after 1 to 2 days of treatment; the heat wrap was also associated with greater improvement on the RDQ (mean differences, 2.00 on a 0 to 24 scale; 95% CI, 0.86 to 3.14, and 2.20; 95% CI, 1.11 to 3.29, respectively). |
| | | Heat vs. exercise, acute LBP: Pain and function | Low | A systematic review included 1 trial that found no clear differences between heat vs. exercise in pain relief or function. |
| | | Superficial cold vs. placebo | Insufficient | No study compared superficial cold vs. placebo or no cold treatment. |
| | | Cold plus naproxen vs. naproxen alone, acute LBP: Pain | Insufficient | One small trial with methodological shortcomings found cold plus naproxen to be associated with better pain scores vs. naproxen alone based on the McGill Pain Questionnaire (scoring methods unclear) |

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| **Nonpharmacological noninvasive therapies** | Superficial heat or cold | Heat vs. cold | Insufficient | There was insufficient evidence from 3 trials to determine effects of heat vs. cold due to methodological limitations and imprecision. |
| | | Heat vs. no heat or placebo: Adverse events, flushing | Low | Heat was not associated with increased risk of skin flushing vs. no heat or placebo in 2 trials; no serious adverse events were reported with use of heat. |

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| | | LLLT vs. sham laser, acute LBP | Insufficient | There was insufficient evidence from 1 trial to determine effectiveness of LLLT vs. sham laser due to serious methodological shortcomings and imprecision. |
| | | LLLT vs. sham laser, chronic LBP: Pain and function | Low | Three of 4 trials found LLLT to be more effective than sham laser for pain, although methods for assessing pain and duration of followup varied; 2 trials found LLLT to be more effective than sham laser for function, with small magnitude of effect. |
| | | LLLT plus NSAID vs. sham plus NSAID, acute or subacute LBP: Pain and function | Low | One trial found LLLT plus an NSAID to be associated with lower pain intensity vs. sham laser plus an NSAID or the NSAID alone (mean differences, 9 to 14 points on a 0 to 100 VAS); effects on the ODI also favored combination treatment but were smaller (differences <6 points). |
| | | LLLT plus another intervention vs. the other intervention alone, chronic LBP: Pain and function | Insufficient | There was insufficient evidence from 3 trials to determine effects of LLLT plus exercise vs. sham laser plus exercise alone due to methodological shortcomings and inconsistency. |
| | | LLLT vs. another intervention: Pain and function | Insufficient | There was insufficient evidence to determine effects of LLLT vs. another intervention due to methodological shortcomings and imprecision. |
| | | LLLT, differing wavelengths or doses | Insufficient | There was insufficient evidence to determine effects of different wavelengths or doses of LLLT due to methodological limitations and imprecision. |
| | | LLLT: Adverse events | Low | Harms were not well reported in trials of LLLT, but no serious adverse events and no harms were reported. |

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| **Nonpharmacological noninvasive therapies** | Low- level laser therapy | LLLT vs. sham laser, acute LBP | Insufficient | There was insufficient evidence from 1 trial to determine effectiveness of LLLT vs. sham laser due to serious methodological shortcomings and imprecision. |
| | | LLLT vs. sham laser, chronic LBP:<br>Pain and function | Low | Three of 4 trials found LLLT to be more effective than sham laser for pain, although methods for assessing pain and duration of followup varied; 2 trials found LLLT to be more effective than sham laser for function, with small magnitude of effect. |
| | | LLLT plus NSAID vs. sham plus NSAID, acute or subacute LBP: Pain and function | Low | One trial found LLLT plus an NSAID to be associated with lower pain intensity vs. sham laser plus an NSAID or the NSAID alone (mean differences, 9 to 14 points on a 0 to 100 VAS); effects on the ODI also favored combination treatment but were smaller (differences <6 points). |

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| | | LLLT plus another intervention vs. the other intervention alone, chronic LBP: Pain and function | Insufficient | There was insufficient evidence from 3 trials to determine effects of LLLT plus exercise vs. sham laser plus exercise alone due to methodological shortcomings and inconsistency. |
| | | LLLT vs. another intervention:<br>Pain and function | Insufficient | There was insufficient evidence to determine effects of LLLT vs. another intervention due to methodological shortcomings and imprecision. |
| | | LLLT, differing wavelengths or doses | Insufficient | There was insufficient evidence to determine effects of different wavelengths or doses of LLLT due to methodological limitations and imprecision. |
| | | LLLT: Adverse events | Low | Harms were not well reported in trials of LLLT, but no serious adverse events and no harms were reported. |
| | Short-wave diatherm y | Short-wave diathermy vs. sham diathermy, mixed-duration LBP: Effectiveness and adverse events | Insufficient | There was insufficient evidence from 5 RCTs to determine effects of short-wave diathermy vs. sham diathermy due to methodological limitations and imprecision. |
| | | Short-wave diathermy: Adverse events | Insufficient | No study evaluated harms of short-wave diathermy. |
| | Lumbar supports | Lumbar supports vs. no lumbar supports or an inactive treatment, acute or subacute LBP: Pain and function | Insufficient | There was insufficient evidence from 5 trials to determine effects of lumbar supports vs. no lumbar supports or an inactive treatment due to methodological shortcomings and inconsistent results |
| | | Lumbar supports vs. no lumbar supports, chronic LBP | Insufficient | There was insufficient evidence from 2 trials to determine effects of lumbar supports vs. no lumbar supports due to methodological shortcomings and inconsistent results. |

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| **Nonpharmacological noninvasive therapies** | Lumbar supports | Lumbar supports vs. no lumbar supports, mixed-duration LBP: Pain and function | Low | One trial found an inextensible, but not an extensible, lumbar supports to be associated with greater improvement in function vs. no lumbar support, but effects were small. There was no clear effect on function. |
| | | Lumbar support plus education vs. education, acute or subacute LBP: Pain and function | Low | One trial found no differences between a lumbar support plus an education program vs. an education program alone in pain or function after 1 year |

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| | | Lumbar support plus exercise vs. exercise alone, chronic LBP: Pain and function | Low | One trial found no difference between a lumbar support plus exercise (muscle strengthening) vs. exercise alone in short-term (8 week) or long-term (6 month) pain or function. |
| | | Lumbar support vs. other active treatments: Pain and function | Low | Three trials found no clear differences between lumbar supports vs. other active treatments in pain or function. |
| | | Lumbar supports vs. lumbar supports: Pain and function | Insufficient | There was insufficient evidence from 2 trials to determine comparative effects of different types of lumbar supports for chronic LBP or back pain of mixed duration due to heterogeneous comparisons, methodological shortcomings, and imprecision. |
| | | Lumbar supports: Adverse events | Low | Trials reported no harms associated with use of lumbar supports. |
| | Traction | Traction vs. placebo, sham, or no treatment, LBP with or without radicular symptoms: Pain, function, other outcomes | Insufficient | A systematic review included 13 trials that found no clear differences and inconsistent effects of traction vs. placebo, sham, or no treatment in pain, function, or other outcomes, although 2 trials reported favorable effects on pain in patients with radicular back pain. |
| | | Traction vs. physiotherapy, LBP with or without radicular symptoms | Low | A systematic review included 5 trials that found no clear differences between traction plus physiotherapy vs. physiotherapy alone. |

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| **Nonpharmacological noninvasive therapies** | Traction | Traction vs. other interventions, LBP with or without radicular symptoms: Pain and function | Low | A systematic review included 15 trials of traction vs. other interventions that found no clear between traction vs. other active interventions in pain or function. |
| | | Traction vs. traction | Low | A systematic review included 5 trials that found no clear differences among different types of traction. |
| | | Traction: Adverse events | Low | Eleven trials of traction in a systematic review reported no adverse events or no difference in risk of adverse events vs. placebo or other interventions. Three subsequent trials reported findings consistent with the systematic review. |
| | Taping | Kinesio Taping® vs. sham taping, chronic LBP: Pain and function | Insufficient for pain, low for function | Two trials found no differences between Kinesio Taping vs. sham taping in back-specific function after 5 to 12 weeks; effects on pain were inconsistent. |

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| | | Functional Fascial Taping® plus exercise vs. sham taping plus exercise, chronic LBP: Pain and function | Insufficient | There was insufficient evidence from 1 trial to determine effects of Functional Fascial Taping plus exercise vs. sham taping plus exercise due to methodological limitations and imprecision. |
| | | Kinesio Taping vs. exercise therapy, chronic LBP: Pain and function | Low | Two trials found no differences between Kinesio Taping vs. exercise therapy in pain or function. |
| | | Taping: Adverse events | Insufficient | No trial of taping reported harms. |

CI = confidence interval; EMG = electromyography; EMS = electrical muscle stimulation; IFT = interferential therapy; LBP = low back pain; LLLT = low-level laser therapy; MCE = motor control exercise; NSAID = nonsteroidal anti-inflammatory drug; ODI = Oswestry Disability Index; OR = odds ratio; PENS = percutaneous electrical nerve stimulation; RDQ = Roland-Morris Disability Questionnaire; RR = relative risk; SF-12 = 12-item short form health survey; SF-36 = 36-item short form health survey; SMD = standardized mean difference; SMR = skeletal muscle relaxant; SSRI = selective serotonin reuptake inhibitor; TENS = transcutaneous electrical nerve stimulation; VAS = visual analog scale; WMD = weighted mean difference.

**References:**


2. Chou, R., Deyo, R., Friedly, J., Skelly, A., Hashimoto, R., Weimer, M., . . . Brodt, E. (2016). AHRQ Comparative Effectiveness Reviews Noninvasive Treatments for Low Back Pain. Rockville (MD): Agency for Healthcare Research and Quality (US).


**Primary Literature published since 2016 AHRQ comparative effectiveness review**

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** High Intensity Laser vs. Ultrasound Therapy; **Outcome:** Pain

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | |
| Boyraz, I., et al., 2015, *BioMed Research International* | To evaluate the efficiency of high intensity laser and ultrasound therapy in patients who were diagnosed with lumbar disc herniation and who were capable of performing | RCT; The patients were randomly divided into three groups: Group 1 received 10 sessions of high intensity laser to the lumbar region, Group 2 received 10 sessions of ultrasound, and Group 3 received medical therapy for 10 days and isometric lumbar exercises. The efficacy of the treatment modalities was compared with the assessment of the patients before the therapy at | 65 patients diagnosed with lumbar disc; 20 patients in Group 1, 25 in Group 2, and 20 in Group 3 | The comparison of parameters in Group 1 before the treatment and at the end of the therapy revealed significant changes in VAS ($P < 0.05$).<br><br>The comparison of parameters in Group 2 before the therapy and at the end of the therapy revealed significant changes in VAS score ($P < 0.05$).<br><br>The comparison of parameters in Group 3 before the therapy and at the end of the | Study Limitations =<br>☐ None<br>***RCTS***<br>☒ Lack of blinding<br>☒ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness*

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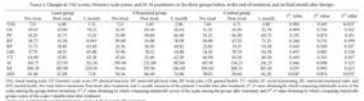
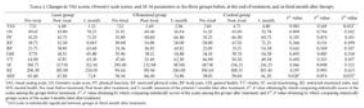
| | physical exercises | the end of the therapy, and in third month after the therapy. | | therapy revealed significant changes is VAS ($P < 0.05$).<br><br>**Comparing the changes between groups, statistically significant difference was observed in VAS score in third month between Ultrasound Group and Medical Therapy Group. However, the evaluation of the patients after ten days of treatment did not show significant differences between the groups compared to baseline values.**<br>  | ☐ Difference in important prognostic factors at baseline | *of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☐ Low<br>☒ Very Low |


**References:**

1. Boyraz, I., et al. (2015). "Comparison of high-intensity laser therapy and ultrasound treatment in the patients with lumbar discopathy." BioMed Research International 2015: 304328.


