

## PICO 10

## Review information

## Authors

the Danish Health Authority<sup>1</sup>

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Citation example: tDHA. Standard. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

## Characteristics of studies

## Characteristics of included studies

## Aalto 2011

Methods	<p><b>Study design:</b> Randomized controlled trial</p> <p><b>Study grouping:</b> Parallel group</p>
Participants	<p><b>Baseline Characteristics</b></p> <p>intervention control Overall</p> <p><b>Included criteria:</b> The inclusion criteria were: (1) presence of back, buttock, and/or lower extremity pain, with radiographic evidence (computed tomography, magnetic resonance imaging (MRI), rhizography) of compression of the cauda equina and/or exiting nerve roots due to degenerative changes (ligamentum flavum, facet joints, osteophytes and/or disc material). (2) The surgeon's judgement that the patient had clinically significant degenerative LSS as the main diagnosis indicative for operative treatment. A previous spine operation or co-existing disc herniation was permitted.</p> <p><b>Excluded criteria:</b> The exclusion criteria included emergency or urgent spinal operation precluding recruitment and protocol investigations; cognitive impairment prohibiting completion of the questionnaires or other failures in co-operation; the presence of metallic particles in the body contra-indicating the MRI-investigation.</p> <p><b>Pretreatment:</b> Non in the primary groups</p>
Interventions	<p><b>Intervention Characteristics</b></p> <p>intervention</p> <ul style="list-style-type: none"> <li>● <i>description:</i> Three months postoperatively supervised exercise training sessions. At the first and second visit, a physiotherapist supervised the stretching and strengthening exercises. Exercising continued at home and at the next training sessions. maximum six members of A-group per one physiotherapist enabling individually estimated exercises. On the 6th and 12th visits, the volume and/or type of exercises, if needed, were progressively increased</li> <li>● <i>dose:</i> Three months postoperatively, once a week supervised exercise training sessions (90 min each, lasting 12 weeks. This 12-week intervention was repeated at the one-year follow-up in order to check the appropriateness of the home exercises and to motivate patients to keep training.</li> <li>● <i>standard treatment:</i> All the patients received routine (not-study-related) preoperative information at the hospital about immediate postoperative mobilisation. They were advised "to stay active" with no restrictions in normal daily living. Patients had routine operation-related control in the orthopaedic or neurosurgical clinic at 2-3 months postoperatively. At this time point, the surgeon also confirmed that there were no restrictions prohibiting rehabilitation. Since there were no restrictions with other postoperative treatment by the study protocol, the surgeons and also GPs could prescribe other possible treatments postoperatively if needed (analgetics, physiotherapy etc.).</li> </ul> <p>control</p> <ul style="list-style-type: none"> <li>● <i>description:</i> No treatment or self-management represented the only "standard treatment" for patients in B-group.</li> <li>● <i>dose:</i> not described</li> <li>● <i>standard treatment:</i> All the patients received routine (not-study-related) preoperative information at the hospital about immediate postoperative mobilisation. They were advised "to stay active" with no restrictions in normal daily living. Patients had routine operation-related control in the orthopaedic or neurosurgical clinic at 2-3 months postoperatively. At this time point, the surgeon also confirmed that there were no restrictions prohibiting rehabilitation. Since there were no restrictions with other postoperative treatment by the study protocol, the surgeons and also GPs could prescribe other possible treatments postoperatively if needed (analgetics, physiotherapy etc.).</li> </ul>
Outcomes	<p>ODI</p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> Continuous Outcome</li> <li>● <b>Reporting:</b> Fully reported</li> <li>● <b>Scale:</b> ODI</li> <li>● <b>Range:</b> 0-100</li> <li>● <b>Direction:</b> Lower is better</li> </ul> <p>VAS (Back Pain)</p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> Continuous Outcome</li> <li>● <b>Reporting:</b> Fully reported</li> <li>● <b>Scale:</b> VAS</li> <li>● <b>Range:</b> 0-10</li> <li>● <b>Direction:</b> Lower is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul> <p>VAS (leg pain)</p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> Continuous Outcome</li> <li>● <b>Reporting:</b> Fully reported</li> <li>● <b>Scale:</b> VAS</li> <li>● <b>Range:</b> 0-10</li> <li>● <b>Direction:</b> Lower is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul> <p>Treadmill (gagtest)</p>