**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** High Intensity Laser Therapy vs. Ultrasound Therapy; **Outcome:** Function

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | |
| Boyraz, I., et al., 2015, *BioMed Research International* | To evaluate the efficiency of high intensity laser and ultrasound therapy in patients who were diagnosed with lumbar disc herniation and who were capable of performing | RCT; The patients were randomly divided into three groups: Group 1 received 10 sessions of high intensity laser to the lumbar region, Group 2 received 10 sessions of ultrasound, and Group 3 received medical therapy for 10 days and isometric lumbar exercises. The efficacy of the treatment modalities was compared with the assessment of the patients before the therapy at the end of the therapy, and in third month after the therapy. | 65 patients diagnosed with lumbar disc; 20 patients in Group 1, 25 in Group 2, and 20 in Group 3 | **There was no statistically significant change in the Oswestry scale scores between groups before, at the end of treatment or in the third month after therapy.**<br>  | Study Limitations =<br>☐ None<br>***RCTS***<br>☒ Lack of blinding<br>☒ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

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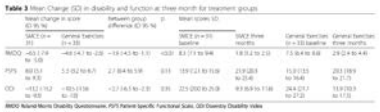
| | physical exercises | | | | | Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☐ Low<br>☒ Very Low |

**References:**

1. Boyraz, I., et al. (2015). "Comparison of high-intensity laser therapy and ultrasound treatment in the patients with lumbar discopathy." BioMed Research International 2015: 304328.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** General exercise vs. specific movement control exercise; **Outcome:** Disability

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
|---|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | | |
| Lehtola, V., et al., 2016, *BMC Musculoskeletal Disorders* | To compare effects of general exercise versus specific movement control exercise (SMCE) on disability and function in patients with movement control impairment (MCI) within the recurrent sub-acute LBP group | RCT; Participants having a MCI attended five treatment sessions of either specific or general exercises. In both groups, a short application of manual therapy was applied. The primary outcome was disability, assessed by the Roland-Morris Disability Questionnaire (RMDQ). The measurements were taken at baseline, immediately after the three months interventions and at twelve-month follow-up. | 70 patients; 61 patients completed at twelve months (SMCE n = 30 and general exercise n = 31) | Patients in both groups reported significantly less disability (RMDQ) at twelve months follow-up. **However, the mean change on the RMDQ between baseline and the twelve-month measurement showed statistically significantly superior improvement for the SMCE group -1.9 points (-3.9 to -0.5) 95 % (CI)**. The result did not reach the clinically significant three point difference. **There was no statistical difference between the groups measured with Oswestry Disability Index (ODI).**<br>  | Study Limitations =<br>☐ None<br>***RCTS***<br>☒ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☒ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*<br><br>☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient |

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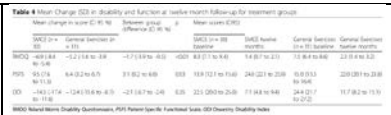
| | | | |  | | ☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☐ Low<br>☒ Very Low |


**References:**

1. Lehtola, V., et al. (2016). "Sub-classification based specific movement control exercises are superior to general exercise in sub-acute low back pain when both are combined with manual therapy: A randomized controlled trial." BMC Musculoskeletal Disorders 17: 135.


| **PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers. | | | | | | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*<br><br>☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect |
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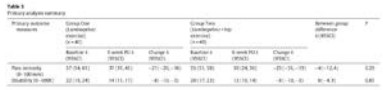
| **Modality:** Hip strengthening exercise therapy; **Outcome:** Disability | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 1 # of RCTs: 1** | | | | | | |
| Kendall, K.D., et al., 2015, *Journal of Science & Medicine in Sport* | To compare the efficacy of two exercise programmes in reducing pain and disability for individuals with non-specific low back pain and to examine the underlying mechanical factors related to pain and disability for individuals with NSLBP | RCT; Participants were recruited from eleven community-based general medical practices and randomized into two groups completing either a lumbopelvic motor control or a combined lumbopelvic motor control and progressive hip strengthening exercise therapy programme. All participants received an education session, 6 rehabilitation sessions including real time ultrasound training, and a home based exercise programme manual and log book. The primary outcomes were pain (0-100 mm visual analogue scale), and disability (Oswestry Disability Index V2). The secondary outcomes were hip strength (N/kg) and two-dimensional frontal plane | 80 participants | **There was no statistical difference in the change in disability (x = -0.3%, t = -0.19, p = 0.85, 95%CI -3.5, 2.8) between groups.**<br><br>**Table 4**<br>Event rate analysis summary.<br>Outcome \| Group One (Lumbopelvic exercise) (n = 40) Proportion(#) \| Group Two (Lumbopelvic + hip exercise) (n = 40) Proportion(#) \| Proportion of success ratio x̄(95%CI)<br>Successful treatment<br>Change in pain 60% (24) 68% (27) 1.12 (0.81, 1.6)<br>Change in disability 45% (18) 43% (17) 0.94 (0.6, 1.5)<br><br>  | Study Limitations =<br>☐ None<br>***RCTS***<br>☒ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | |

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| | | biomechanics (degree) measure during the static Trendelenburg test and while walking. All outcomes were measured at baseline and at 6-week follow up. | | | | Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☐ Low<br>☒ Very Low |

**References:**

1. Kendall, K. D., et al. (2015). "The effect of the addition of hip strengthening exercises to a lumbopelvic exercise programme for the treatment of non-specific low back pain: A randomized controlled trial." Journal of Science & Medicine in Sport 18(6): 626-631.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Home conventional exercise vs. exercise with augmented feedback; **Outcome:** Disability

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | |
| Hugli, A.S., et al., *Journal of Bodywork & Movement Therapies* | To explore the differences in home exercise (HE) adherence between patients who perform conventional exercises and those who exercise with Augmented Feedback (AF). Twenty patients with NSLBP and MCI were randomly allocated into two groups | RCT; Twenty patients with NSLBP and MCI were randomly allocated into two groups. The physiotherapy group (PT group) completed conventional exercises, and the AF group exercised with an AF system that was designed for use in therapy settings. The main outcome measure was self-reported adherence to the home exercise regimen. Secondary outcomes included disability and movement control. The Oswestry Disability Index (ODI) and the Patient Specific Functional Scale (PSFS) were used to ass self-perceived disability due to LBP. Movement control | 20 patients | There was no significant difference in HE duration between the groups (W = 64, p = 0.315). The AF group exercised for a median of 9 min and 4 s (IQR = 3'59"), and the PT group exercised for 4 min and 19 s (IQR = 8'30"). Exercising with AF led to HE times that were similar to those of conventional exercise, and AF might be used as an alternative therapy method for home exercise.<br><br>**At the end of therapy, both groups exhibited decreased self-perceived disability as evaluated with the ODI (*p* = 0.0002). The median scores of the AF group improved from 15% (IQR = 5.5) to 8% (IQR = 7; *p* = 0.01). The PT group improved from 15% (IQR = 5.5) to 8% (IQR = 13) to 5% (IQR = 10.5; *p* = 0.01).** | Study Limitations =<br>☐ None<br>***RCTS***<br>☒ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

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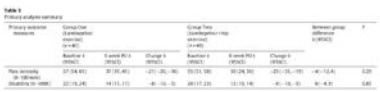
| | | impairment (MCI) tests were used to assess the patients' movement control of their lumbar spines. | | **Both groups exhibited decreases in self-perceived disability, although no group difference was observed ($p = 0.32$).** The median score of the AF group improved from 5.5 (IQR = 1.75) to 2.5 (IQR = 2.5; $p = 0.001$), and the median score of the PT group improved from 6 (IQR = 3.75) to 1 (IQR = 2.75); $p = 0.001$).<br><br>**Table 3** Change of ODI, MCI, PSFS pre-to post-intervention.<br>$n = 20$ \| Baseline (t1) \| Post intervention (t2) \| $p$-value<br>ODI [%] (Med., IQR)[a] \| 16 (10.5) \| 7 (8.5) \| $p = 0.0002$<br>MCI (Mode, rel. frequency)[b] \| \| \| $p = 0.004$<br>MCI 0—1 points \| \| 13 (65%) \|<br>MCI 2—3 points \| 11 (55%) \| 5 (25%) \|<br>MCI 4—5 points \| 9 (45%) \| 2 (10%) \|<br>PSFS Activity 1 [Pts.] (Med., IQR)[a] \| 6 (3.25) \| 2 (2.25) \| $p = 0.0001$<br>PSFS Activity 2 [Pts.] (Med., IQR)[a] \| 5 (2.25) \| 1 (4.25) \| $p = 0.0014$<br>PSFS Activity 3 [Pts.] (Med., IQR)[a] \| 5 (3) \| 1,5 (3) \| $p = 0.0006$<br>*n*: subjects; t1: prior to intervention; t2: after the intervention; ODI: Oswestry Disability Index; MCI: movement control impairment Tests; PSFS: Patient Specific Functional Scale; Pts.: Points; Med: Median; IQR: Interquartile range; rel. frequency: relative frequency.<br>[a] Wilcoxon rank sum Test.<br>[b] $X^2$ Test; for analysis alpha was set at $\alpha = 0.05$.<br><br>**Table 4** Between group comparison at the end of the intervention A- & PT Group.<br>Measure \| AF group \| PT group \| $p$-value<br>ODI [%], (Med., IQR)[a] \| 8 (7) \| 5 (10.5) \| $p = 0.91$<br>MCI (Mode, rel. frequency.)[b] \| \| \| $p = 0.55$<br>MCI 0—1 points \| 5 (25%) \| 8 (40%) \|<br>MCI 2—3 points \| 3 (15%) \| 2 (10%) \|<br>MCI 4—5 points \| 2 (10%) \| 0 (0%) \|<br>PSFS Activity 1 [Pts.] (Med, IQR)[a] \| 2.5 (2.5) \| 1 (2.75) \| $p = 0.32$<br>PSFS Activity 2 [Pts.] (Med, IQR)[a] \| 1.5 (4.25) \| 1 (3.25) \| $p = 0.97$<br>PSFS Activity 3 [Pts.] (Med, IQR)[a] \| 3 (3) \| 1 (2) \| $p = 0.56$<br>AF: Augmented Feedback; PT: conventional physiotherapy; ODI: Oswestry Disability Index; Med: Median; IQR: Interquartile range; MCI: movement control impairment tests; rel. frequency: relative frequency; Patient Specific Functional Scale; Pts.: points.<br>[a] Wilcoxon rank sum Test.<br>[b] $X^2$; PSFS: for analysis alpha was set at $\alpha = 0.05$. | | Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☐ Low<br>☒ Very Low |

**References:**

1. Hugli, A. S., et al. (2015). "Adherence to home exercises in non-specific low back pain. A randomised controlled pilot trial." Journal of Bodywork & Movement Therapies 19(1): 177-185

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Hip strengthening exercise therapy; **Outcome:** Pain

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | |
| Kendall, K.D., et al., 2015, *Journal of Science & Medicine in Sport* | To compare the efficacy of two exercise programmes in reducing pain and disability for individuals with non-specific low back pain and to examine the underlying mechanical factors related to pain and disability for individuals with NSLBP | RCT; Participants were recruited from eleven community-based general medical practices and randomized into two groups completing either a lumbopelvic motor control or a combined lumbopelvic motor control and progressive hip strengthening exercise therapy programme. All participants received an education session, 6 rehabilitation sessions including real time ultrasound training, and a home based exercise programme manual and log book. The primary outcomes were pain (0-100 mm visual analogue scale), and disability (Oswestry Disability Index V2). The secondary outcomes were hip strength (N/kg) and two-dimensional frontal plane biomechanics (degree) measure during the static Trendelenburg test and while walking. All outcomes were measured at baseline and at 6-week follow up. | 80 participants | **There was no statistical difference in the change in pain (x = -4.0 mm, t = -1.07, p = 0.29, 95%CI -11.5, 3.5) between groups**. Within group comparisons revealed clinically meaningful reductions in pain for both Group One (x = -20.9 mm, 95%CI -25.7, -16.1) and Group Two (x = -24.9, 95%CI -30.8, -19.0).<br>**Table 4**<br>Event rate analysis summary.<br>Outcome \| Group One (Lumbopelvic exercise) (n = 40) Proportion(#) \| Group Two (Lumbopelvic + hip exercise) (n = 40) Proportion(#) \| Proportion of success ratio x̄(95%CI)<br>Successful treatment<br>Change in pain 60% (24) 68% (27) 1.12 (0.81, 1.6)<br>Change in disability 45% (18) 43% (17) 0.94 (0.6, 1.5)<br>  | Study Limitations =<br>☐ None<br>***RCTS***<br>☒ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☐ Low
☒ Very Low

**References:**

1. Kendall, K. D., et al. (2015). "The effect of the addition of hip strengthening exercises to a lumbopelvic exercise programme for the treatment of non-specific low back pain: A randomized controlled trial." Journal of Science & Medicine in Sport 18(6): 626-631.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Conventional exercises vs exercise with augmented feedback; **Outcome:** Movement Control

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | |
| Hugli, A.S., et al., *Journal of Bodywork & Movement Therapies* | To explore the differences in home exercise (HE) adherence between patients who perform conventional exercises and those who exercise with Augmented Feedback (AF). Twenty patients with NSLBP and MCI were randomly allocated into two groups | RCT; Twenty patients with NSLBP and MCI were randomly allocated into two groups. The physiotherapy group (PT group) completed conventional exercises, and the AF group exercised with an AF system that was designed for use in therapy settings. The main outcome measure was self-reported adherence to the home exercise regimen. Secondary outcomes included disability and movement control. The Oswestry Disability Index (ODI) and the Patient Specific Functional Scale (PSFS) were used to ass self-perceived disability due to LBP. Movement control impairment (MCI) tests were used to assess the patients' movement control of their lumbar spines. | 20 patients | There was no significant difference in HE duration between the groups (W = 64, p = 0.315). The AF group exercised for a median of 9 min and 4 s (IQR = 3'59"), and the PT group exercised for 4 min and 19 s (IQR = 8'30"). Exercising with AF led to HE times that were similar to those of conventional exercise, and AF might be used as an alternative therapy method for home exercise.<br><br>**At the end of therapy, the entire group exhibited a significant improvement in movement control ($p$ = 0.004). There was no significant group difference ($p$ = 0.55) nor were there significant within-group pre-post differences. The AF group improved in movement control (X2 = 18.75, $p$ = 0.09) as did the PT group (X2 = 10.97; $p$ = 0.28).** | Study Limitations =<br>☐ None<br>***RCTS***<br>☒ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
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Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☐ Low
☒ Very Low

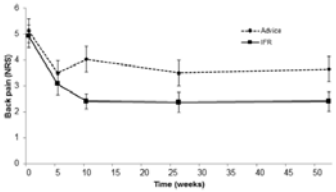
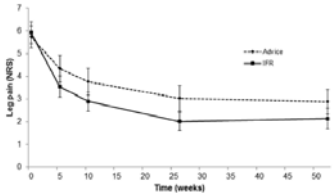
| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | **Table 3** Change of ODI, MCI, PSFS pre-to post-intervention.<br>*n* = 20 \| Baseline (t1) \| Post intervention (t2) \| *p*-value<br>ODI [%] (Med., IQR)[a] \| 16 (10.5) \| 7 (8.5) \| $p = 0.0002$<br>MCI (Mode, rel. frequency)[b] \| \| \| $p = 0.004$<br>MCI 0—1 points \| \| 13 (65%) \|<br>MCI 2—3 points \| 11 (55%) \| 5 (25%) \|<br>MCI 4—5 points \| 9 (45%) \| 2 (10%) \|<br>PSFS Activity 1 [Pts.] (Med., IQR)[a] \| 6 (3.25) \| 2 (2.25) \| $p = 0.0001$<br>PSFS Activity 2 [Pts.] (Med., IQR)[a] \| 5 (2.25) \| 1 (4.25) \| $p = 0.0014$<br>PSFS Activity 3 [Pts.] (Med., IQR)[a] \| 5 (3) \| 1,5 (3) \| $p = 0.0006$<br>*n*: subjects; t1: prior to intervention; t2: after the intervention; ODI: Oswestry Disability Index; MCI: movement control impairment Tests; PSFS: Patient Specific Functional Scale; Pts.: Points; Med: Median; IQR: Interquartile range; rel. frequency: relative frequency.<br>[a] Wilcoxon rank sum Test.<br>[b] $X^2$ Test; for analysis alpha was set at $\alpha = 0.05$.<br><br>**Table 4** Between group comparison at the end of the intervention A- & PT Group.<br>Measure \| AF group \| PT group \| *p*-value<br>ODI [%], (Med., IQR)[a] \| 8 (7) \| 5 (10.5) \| $p = 0.91$<br>MCI (Mode, rel. frequency.)[b] \| \| \| $p = 0.55$<br>MCI 0—1 points \| 5 (25%) \| 8 (40%)<br>MCI 2—3 points \| 3 (15%) \| 2 (10%)<br>MCI 4—5 points \| 2 (10%) \| 0 (0%)<br>PSFS Activity 1 [Pts.] (Med, IQR)[a] \| 2.5 (2.5) \| 1 (2.75) \| $p = 0.32$<br>PSFS Activity 2 [Pts.] (Med, IQR)[a] \| 1.5 (4.25) \| 1 (3.25) \| $p = 0.97$<br>PSFS Activity 3 [Pts.] (Med, IQR)[a] \| 3 (3) \| 1 (2) \| $p = 0.56$<br>AF: Augmented Feedback; PT: conventional physiotherapy; ODI: Oswestry Disability Index; Med: Median; IQR: Interquartile range; MCI: movement control impairment tests; rel. frequency: relative frequency; Patient Specific Functional Scale; Pts.: points.<br>[a] Wilcoxon rank sum Test.<br>[b] $X^2$; PSFS: for analysis alpha was set at $\alpha = 0.05$. | | |

**References:**

1. Hugli, A. S., et al. (2015). "Adherence to home exercises in non-specific low back pain. A randomised controlled pilot trial." Journal of Bodywork & Movement Therapies 19(1): 177-185.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Physical Therapy (individualized functional restoration vs. guideline-based advice); **Outcome:** Pain

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | |
| Hahne, A.J., et al., 2017, *Spine Journal: Official Journal of the North American Spine Society* | To determine the effectiveness of physical therapist-delivered individualized functional restoration as an adjunct to guideline-based advice in people with lumbar disc herniation and associated radiculopathy | RCT; The participants were randomly allocated to receive either individualized functional restoration incorporating advice (10 sessions) or guideline-based advice alone (2 sessions) over a 10-week period. Treatment was administered by 11 physical therapists at private clinics in Melbourne, Australia. Primary outcomes were activity limitation (Oswestry Disability Index) and separate 0-10 numerical pain rating scales for leg pain and back pain. Measures were taken at baseline and at 5, 10, 26, and 52 weeks. | 54 participants | Between-group differences for activity limitation favored the addition of individualized functional restoration to advice alone at 10 weeks (7.7, 95% confidence interval [CI] 0.3-15.1) and 52 weeks (8.2, 95% CI 0.7-15.6), as well as **back pain at 10 weeks (1.4, 95% CI 0.2-2.7).** There were no significant differences between groups for leg pain at any follow-up.<br>  <br><br>  <br> | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☒ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
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Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

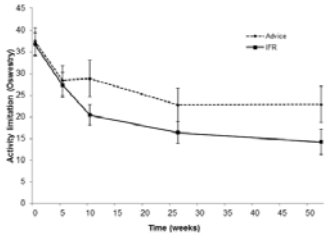
Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☐ Low
☒ Very Low

**References:**

1. Hahne, A. J., et al. (2017). "Individualized functional restoration as an adjunct to advice for lumbar disc herniation with associated radiculopathy. A preplanned subgroup analysis of a randomized controlled trial." Spine Journal: Official Journal of the North American Spine Society 17(3): 346-359.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Physical Therapy (individualized functional restoration vs. guideline-based advice); **Outcome:** Function

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | |
| Hahne, A.J., et al., 2017, *Spine Journal: Official Journal of the North American Spine Society* | To determine the effectiveness of physical therapist-delivered individualized functional restoration as an adjunct to guideline-based advice in people with lumbar disc herniation and associated radiculopathy | RCT; The participants were randomly allocated to receive either individualized functional restoration incorporating advice (10 sessions) or guideline-based advice alone (2 sessions) over a 10-week period. Treatment was administered by 11 physical therapists at private clinics in Melbourne, Australia. Primary outcomes were activity limitation (Oswestry Disability Index) and separate 0-10 numerical pain rating scales for leg pain and back pain. Measures were taken at baseline and at 5, 10, 26, and 52 weeks. | 54 participants | **Between-group differences for activity limitation favored the addition of individualized functional restoration to advice alone at 10 weeks (7.7, 95% confidence interval [CI] 0.3-15.1) and 52 weeks (8.2, 95% CI 0.7-15.6).** Several secondary outcomes also favored individualized functional restoration over advice.<br>  | Study Limitations =<br>☐ None<br>***RCTS***<br>☐ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☒ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
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Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

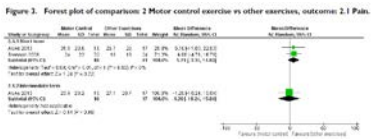
Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☐ Low
☒ Very Low

**References:**

1. Hahne, A. J., et al. (2017). "Individualized functional restoration as an adjunct to advice for lumbar disc herniation with associated radiculopathy. A preplanned subgroup analysis of a randomized controlled trial." Spine Journal: Official Journal of the North American Spine Society 17(3): 346-359.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Motor Control Exercise vs. Other Exercise; **Outcome:** Pain