	<ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Reporting:</b> Fully reported</li> <li>● <b>Range:</b> 0-1000</li> <li>● <b>Unit of measure:</b> m</li> <li>● <b>Direction:</b> Higher is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul> <p><i>Behov for smertestillende</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> DichotomousOutcome</li> <li>● <b>Range:</b> ja-nej</li> <li>● <b>Direction:</b> Lower is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul> <p><i>Livskvalitet</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Reporting:</b> Fully reported</li> <li>● <b>Scale:</b> EQ5D</li> <li>● <b>Range:</b> 0-1</li> <li>● <b>Direction:</b> Higher is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul> <p><i>Antal fald</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Reporting:</b> Fully reported</li> <li>● <b>Range:</b> 0-?</li> <li>● <b>Unit of measure:</b> antal</li> <li>● <b>Direction:</b> Lower is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul>
<b>Identification</b>	<p><b>Sponsorship source:</b> TJ Aalto was supported for this study a EVO grant by a Kuopio University Hospital, and a research grant from the Finnish Cultural Foundation (Hulda Tossavainen found. 2003; Ailiand Leo Davidsson found. 2009; St. Michel Central Hospital 200-yearFund 2010)</p> <p><b>Country:</b> Finland</p> <p><b>Setting:</b> patients with clinically and radiologically defined LSS, Selection for surgery (secondary level care) was made by the orthopaedist or neurosurgeon between October 2001 and October 2004 in the University Hospital.</p> <p><b>Comments:</b> .</p> <p><b>Authors name:</b> Timo J. Aalto</p> <p><b>Institution:</b> Kyyhkyla Rehabilitation Center and Hospital/Hallinto, Kyyhkyla 'ntie 9, 50700 Mikkeli, Finland</p> <p><b>Email:</b> imo.aalto@kyyhkyla.fi</p> <p><b>Address:</b> Kyyhkylantie 9, 50700 Mikkeli, Finland</p>
<b>Notes</b>	

## Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	n
Allocation concealment (selection bias)	Unclear risk	n
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	Unclear risk	n
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

## McGregor 2011

<b>Methods</b>	<p><b>Study design:</b> Randomized controlled trial</p> <p><b>Study grouping:</b> Parallel group</p>
<b>Participants</b>	<p><b>Baseline Characteristics</b></p> <p>intervention, rehabilitation only control, booklet only rehabilitation and booklet control, usual care Overall</p> <p><b>Included criteria:</b> Patients awaiting spinal surgery with either (a) signs symptoms and radiological evidence of lateral nerve root compression, that is patients presenting with radicular pain with an associated neurological deficit or with neurogenic claudication, or (b) lumbar disc prolapse that is patients with root symptoms and signs and MRI confirmation of lumbar disc herniation</p> <p><b>Excluded criteria:</b> Any condition where either the intervention or the rehabilitation may have an adverse effect on the individual, previous spinal surgery, spinal surgery where a fusion procedure was planned because of the unknown hazards of the activity program for this type of surgery, pregnant women, inadequate ability to complete the trial assessment forms, unable to attend or unsuitable for rehabilitation classes</p> <p><b>Pretreatment:</b> no significant differences</p>
<b>Interventions</b>	<p><b>Intervention Characteristics</b></p> <p>intervention, rehabilitation only</p> <ul style="list-style-type: none"> <li>● <i>description:</i> stretching, stability exercises, strengthening and endurance training for the back, abdominal and leg muscles, ergonomic training, advice on lifting and setting targets and selfmotivation and discussion along with and open group discussion at the end of each class</li> <li>● <i>dose:</i> 1 time 2 gange om ugen i 12 uger 6-8 uger efter operationen</li> </ul> <p>control, booklet only</p> <ul style="list-style-type: none"> <li>● <i>description:</i> Received a copy of "Your Back Operation" on discharge from hospital</li> <li>● <i>dose:</i> .</li> </ul>