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | |
| Macedo, L.G., et al., 2016, *Cochrane Database of Systematic Reviews* | To evaluate the effectiveness of motor control exercise (MCE) for patients with acute non-specific low back pain (LBP) | Systematic review with meta-analysis | Two trials; 89 participants for outcome of pain and 116 for disability | **There is no clinically important effect for pain intensity with moderate-quality evidence at short term (MD 5.74, 95% CI -3.34 to 14.82; two trials) and low-quality evidence at intermediate term (MD -1.20, 95% CI -18.24 to 15.84, one trial).**<br>  | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies |

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Quality (certainty) of evidence for studies as a whole:
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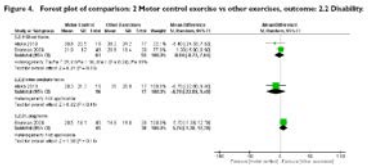
☐ Moderate
☒ Low
☐ Very Low

**References:**

1. Macedo, L. G., et al. (2016). "Motor control exercise for acute non-specific low back pain." Cochrane Database of Systematic Reviews 2: Cd012085.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Motor Control Exercise vs. Other Exercise; **Outcome:** Disability

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | |
| Macedo, L.G., et al., 2016, *Cochrane Database of Systematic Reviews* | To evaluate the effectiveness of motor control exercise (MCE) for patients with acute non-specific low back pain (LBP) | Systematic review with meta-analysis | Two trials; 89 participants for outcome of pain and 116 for disability | **There is moderate-quality evidence of no clinically important effect at short term (MD -0.84, 95% CI -8.72 to 7.04, two trials), and low-quality evidence at intermediate term (MD -6.70, 95% CI -22.80 to 9.40, one trial), and long-term follow-up (MD 5.70, 95% CI -1.38 to 12.78, one trial)**<br>  | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies |

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**Modality:** Motor Control Exercise vs. Manual Therapy; **Outcome:** Pain

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | |
| Saragiotto, B.T., et al., 2016, *Spine* | To evaluate the effectiveness of motor control exercise (MCE) in patients with nonspecific low back pain (LBP) | Systematic review with meta-analysis | One trial; 123 participants | **There is low-quality evidence that there is no clinically important effect for pain at short term (MD 9.00, 95% CI -1.56 to 19.56).** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies |

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☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☒ Low
☐ Very Low

**References:**

1. Saragiotto, B. T., et al. (2016). "Motor Control Exercise for Nonspecific Low Back Pain: A Cochrane Review." Spine (Phila Pa 1976) 41(16): 1284-1295.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Motor Control Exercise vs. Manual Therapy; **Outcome:** Disability

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | |
| Saragiotto, B.T., et al., 2016, *Spine* | To evaluate the effectiveness of motor control exercise (MCE) in patients with nonspecific low back pain (LBP) | Systematic review with meta-analysis | One trial; 123 participants | **There is low-quality evidence that there is no clinically important effect for function at short term (MD 4.00, 95% CI -3.38 to 11.38) and long term (MD 3.70, 95% CI -4.10 to 11.50).** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies |

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**Modality:** Motor Control Exercise vs. Supplement to Medical Management; **Outcome:** Pain

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | |
| Macedo, L.G., et al., 2016, *Cochrane Database of Systematic Reviews* | To evaluate the effectiveness of motor control exercise (MCE) for patients with acute non-specific low back pain (LBP)) | Systematic review with meta-analysis | One trial; 42 participants | **There is low-quality evidence that there is no clinically important effect for adding MCE to medical management for pain at short-term (MD -9.30; 95% CI -20.41 to 1.81, one trial).** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☒ Low
☐ Very Low

**References:**

1. Macedo, L. G., et al. (2016). "Motor control exercise for acute non-specific low back pain." Cochrane Database of Systematic Reviews 2: Cd012085.

| **PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers. | | | | | | |
|---|---|---|---|---|---|---|
| **Modality:** Motor Control Exercise vs. Supplement to Medical Management; **Outcome:** Disability | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | | |
| Macedo, L.G., et al., 2016, *Cochrane Database of Systematic Reviews* | To evaluate the effectiveness of motor control exercise (MCE) for patients with acute non-specific low back pain (LBP) | Systematic review with meta-analysis | One trial; 41 for disability | **There is low-quality evidence that there is no clinically important effect for function at short term (MD -0.90, 95% CI -4.77 to 2.97, one trial).** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies | |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☒ Low
☐ Very Low

**References:**

1. Macedo, L. G., et al. (2016). "Motor control exercise for acute non-specific low back pain." Cochrane Database of Systematic Reviews 2: Cd012085.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Motor Control Exercise vs. Supplement to Medical Management; **Outcome:** Risk of recurrence

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | |
| Macedo, L.G., et al., 2016, *Cochrane Database of Systematic Reviews* | To evaluate the effectiveness of motor control exercise (MCE) for patients with acute non-specific low back pain (LBP) | Systematic review with meta-analysis | One trial; 39 participants | **There is low-quality evidence that adding MCE to medical management decreases the risk of recurrence by 64% compared with medical management alone (RR 0.36, 95% CI 0.18-0.72, one trial)** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☒ Low
☐ Very Low

**References:**

1. Macedo, L. G., et al. (2016). "Motor control exercise for acute non-specific low back pain." Cochrane Database of Systematic Reviews 2: Cd012085.

| **PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers. | | | | | | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*<br><br>☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |
|---|---|---|---|---|---|---|
| **Modality:** Pilates to minimal intervention; **Outcome:** Pain | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | | |
| Yamato TP, et al., 2015, *Cochrane Database of Systematic Reviews* | To determine the effects of the Pilates method for patients with non-specific acute, subacute or chronic low back pain | Systematic review with meta-analysis | 10 studies, sample of 510 participants | **There is low quality evidence that Pilates reduces pain compared with minimal intervention, with a medium effect size at short-term follow-up (less than three months after randomization) (MD -14.05, 95% CI -18.91 to -9.19).**<br><br>**For immediate-term follow-up (at least three months but less than 12 months after randomization), two trials provided moderate quality evidence that Pilates reduces pain compared to minimal intervention, with a medium effect size (MD -10.54, 95% CI -18.46 to -2.62).** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies | |

**References:**


1. Yamato, T. P., et al. (2015). "Pilates for low back pain." Cochrane Database of Systematic Reviews(7): Cd010265.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Pilates to minimal intervention; **Outcome:** Disability

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | |
| Yamato TP, et al., 2015, *Cochrane Database of Systematic Reviews* | To determine the effects of the Pilates method for patients with non-specific acute, subacute or chronic low back pain | Systematic review with meta-analysis | 10 studies, sample of 510 participants | **Based on five trials, there is low quality evidence that Pilates improves disability compared with minimal intervention, with a small effect size at short-term follow-up (MD -7.95, 95% CI -13.23 to -2.67), and moderate quality evidence for an intermediate-term effect with a medium effect size (MD -11.17, 95% CI -18.41 to -3.92).** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☐ Methods and/or results were inconsistent across studies |

Lower Quality Rating if:
☐ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☒ Low
☐ Very Low

**References:**

1. Yamato, T. P., et al. (2015). "Pilates for low back pain." Cochrane Database of Systematic Reviews(7): Cd010265.

| **PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers. | | | | | | |
|---|---|---|---|---|---|---|
| **Modality:** Pilates to minimal intervention; **Outcome:** Function | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | | |
| Yamato TP, et al., 2015, *Cochrane Database of Systematic Reviews* | To determine the effects of the Pilates method for patients with non-specific acute, subacute or chronic low back pain | Systematic review with meta-analysis | 10 studies, sample of 510 participants | **Based on one trial and low quality evidence, a significant short-term effect with a small effect size was reported for function (MD 1.10, 95% CI 0.23 to 1.97).** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*<br><br>☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |

**References:**

1. Yamato, T. P., et al. (2015). "Pilates for low back pain." Cochrane Database of Systematic Reviews(7): Cd010265.

| **PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers. | | | | | | |
|---|---|---|---|---|---|---|
| **Modality:** Pilates to minimal intervention; **Outcome:** Global Impression of Recovery | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | | |
| Yamato TP, et al., 2015, *Cochrane Database of Systematic Reviews* | To determine the effects of the Pilates method for patients with non-specific acute, subacute or chronic low back pain | Systematic review with meta-analysis | 10 studies, sample of 510 participants | **Based on one trial and low quality evidence, a significant short-term effect with a small effect size was reported for global impression of recovery (MD 1.50, 95% CI 0.70 to 2.30).** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies | |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☒ Low
☐ Very Low

**References:**

1. Yamato, T. P., et al. (2015). "Pilates for low back pain." Cochrane Database of Systematic Reviews(7): Cd010265.

| **PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers. | | | | | | |
|---|---|---|---|---|---|---|
| **Modality:** Pilates to Other Exercises; **Outcome:** Disability | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | | |
| Yamato TP, et al., 2015, *Cochrane Database of Systematic Reviews* | To determine the effects of the Pilates method for patients with non-specific acute, subacute or chronic low back pain | Systematic review with meta-analysis | 10 studies, sample of 510 participants | **There is moderate quality evidence that there is no significant difference between Pilates and other exercise either in the short term (MD -3.29, 95% CI -6.82 to 0.24) or in the intermediate term (MD -0.91, 95% CI -5.02 to 3.20) based on two studies for each comparison.** | Study Limitations =<br>☒ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☐ Quality of the studies was not appraised or studies were of low quality<br>☐ Methods and/or results were inconsistent across studies | Lower Quality Rating if:<br>☐ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*<br><br>☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br>Increase Quality Rating if:<br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☒ Low<br>☐ Very Low |

**References:**

1. Yamato, T. P., et al. (2015). "Pilates for low back pain." Cochrane Database of Systematic Reviews(7): Cd010265.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Pilates to Other Exercises; **Outcome:** Harms

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | |
| Yamato TP, et al., 2015, *Cochrane Database of Systematic Reviews* | To determine the effects of the Pilates method for patients with non-specific acute, subacute or chronic low back pain | Systematic review with meta-analysis | 10 studies, sample of 510 participants | **Two trials assessed adverse events, one did not find any adverse events, and another reported minor events** | Study Limitations =<br>☒ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☐ Quality of the studies was not appraised or studies were of low quality<br>☐ Methods and/or results were inconsistent across studies |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

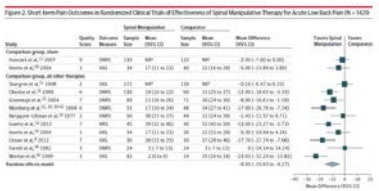
Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☒ Low
☐ Very Low

**References:**

**1.** Yamato, T. P., et al. (2015). "Pilates for low back pain." Cochrane Database of Systematic Reviews(7): Cd010265.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Spinal Manipulative vs. Other Treatments; **Outcome:** Pain

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | |
| Paige, N.M., et al., 2017, *JAMA* | To systematically review studies of the effectiveness and harms of spinal manipulative therapy (SMT) for acute (</-6 weeks) low back pain | Systematic review with meta-analysis | 26 eligible RCTs in systematic review; 20 studies reported pain outcomes (1,699 patients) | **The overall random-effects polled estimate for short-term pain was a mean effort of -9.95 mm (95% CI, -15.6 to -4.3), favoring treatments with SMT compared with other treatments. There was heterogeneity in the results ($I^2$ = 67%).**<br><br>**For immediate-term pain, the overall random-effects pooled estimate was -9.76mm (95% CI, -17.0 to -2.5) compared with other treatments.**<br><br>  | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

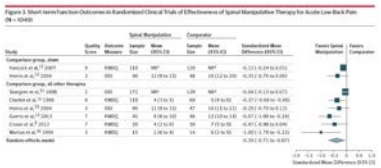
Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☒ Low
☐ Very Low

**References:**


1. Paige, N. M., et al. (2017). "Association of spinal manipulative therapy with clinical benefit and harm for acute low back pain: Systematic review and meta-analysis." JAMA **317**(14): 1451-1460.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Spinal Manipulative vs Other Treatments; **Outcome:** Function

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | |
| Paige, N.M., et al., 2017, *JAMA* | To systematically review studies of the effectiveness and harms of spinal manipulative therapy (SMT) for acute (</-6 weeks) low back pain | Systematic review with meta-analysis | 26 eligible RCTs in systematic review; 17 studies reported functional outcomes (1,381 patients) | **The overall random-effects pooled estimate for short-term function was an effect size of -.0.39 (95% CI, -0.71 to -0.07) favoring treatment with SMT. There was heterogeneity in the results ($I^2$ = 72%).**<br><br>**For immediate-term function, the overall random-effects pooled estimate was an effect size of -0.24 (95% CI, -0.55 to 0.08).**<br><br>  | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☒ Low
☐ Very Low

**References:**


1. Paige, N. M., et al. (2017). "Association of spinal manipulative therapy with clinical benefit and harm for acute low back pain: Systematic review and meta-analysis." JAMA **317**(14): 1451-1460.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Spinal Manipulative; **Outcome:** Harms

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | |
| Paige, N.M., et al., 2017, *JAMA* | To systematically review studies of the effectiveness and harms of spinal manipulative therapy (SMT) for acute (</-6 weeks) low back pain | Systematic review with meta-analysis | 26 eligible RCTs | **18 studies did not describe assessment of harms, 3 made nonspecific comments about harms (ie, no adverse effects were documented), and 5 reported on specific harms, none of which were considered related to the treatment except that "the treatment hurts" was statistically more common in the group of patients receiving SMT (along with other interventions) compared with those receiving conventional medical care.**<br>  | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☐ Methods and/or results were inconsistent across studies |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☒ Low
☐ Very Low

**References:**

**1.** Paige, N. M., et al. (2017). "Association of spinal manipulative therapy with clinical benefit and harm for acute low back pain: Systematic review and meta-analysis." JAMA **317**(14): 1451-1460.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Manual-thrust manipulation vs. mechanical-assisted manipulation vs usual care; **Outcome:** Disability

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | |
| Schneider, M., et al., 2015, *Spine* | To compare effectiveness of: manual-thrust manipulation (MTM) versus mechanical-assisted manipulation (MAM); and manipulation versus usual medical care (UMC) | RCT; Adults with onset of LBP within the past 12 weeks were randomized to 1 of 3 treatment groups: MTM; MAM; or UMC. Outcomes measures included the Oswestry LBP disability index (0 to 100 scale) and numeric pain rating (0 to 10 scale). Participants in the manipulation groups were treated twice weekly over 4 weeks; subjects in UMC were seen for 3 visits during this time. Outcomes measures were captured at baseline, 4 weeks, 4 months and 6 months. | 107 patients | **MTM showed a statistically significant advantage at 4 weeks compared to MAM (disability = -8.1, p = .009) and UMC (disability = -6,5, p = .032).** Responder analysis , defined as 30% and 50% reductions in **Oswestry scores revealed a significantly greater proportion of responders at 4 weeks in MTM (76%; 50%) compared to MAM (50%; 16%) and UMC (48%; 39%).** No statistically significant group differences were found between MAM and UMC, and for any comparison at 3 or 6 months.<br><br>No adverse events were reported. | Study Limitations =<br>☐ None<br>***RCTS***<br>☒ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☐ Low
☒ Very Low

**References:**

1. Schneider, M., et al. (2015). "A comparison of spinal manipulation methods and usual medical care for acute and sub-acute low back pain: a randomized clinical trial." Spine 40(4): 209-217.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Manual-thrust manipulation vs. mechanical-assisted manipulation vs usual care; **Outcome:** Pain

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | |
| Schneider, M., et al., 2015, *Spine* | To compare effectiveness of: manual-thrust manipulation (MTM) versus mechanical-assisted manipulation (MAM); and manipulation versus usual medical care (UMC) | RCT; Adults with onset of LBP within the past 12 weeks were randomized to 1 of 3 treatment groups: MTM; MAM; or UMC. Outcomes measures included the Oswestry LBP disability index (0 to 100 scale) and numeric pain rating (0 to 10 scale). Participants in the manipulation groups were treated twice weekly over 4 weeks; subjects in UMC were seen for 3 visits during this time. Outcomes measures were captured at baseline, 4 weeks, 4 months and 6 months. | 107 patients | **MTM showed a statistically significant advantage at 4 weeks compared to MAM (pain = 1.4, p = .002) and UMC (pain = -1.7, p < .001). Similar between-group results were found for pain: MTM (94%; 76%); MAM (69%; 47%); and UMC (56%; 41%).** No statistically significant group differences were found between MAM and UMC, and for any comparison at 3 or 6 months.<br><br>No adverse events were reported.. | Study Limitations =<br>☐ None<br>***RCTS***<br>☒ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

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Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

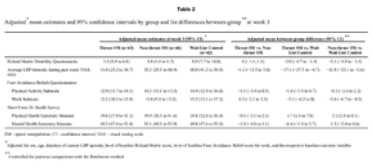
Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☐ Low
☒ Very Low

**References:**

1. Schneider, M., et al. (2015). "A comparison of spinal manipulation methods and usual medical care for acute and sub-acute low back pain: a randomized clinical trial." Spine 40(4): 209-217.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Thrust spinal manipulation vs. non-thrust, flexion-distraction spinal manipulation; **Outcome:** Disability

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | |
| Xia, T., et al., 2016, *Spine* | To compare short-term effects of a side-lying, thrust spinal manipulation (SM) procedure and a non-thrust, flexion-distraction SM procedure in adults with subacute or chronic low back pain (LBP) over 2 weeks | RCT; Participants were eligible if they were 21 – 54 years old, had LBP for at least 4 weeks, scored 6 or above on the Roland-Morris disability questionnaire, and met the diagnostic classification of 1, 2, or 3 according to the Quebec Task Force Classification for Spinal Disorders. Participants were allocated in a 3:3:2 ratio to 4 sessions of thrust or non-thrust SM procedures directed at the lower lumbar and pelvic regions, or to a 2-week wait list control. The primary outcomes was LBP-related disability using Roland-Morris disability questionnaire and the secondary outcomes were LBP intensity using visual analog scale, Fear-Avoidance Beliefs Questionnaire, and the 36-Item Short Form Health Survey. The study was conducted at the Palmer Center for Chiropractic Research with care provided by experienced doctors of chiropractic Clinicians. | 192 participants | **The mean (SD) decrease in LBP intensity was 23.5 mm (28.3) for the thrust group, 17.8 mm (25.8) for the non-thrust SM group, and 6.1 mm (19.6) for the wait list group.**<br><br>**Adjusted mean pain intensity at week 3 was not different between the two SM groups, but both SM groups had significantly lower scores than the wait list group.** The FABQ and the SF-36 measures showed similar patterns, but there was no significant difference between the SM groups and the wait list group on the FABQ physical activity subscale or SF-36 health summary.<br><br>  | Study Limitations =<br>☐ None<br>***RCTS***<br>☒ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

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☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

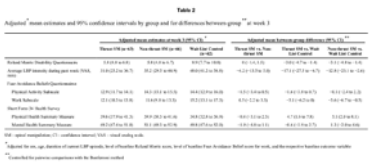
Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☐ Low
☒ Very Low

**References:**

1. Xia, T., et al. (2016). "Similar Effects of Thrust and Nonthrust Spinal Manipulation Found in Adults With Subacute and Chronic Low Back Pain: A Controlled Trial With Adaptive Allocation." Spine 41(12): E702-709.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Thrust spinal manipulation vs. non-thrust, flexion-distraction spinal manipulation; **Outcome:** Disability

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | |
| Xia, T., et al., 2016, *Spine* | To compare short-term effects of a side-lying, thrust spinal manipulation (SM) procedure and a non-thrust, flexion-distraction SM procedure in adults with subacute or chronic low back pain (LBP) over 2 weeks | RCT; Participants were eligible if they were 21 – 54 years old, had LBP for at least 4 weeks, scored 6 or above on the Roland-Morris disability questionnaire, and met the diagnostic classification of 1, 2, or 3 according to the Quebec Task Force Classification for Spinal Disorders. Participants were allocated in a 3:3:2 ratio to 4 sessions of thrust or non-thrust SM procedures directed at the lower lumbar and pelvic regions, or to a 2-week wait list control. The primary outcomes was LBP-related disability using Roland-Morris disability questionnaire and the secondary outcomes were LBP intensity using visual analog scale, Fear-Avoidance Beliefs Questionnaire, and the 36-Item Short Form Health Survey. The study was conducted at the Palmer Center for Chiropractic Research with care provided by experienced doctors of chiropractic Clinicians. | 192 participants | **The mean SD decrease in RMDQ was 4.0 (4.2) for the thrust SM group, 3.8 (4.1) for the non-thrust SM group, and 1.0 (3.0) for the wait list group.**<br><br>**Adjusted mean RMDQ at week 3 was not different between the two SM groups, but both SM groups had significantly lower scores than the wait list group.**<br><br>  | Study Limitations =<br>☐ None<br>***RCTS***<br>☒ Lack of blinding<br>☐ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☐ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

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☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

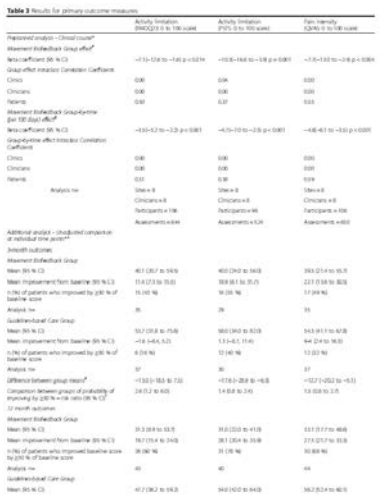
Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☐ Low
☒ Very Low

**References:**

1. Xia, T., et al. (2016). "Similar Effects of Thrust and Nonthrust Spinal Manipulation Found in Adults With Subacute and Chronic Low Back Pain: A Controlled Trial With Adaptive Allocation." Spine 41(12): E702-709.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Motion-Sensor Biofeedback; **Outcome:** Pain

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | |
| Kent, P., et al., 2015, *BMC Musculoskeletal Disorders* | To (i) test the hypothesis that modifying patterns of painful lumbo-pelvic movement using motion-sensor biofeedback in people with low back pain would lead to reduced pain and activity limitation compared with guidelines-based care, and (ii) facilitate sample size calculations for a fully powered trial | RCT; Compared two groups of patients, randomized at the clinic level, seeking medical or physiotherapy primary care for sub-acute and chronic back pain. The intervention group received modification of movement patterns augmented by motion-sensor movement biofeedback (ViMove, dorsaVi.com) plus guidelines-based medical or physiotherapy care. The control group received a placebo (wearing the motion-sensors without biofeedback) plus guidelines-based medical or physiotherapy care. Primary outcomes were self-reported pain intensity (VAS) and activity limitation (Roland Morris Disability Questionnaire (RMDQ), Patient Specific Functional Scale (PSFS)), all on 0-100 scales. Both groups received 6-8 treatment sessions. Outcomes were measured seven times during 10-weeks of treatment and at 12, 26 and 52 week follow-up, with 17.0 % dropout. Patients were not informed of group allocation or the study hypothesis. | Intervention group = 58 and control group = 54 | Across one-year, there were significant between-group differences favouring the intervention group [generalized linear model coefficient (95 % CI): group effect for pain. QVAS -7.7 (-13.0; -2.4); and group by time effect differences (per 100 days) QVAS -4.8 (-6.1; -3.5)], all p < 0.001. **Risk ratios between groups of probability of improving by >30 % at 12-months = QVAS 3.3 (1.8; 5.9).**<br>  | Study Limitations =<br>☐ None<br>***RCTS***<br>☒ Lack of blinding<br>☒ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☒ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
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Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☐ Low
☒ Very Low

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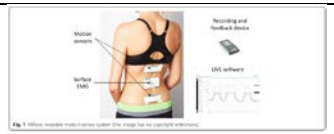
|---|---|---|---|---|---|---|
| | |  | |  | | |

**References:**

1. Kent, P., et al. (2015). "The effect of changing movement and posture using motion-sensor biofeedback, versus guidelines-based care, on the clinical outcomes of people with sub-acute or chronic low back pain-a multicentre, cluster-randomised, placebo-controlled, pilot trial." BMC Musculoskeletal Disorders 16: 131.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Motion-Sensor Biofeedback; **Outcome:** Function

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | |
| Kent, P., et al., 2015, *BMC Musculoskeletal Disorders* | To (i) test the hypothesis that modifying patterns of painful lumbo-pelvic movement using motion-sensor biofeedback in people with low back pain would lead to reduced pain and activity limitation compared with guidelines-based care, and (ii) facilitate sample size calculations for a fully powered trial | RCT; Compared two groups of patients, randomized at the clinic level, seeking medical or physiotherapy primary care for sub-acute and chronic back pain. The intervention group received modification of movement patterns augmented by motion-sensor movement biofeedback (ViMove, dorsaVi.com) plus guidelines-based medical or physiotherapy care. The control group received a placebo (wearing the motion-sensors without biofeedback) plus guidelines-based medical or physiotherapy care. Primary outcomes were self-reported pain intensity (VAS) and activity limitation (Roland Morris | Intervention group = 58 and control group = 54 | Across one-year, there were significant between-group differences favouring the intervention group [generalized linear model coefficient (95 % CI): group effect PSFS -10.3 (-16.6; -3.9) and group by time effect differences (per 100 days) PSFS -4.7 (-7.0; -2.5), all p < 0.001. **Risk ratios between groups of probability of improving by >30 % at 12-months = PSFS 2.5 (1.5; 4.0).** | Study Limitations =<br>☐ None<br>***RCTS***<br>☒ Lack of blinding<br>☒ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☒ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

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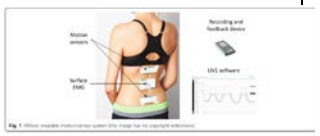
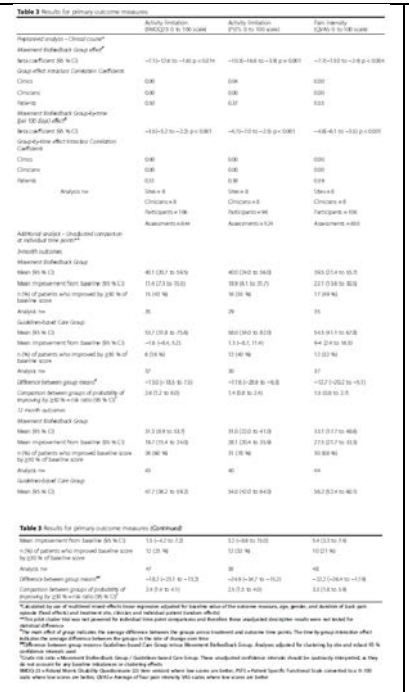
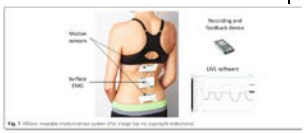
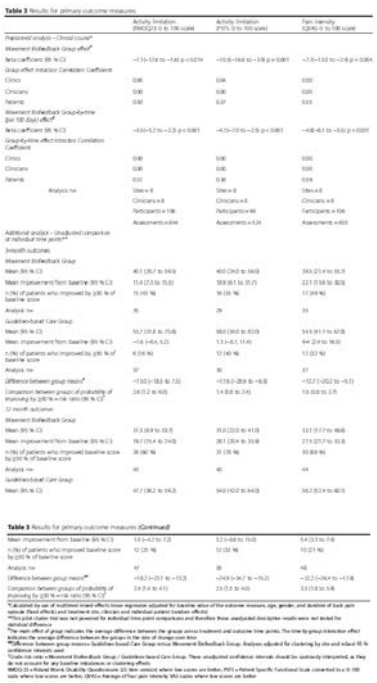
Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

| | | | | | | |
|---|---|---|---|---|---|---|
| | | Disability Questionnaire (RMDQ), Patient Specific Functional Scale (PSFS)), all on 0-100 scales. Both groups received 6-8 treatment sessions. Outcomes were measured seven times during 10-weeks of treatment and at 12, 26 and 52 week follow-up, with 17.0 % dropout. Patients were not informed of group allocation or the study hypothesis.<br>  | |  | | Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☐ Low<br>☒ Very Low |

**References:**


1. Kent, P., et al. (2015). "The effect of changing movement and posture using motion-sensor biofeedback, versus guidelines-based care, on the clinical outcomes of people with sub-acute or chronic low back pain-a multicentre, cluster-randomised, placebo-controlled, pilot trial." BMC Musculoskeletal Disorders 16: 131.


| **PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers. | | | | | | Lower Quality Rating if:<br>☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*<br><br>☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* |
|---|---|---|---|---|---|---|
| **Modality:** Motion-Sensor Biofeedback; **Outcome:** Activity Limitation | | | | | | |
| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* | |
| **Total # of Studies: 1 # of RCTs: 1** | | | | | | |
| Kent, P., et al., 2015, *BMC* | To (i) test the hypothesis that modifying patterns of | RCT; Compared two groups of patients, randomized at the clinic level, seeking medical or | Intervention group = 58 and control group = 54 | Across one-year, there were significant between-group differences favouring the intervention group [generalized linear | Study Limitations =<br>☐ None<br>***RCTS*** | |

| | | | | | | |
|---|---|---|---|---|---|---|
| *Musculoskeletal Disorders* | painful lumbo-pelvic movement using motion-sensor biofeedback in people with low back pain would lead to reduced pain and activity limitation compared with guidelines-based care, and (ii) facilitate sample size calculations for a fully powered trial | physiotherapy primary care for sub-acute and chronic back pain. The intervention group received modification of movement patterns augmented by motion-sensor movement biofeedback (ViMove, dorsaVi.com) plus guidelines-based medical or physiotherapy care. The control group received a placebo (wearing the motion-sensors without biofeedback) plus guidelines-based medical or physiotherapy care. Primary outcomes were self-reported pain intensity (VAS) and activity limitation (Roland Morris Disability Questionnaire (RMDQ), Patient Specific Functional Scale (PSFS)), all on 0-100 scales. Both groups received 6-8 treatment sessions. Outcomes were measured seven times during 10-weeks of treatment and at 12, 26 and 52 week follow-up, with 17.0 % dropout. Patients were not informed of group allocation or the study hypothesis.<br>  | | model coefficient (95 % CI): group effect RMDQ -7.1 (95 % CI-12.6;-1.6); and group by time effect differences (per 100 days) RMDQ -3.5 (-5.2; -2.2), all p < 0.001**. Risk ratios between groups of probability of improving by >30 % at 12-months =RMDQ 2.4 (95 % CI 1.5; 4.1).**<br>  | ☒ Lack of blinding<br>☒ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☒ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline | ☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*<br><br>☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*<br><br><u>Increase Quality Rating if:</u><br>☐ Large Effect<br>☐ Dose-response gradient<br>☐ Plausible confounders or other biases increase certainty of effect<br><br>Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☐ Low<br>☒ Very Low |

**References:**

1. Kent, P., et al. (2015). "The effect of changing movement and posture using motion-sensor biofeedback, versus guidelines-based care, on the clinical outcomes of people with sub-acute or chronic low back pain-a multicentre, cluster-randomised, placebo-controlled, pilot trial." BMC Musculoskeletal Disorders 16: 131.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Motion-Sensor Biofeedback; **Outcome:** Harms

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of RCTs: 1** | | | | | |
| Kent, P., et al., 2015, *BMC Musculoskeletal Disorders* | To (i) test the hypothesis that modifying patterns of painful lumbo-pelvic movement using motion-sensor biofeedback in people with low back pain would lead to reduced pain and activity limitation compared with guidelines-based care, and (ii) facilitate sample size calculations for a fully powered trial | RCT; Compared two groups of patients, randomized at the clinic level, seeking medical or physiotherapy primary care for sub-acute and chronic back pain. The intervention group received modification of movement patterns augmented by motion-sensor movement biofeedback (ViMove, dorsaVi.com) plus guidelines-based medical or physiotherapy care. The control group received a placebo (wearing the motion-sensors without biofeedback) plus guidelines-based medical or physiotherapy care. Primary outcomes were self-reported pain intensity (VAS) and activity limitation (Roland Morris Disability Questionnaire (RMDQ), Patient Specific Functional Scale (PSFS)), all on 0-100 scales. Both groups received 6-8 treatment sessions. Outcomes were measured seven times during 10-weeks of treatment and at 12, 26 and 52 week follow-up, with 17.0 % dropout. Patients were not informed of group allocation or the study hypothesis. | Intervention group = 58 and control group = 54 | **17 instances (2.7%) of device-related side effects. All involved some form of transient skin irritation from the hypoallergenic tape used to mount a motion-sensor**. There occurred in six Movement Biofeedback Group patients and 11 Guideline-based Care Group patients but did not preclude wearing the device at the next scheduled outcome measurement time-point. | Study Limitations =<br>☐ None<br>***RCTS***<br>☒ Lack of blinding<br>☒ Lack of allocation concealment<br>☐ Stopped early for benefit<br>☐ Incorrect analysis of ITT<br>☐ Selective reporting of measures (e.g., no effect outcome)<br>☒ Large losses to F/U<br>☐ Difference in important prognostic factors at baseline |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

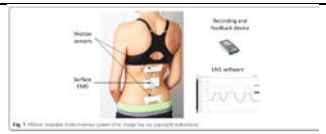
☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Quality (certainty) of evidence for studies as a whole:
☐ High
☐ Moderate
☐ Low
☒ Very Low

| | | | | | | |
|---|---|---|---|---|---|---|
| | |  | | | | |

**References:**

1. Kent, P., et al. (2015). "The effect of changing movement and posture using motion-sensor biofeedback, versus guidelines-based care, on the clinical outcomes of people with sub-acute or chronic low back pain-a multicentre, cluster-randomised, placebo-controlled, pilot trial." BMC Musculoskeletal Disorders 16: 131.

**PICO Question:** What are the comparative benefits and harms of different nonpharmacological, noninvasive therapies, or combinations thereof for acute or subacute low back pain? Includes but is not limited to multidisciplinary rehabilitation, exercise (various types), physical modalities (ultrasound, transcutaneous electrical nerve stimulation, electrical muscle stimulation, interferential therapy, heat [various forms], and ice), traction tables/devices, back supports/bracing, spinal manipulation, various psychological therapies, acupuncture, massage therapy (various types), yoga, magnets, and low level lasers.

**Modality:** Cognitive Behavioral Therapy; **Outcome:** Improvement of any outcome measure

| *Author/Date* | *Purpose of Study* | *Study Design & Methods* | *Sample* | *Outcomes* | *Design Limitations* |
|---|---|---|---|---|---|
| **Total # of Studies: 1 # of Systematic Reviews: 1** | | | | | |
| Mariano, T.Y., et al., 2018, *Current Pain & Headache Reports* | To characterize and highlight the knowledge gap between cognitive behavioral therapy (CBT)'s efficacy for chronic low back pain (CLBP)'s compared to subacute low back pain (sALBP). | Systematic Review | 6 studies | Given the wide variation in trial design, methods, and outcome variables, no statistical meta-analysis was performed.<br><br>**Despite proven benefits of CBT for treating CLBP, the present systematic review revealed only a handful of prospective studies in the past two decades that have attempted to use CBT in some form to treat the precursor condition of sALBP.** | Study Limitations =<br>☐ None<br>***Systematic Review***<br>☐ Review did not address focused clinical question<br>☐ Search was not detailed or exhaustive<br>☒ Quality of the studies was not appraised or studies were of low quality<br>☒ Methods and/or results were inconsistent across studies |

Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, populations, interventions, or outcomes varied)*

☐ Studies are indirect *(PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☒ Studies are imprecise (*When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain)*

☐ Publication Bias *(e.g. pharmaceutical company sponsors study on effectiveness of drug, only small, positive studies found)*

Increase Quality Rating if:
☐ Large Effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | | | | Quality (certainty) of evidence for studies as a whole:<br>☐ High<br>☐ Moderate<br>☐ Low<br>☒ Very Low |

**References:**


1. Mariano, T. Y., et al. (2018). "Cognitive Behavioral Therapy (CBT) for Subacute Low Back Pain: a Systematic Review." Current Pain & Headache Reports 22(3): 15.

# Appendix A. GRADE criteria for rating a body of evidence on an intervention

Developed by the GRADE Working Group

***Grades and interpretations:***

| |
|---|
| High: Further research is very unlikely to change our confidence in the estimate of effect. |
| Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. |
| Low: 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: Any estimate of effect is very uncertain. |

***Type of evidence and starting level***

| |
|---|
| Randomized trial–high |
| Observational study–low |
| Any other evidence–very low |

***Criteria for increasing or decreasing level***

| |
|---|
| **Reductions** |
| Study quality has serious (–1) or very serious (–2) problems |
| Important inconsistency in evidence (–1) |
| Directness is somewhat (–1) or seriously (–2) uncertain |
| Sparse or imprecise data (–1) |
| Reporting bias highly probable (–1) |
| **Increases** |
| Evidence of association† strong (+1) or very strong (+2) |
| Dose-response gradient evident (+1) |
| All plausible confounders would reduce the effect (+1) |
| †Strong association defined as significant relative risk (factor of 2) based on consistent evidence from two or more studies with no plausible confounders |
| Very strong association defined as significant relative risk (factor of 5) based on direct evidence with no threats to validity. |

## Appendix B. Trustworthy Guideline rating scale

The University of Pennsylvania's Center for Evidence-Based Practice Trustworthy Guideline rating scale is based on the Institute of Medicine's "Standards for Developing Trustworthy Clinical Practice Guidelines" (IOM), as well as a review of the AGREE Enterprise and Guidelines International Network domains.

The purpose of this scale is to focus on the weaknesses of a guideline that may reduce the trust a clinical user can have in the guideline, and distinguish weaknesses in documentation (e.g. guide-line does not have a documented updating process) from weaknesses in the guidance itself (e.g. recommendations are outdated). Current quality scales like AGREE emphasize documentation. They are important checklists for developers of new guidelines, but are less useful for grading existing guidelines. These scales also are harder for clinicians and other persons who are not methodology experts to apply, and their length discourages their use outside formal technology assessment reports. This new scale is brief, balanced, and easy and consistent to apply.

We do not attempt to convert the results of this assessment into a numeric score. Instead we present a table listing the guidelines and how they are rated on each standard. This facilitates qualitative understanding by the reader, who can see for what areas the guideline base as a whole is weak or strong as well as which guidelines are weaker or stronger.

**1. Transparency**

| | |
|---|---|
| A | Guideline development methods are fully disclosed. |
| B | Guideline development methods are partially disclosed. |
| C | Guideline development methods are not disclosed. |

The grader must refer to any cited methods supplements or other supporting material when evaluating the guideline. Methods should include:
Who wrote the initial draft.
How the committee voted on or otherwise approved recommendations.
Evidence review, external review and methods used for updating are not addressed in this standard.

**2. Conflict of interest**

| | |
|---|---|
| A | Funding of the guideline project is disclosed, disclosures are made for each individual panelist, and financial or other conflicts do not apply to key authors of the guideline or to more than 1 in 10 panel members). |
| B | Guideline states that there were no conflicts (or fewer than 1 in 10 panel members), but does not disclose funding source. |
| C | Lead author, senior author, or guideline panel members (at least 1 in 10) have conflict of interest, or guideline project was funded by industry sponsor with no assurance of independence. |
| NR | Guideline does not report on potential conflict of interests. |

For purposes of this checklist, conflicts of interest include employment by, consulting for, or holding stock in companies doing business in fields affected by the guideline, as well as related financial conflicts. This definition should not be considered exclusive. As much as anything, this is a

surrogate marker for thorough reporting, since it may be assumed that guideline projects are funded by the sponsoring organization and many authors think it unnecessary to report a non-conflict.

**3. Guideline development group**

| | |
|---|---|
| A | Guideline development group includes 1) methodological experts and clinicians and 2) representatives of multiple specialties. |
| B | Guideline development group includes one of the above, but not both. |
| C | Guideline developers all from one specialty or organization, and no methodologists. |
| NR | Affiliations of guideline developers not reported |

The purpose of this standard is to ensure that supporters of competing procedures, or clinicians with no vested interest in utilization of one procedure or another, are involved in development of the guideline. Both AGREE II and IOM call for patient or public involvement: very few guideline panels have done so to date, so this is not necessary for guidelines to be rated A. Involvement of methodologists or HTA specialists in the systematic review is sufficient involvement in the guideline development group for our purposes. In the absence of any description of the guideline group, assume the named authors are the guideline group.

**4. Systematic review**

| | |
|---|---|
| A | Guideline includes a systematic review of the evidence or links to a current review. |
| B | Guideline is based on a review which may or may not meet systematic review criteria. |
| C | Guideline is not based on a review of the evidence. |

In order to qualify as a systematic review, the review must do all of the following:
Describe itself as systematic or report search strategies using multiple databases
Define the scope of the review (including key questions and the applicable population)
Either include quantitative or qualitative synthesis of the data or explain why it is not indicated

Note: this element does not address the quality of the systematic review: simply whether or not it exists. Concerns about quality or bias of the review will be discussed in text, where the analyst will explain whether the weaknesses of the review weaken the validity or reliability of the guideline.
Note: a guideline may be rated B on this domain even if the review on which it is based is not available to us. This potential weakness of the guideline should be discussed in text of the report.

**5. Grading the supporting evidence**

| | |
|---|---|
| A | Specific supporting evidence (or lack thereof) for each recommendation is cited and graded |
| B | Specific supporting evidence (or lack thereof) for each recommendation is cited but the recommendation is not graded. |
| C | Recommendations are not supported by specific evidence. |

To score a B on this domain there should be specific citations to evidence tables or individual references for each relevant recommendation in the guideline, or an indication that no evidence was available. Any standardized grading system is acceptable for purposes of this rating. If a guideline

reports that there is no evidence available despite a thorough literature search, it may be scored B on this domain, or even A if evidence for other recommendations is cited and graded.

**6. Recommendations**

| | |
|---|---|
| A | Considerations for each recommendation are documented (i.e. benefits and harms of a particular action, and/or strength of the evidence); and recommendations are presented in an actionable form. |
| B | Either one or the other of the above criteria is met. |
| C | Neither of the above criteria are met |

In order to be actionable, the guideline should specify the specific population to which the guideline applies, the specific intervention in question, and the circumstances under which it should be carried out (or not carried out). The language used in the recommendations should also be consistent with the strength of the recommendation (e.g. directive and active language like “should” or “should not” for strong recommendations, and passive language like “consider” for weak recommendations). A figure or algorithm is considered actionable as long as it is complete enough to incorporate all the applicable patients and interventions. Please see the forthcoming NICE manual (24) for a good discussion of actionability in guidelines.

**7. External review**

| | |
|---|---|
| A | Guideline was made available to external groups for review. |
| B | Guideline was reviewed by members of the sponsoring body only. |
| C | Guideline was not externally reviewed. |
| NR | No external review process is described. |

**8. Updating and currency of guideline**

| | |
|---|---|
| A | Guideline is current and an expiration date or update process is specified. |
| B | Guideline is current but no expiration date or update process is specified. |
| C | Guideline is outdated. |

A guideline is considered current if it is within the developers’ stated validity period, or if no period or expiration data is stated, the guideline was published in the past three years (NOTE: the specific period may be changed at the analyst’s discretion, based on whether the technology is mature and whether there is a significant amount of recent evidence). A guideline must address new evidence when it is updated. A guideline which is simply re-endorsed by the panel without searching for new evidence must be considered outdated.

# Appendix C. Search Strategies

PICO 1:

| Search Strategies | Document Strategies Used |
|---|---|
| **Search Terms/Strategies Used:** | 1 (red adj flag*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (1062)<br>2 exp Back Pain/dg (1799)<br>3 exp Back Injuries/dg (5248)<br>4 exp Back/dg (1070)<br>5 3 or 4 (6300)<br>6 exp Back Pain/ (34495)<br>7 exp Back Injuries/ (22269)<br>8 exp Back/ (18994)<br>9 exp Spine/ (129494)<br>10 7 or 8 or 9 (154558)<br>11 exp Pain/ (352601)<br>12 exp Pain Management/ (26945)<br>13 exp Pain Measurement/ (75086)<br>14 11 or 12 or 13 (387554)<br>15 10 and 14 (21145)<br>16 6 or 15 (44598)<br>17 exp Diagnostic Imaging/ (2393245)<br>18 16 and 17 (10913)<br>19 5 and 14 (772)<br>20 2 or 18 or 19 (10976)<br>21 exp Decision Making/ (172368)<br>22 exp Professional Competence/ (102881)<br>23 exp Diagnosis, Differential/ (422555)<br>24 exp Diagnostic Errors/ (107829)<br>25 exp "Utilization Review"/ (11611)<br>26 exp Needs Assessment/ (26629)<br>27 exp "Referral and Consultation"/ (66854)<br>28 exp decision support techniques/ (69843)<br>29 exp Decision Support Systems, Clinical/ (6537)<br>30 exp "Sensitivity and Specificity"/ (514094)<br>31 exp "Delivery of Health Care"/ (948637)<br>32 exp "Costs and Cost Analysis"/ (211283)<br>33 (red flag* or ((sign* or marker* or indicat* or suggest* or clue* or predict* or alert* or warn*) adj7 ((impend* or imminent* or signific* or high* or great* or increas* or futur*) adj3 (risk* or |

| | |
|---|---|
| | caution* or danger* or complicat* or severity or problem*))))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (177420)<br>34 ((risk* or tool* or measur* or predict* or assess* or identi* or valid* or estimat* or scor* or chance* or precent*) adj7 ((poor* or negativ* or advers* or fail* or bad or unsatisfactory or delay*) adj3 (outcome* or complicat* or result* or progress* or improv* or resolution*))).mp. (41304)<br>35 (OMSPQ or STarT Back or DRAM).mp. (213)<br>36 ((compar* or versus or vs) adj10 ((harm* or advers* or iatrogen* or nosocom*) adj7 benefi*)).mp. (1002)<br>37 (risk* adj2 benefi*).mp. (27267)<br>38 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 (2508773)<br>39 20 and 38 (2590)<br>40 remove duplicates from 39 (2589)<br>41 limit 40 to yr="2007 -Current" (1276)<br>42 limit 41 to english language (1135)<br>43 limit 41 to abstracts (1031)<br>44 42 or 43 (1226)<br>45 limit 44 to (comparative study or controlled clinical trial or evaluation studies or guideline or meta analysis or randomized controlled trial or systematic reviews or validation studies) (218)<br>46 exp Epidemiologic Studies/ (2104112)<br>47 44 and 46 (435)<br>48 47 not 45 (311)<br>49 44 not (45 or 47) (697)<br>50 1 and 20 (49) |
| **Database Searched** | Ovid MEDLINE, Cochrane Database of Systematic Reviews, National Guideline Clearinghouse |
| **Years Searched - All Questions** | January 2008 – January 2018 |
| **Language** | English |
| **Age of Subjects** | Adults, >/= 18 years |

PICO 2:

| Search Strategies | Document Strategies Used |
|---|---|
| **Search Terms/Strategies Used:** | 1 (start back adj3 (tool* or instrument*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (51)<br>2 exp back injuries/ (22269)<br>3 exp back/ (18994)<br>4 exp back pain/ (34495)<br>5 exp neck/ (27733) |

| | |
|---|---|
| | 6 exp neck injuries/ (7479)<br>7 exp neck pain/ (5861)<br>8 exp Spine/ (129494)<br>9 exp spinal diseases/ (110711)<br>10 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 (265209)<br>11 1 and 10 (50)<br>12 start back.mp. (61)<br>13 OMSPQ.mp. (4)<br>14 Orebro Musculoskeletal Pain Screening Questionnaire.mp. (24)<br>15 13 or 14 (26)<br>16 dram.mp. (148)<br>17 10 and 16 (16)<br>18 (Distress and Risk Assessment).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (1644)<br>19 10 and 18 (49)<br>20 (dram adj3 (tool* or instrument*)).mp. (0)<br>21 12 or 15 or 19 (130) |
| **Database Searched** | Ovid MEDLINE, Cochrane Database of Systematic Reviews, National Guideline Clearinghouse |
| **Years Searched - All Questions** | January 2008 – January 2018 |
| **Language** | English |
| **Age of Subjects** | Adults, >/= 18 years |

PICO 3:

| Search Strategies | Document Strategies Used |
|---|---|
| **Search Terms/Strategies Used:** | 1 exp Back Pain/dg (1929)<br>2 exp Back Injuries/dg (5861)<br>3 exp Back/dg (1168)<br>4 2 or 3 (7009)<br>5 exp Back Pain/ (37151)<br>6 exp Back Injuries/ (24538)<br>7 exp Back/ (20457)<br>8 exp Spine/ (140940)<br>9 6 or 7 or 8 (168236)<br>10 exp Pain/ (386051)<br>11 exp Pain Management/ (29330)<br>12 exp Pain Measurement/ (83127)<br>13 10 or 11 or 12 (424341)<br>14 9 and 13 (22744) |

| | |
|---|---|
| | 15 5 or 14 (48054)<br>16 exp Diagnostic Imaging/ (2648326)<br>17 15 and 16 (11870)<br>18 4 and 13 (857)<br>19 1 or 17 or 18 (11945)<br>20 exp Decision Making/ (187300)<br>21 exp Professional Competence/ (109590)<br>22 exp Diagnosis, Differential/ (458713)<br>23 exp Diagnostic Errors/ (118136)<br>24 exp "Utilization Review"/ (12725)<br>25 exp Needs Assessment/ (28874)<br>26 exp "Referral and Consultation"/ (72527)<br>27 exp decision support techniques/ (77484)<br>28 exp Decision Support Systems, Clinical/ (7273)<br>29 exp "Sensitivity and Specificity"/ (568859)<br>30 exp "Delivery of Health Care"/ (1021545)<br>31 exp "Costs and Cost Analysis"/ (229159)<br>32 (red flag* or ((sign* or marker* or indicat* or suggest* or clue* or predict* or alert* or warn*) adj7 ((impend* or imminent* or signific* or high* or great* or increas* or futur*) adj3 (risk* or caution* or danger* or complicat* or severity or problem*)))).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (199040)<br>33 ((risk* or tool* or measur* or predict* or assess* or identi* or valid* or estimat* or scor* or chance* or precent*) adj7 ((poor* or negativ* or advers* or fail* or bad or unsatisfactory or delay*) adj3 (outcome* or complicat* or result* or progress* or improv* or resolution*))).mp. (46352)<br>34 (OMSPQ or STarT Back or DRAM).mp. (239)<br>35 ((compar* or versus or vs) adj10 ((harm* or advers* or iatrogen* or nosocom*) adj7 benefi*)).mp. (1139)<br>36 (risk* adj2 benefi*).mp. (30957)<br>37 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 (2732316)<br>38 19 and 37 (2828)<br>39 remove duplicates from 38 (2578)<br>40 limit 39 to yr="2007 -Current" (1265)<br>41 limit 40 to english language (1124)<br>42 limit 40 to abstracts (1021)<br>43 41 or 42 (1215)<br>44 limit 43 to (comparative study or controlled clinical trial or evaluation studies or guideline or meta analysis or randomized controlled trial or systematic reviews or validation studies) (216)<br>45 exp Epidemiologic Studies/ (2349305)<br>46 43 and 45 (431) |

| | |
|---|---|
| | 47 46 not 44 (309)<br>48 43 not (44 or 46) (690) |
| **Database Searched** | Ovid MEDLINE, Cochrane Database of Systematic Reviews, National Guideline Clearinghouse |
| **Years Searched - All Questions** | January 2008 – January 2018 |
| **Language** | English |
| **Age of Subjects** | Adults, >/= 18 years |

PICO 4, 5:

| Search Strategies | Document Strategies Used |
|---|---|
| **Search Terms/Strategies Used:** | 1 exp Back Pain/ (37151)<br>2 exp Back Injuries/ (24538)<br>3 exp Back/ (20457)<br>4 exp Spine/ (140940)<br>5 2 or 3 or 4 (168236)<br>6 exp Pain/ (386051)<br>7 exp Pain Management/ (29330)<br>8 exp Pain Measurement/ (83127)<br>9 6 or 7 or 8 (424341)<br>10 5 and 9 (22744)<br>11 1 or 10 (48054)<br>12 exp Drug Therapy/ (1346317)<br>13 exp analgesics/ (531866)<br>14 exp neuromuscular agents/ (79563)<br>15 exp Antidepressive Agents/ (145852)<br>16 exp anticonvulsants/ (141443)<br>17 exp Adrenal Cortex Hormones/ (404611)<br>18 exp transdermal patch/ (1014)<br>19 12 or 13 or 14 or 15 or 16 or 17 or 18 (2319552)<br>20 11 and 12 (3594)<br>21 limit 20 to yr="2015 -Current" (445)<br>22 limit 21 to english language (432)<br>23 limit 21 to abstracts (407)<br>24 22 or 23 (440)<br>25 exp Back Pain/dt (3222)<br>26 exp Back Injuries/dt (290)<br>27 25 or 26 (3491)<br>28 exp Back Pain/ (37151)<br>29 exp Back Injuries/ (24538)<br>30 exp Back/ (20457) |

| | |
|---|---|
| | 31 exp Spine/ (140940)<br>32 29 or 30 or 31 (168236)<br>33 exp Pain/ (386051)<br>34 exp Pain Management/ (29330)<br>35 exp Pain Measurement/ (83127)<br>36 33 or 34 or 35 (424341)<br>37 32 and 36 (22744)<br>38 exp hyperthermia, induced/ (30503)<br>39 exp Electric Stimulation Therapy/ (77816)<br>40 exp Physical Therapy Modalities/ (144283)<br>41 exp Cryotherapy/ (25629)<br>42 exp Hot Temperature/ (117985)<br>43 exp Orthopedic Equipment/ (97042)<br>44 exp complementary therapies/ (220432)<br>45 exp Magnetic Field Therapy/ (11578)<br>46 exp Magnets/ (8108)<br>47 exp Magnetics/ (25223)<br>48 exp Laser Therapy/ (60977)<br>49 exp Lasers/ (51029)<br>50 exp Counseling/ (42923)<br>51 exp Psychotherapy/ (192383)<br>52 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 or 49 or 50 or 51 (970272)<br>53 37 and 52 (3543)<br>54 limit 53 to yr="2015 -Current" (463)<br>55 limit 54 to english language (438)<br>56 limit 54 to abstracts (450)<br>57 55 or 56 (462)<br>58 24 or 57 (891)<br>59 remove duplicates from 58 (719)<br>60 limit 59 to (comparative study or controlled clinical trial or evaluation studies or guideline or meta analysis or randomized controlled trial or systematic reviews or validation studies) (297)<br>61 exp Epidemiologic Studies/ (2349305)<br>62 59 and 61 (277)<br>63 62 not 60 (157)<br>64 59 not (60 or 62) (265) |
| **Database Searched** | Ovid MEDLINE, Cochrane Database of Systematic Reviews, National Guideline Clearinghouse |
| **Years Searched - All Questions** | April 2015 – January 2018 |
| **Language** | English |
| **Age of Subjects** | Adults, >/= 18 years |