	<p>rehabilitation and booklet</p> <ul style="list-style-type: none"> <li>● <i>description</i>: stretching, stability exercises, strenghtening and endurance training for the back, abdominal and leg muscles, ergonomic training, advice on lifting and setting targets and selfmotivation and discussion along with and open group discussion a the end of each class + a copy of your back operation</li> <li>● <i>dose</i>: .</li> </ul> <p>control, usual care</p> <ul style="list-style-type: none"> <li>● <i>description</i>: Patients receiving usual care were managed according to the relevant surgeons usual practice</li> <li>● <i>dose</i>: .</li> </ul>
<b>Outcomes</b>	<p><i>ODI</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type</b>: ContinuousOutcome</li> <li>● <b>Reporting</b>: Fully reported</li> <li>● <b>Scale</b>: ODI</li> <li>● <b>Range</b>: 0-100</li> <li>● <b>Direction</b>: Lower is better</li> <li>● <b>Data value</b>: Change from baseline</li> </ul> <p><i>VAS (Back Pain)</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type</b>: ContinuousOutcome</li> <li>● <b>Reporting</b>: Fully reported</li> <li>● <b>Scale</b>: VAS</li> <li>● <b>Range</b>: 0-100</li> <li>● <b>Direction</b>: Lower is better</li> <li>● <b>Data value</b>: Change from baseline</li> </ul> <p><i>VAS (leg pain)</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type</b>: ContinuousOutcome</li> <li>● <b>Reporting</b>: Fully reported</li> <li>● <b>Scale</b>: VAS</li> <li>● <b>Range</b>: 0-100</li> <li>● <b>Direction</b>: Lower is better</li> <li>● <b>Data value</b>: Change from baseline</li> </ul> <p><i>Treadmill (gangtest)</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type</b>: ContinuousOutcome</li> <li>● <b>Reporting</b>: Fully reported</li> <li>● <b>Range</b>: 0-?</li> <li>● <b>Unit of measure</b>: m</li> <li>● <b>Data value</b>: Endpoint</li> </ul> <p><i>Behov for smertestillende</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type</b>: DichotomousOutcome</li> <li>● <b>Reporting</b>: Fully reported</li> <li>● <b>Range</b>: 0-1</li> <li>● <b>Direction</b>: Lower is better</li> <li>● <b>Data value</b>: Endpoint</li> </ul> <p><i>VAS health summary</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type</b>: ContinuousOutcome</li> <li>● <b>Reporting</b>: Fully reported</li> <li>● <b>Scale</b>: VAS</li> <li>● <b>Range</b>: 0-100</li> <li>● <b>Direction</b>: Higher is better</li> <li>● <b>Data value</b>: Change from baseline</li> </ul> <p><i>Antal fald</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type</b>: ContinuousOutcome</li> <li>● <b>Reporting</b>: Fully reported</li> <li>● <b>Scale</b>: antal</li> <li>● <b>Range</b>: 0-?</li> <li>● <b>Direction</b>: Lower is better</li> <li>● <b>Data value</b>: Endpoint</li> </ul>
<b>Identification</b>	<p><b>Sponsorship source</b>: Arthritis Research UK funds supported the work</p> <p><b>Country</b>: England</p> <p><b>Setting</b>: Post operative rehabilitation</p> <p><b>Comments</b>: .</p> <p><b>Authors name</b>: Alison McGregor</p> <p><b>Institution</b>: From the surgery &amp; Cancer Faculty of medicine, Imperial College London, Charing Cross Hospital , London</p> <p><b>Email</b>: a.mcgregor@imperial.ac.uk</p> <p><b>Address</b>: Charing Cross Hospital Campus, London W6 8RP, England</p>
<b>Notes</b>	<p><i>NKR 51 Stenose</i> on 28/02/2017 22:33</p> <p><b>Outcomes</b></p> <p>Det er ikke beskrevet hvor mange der falder bort i de forskellige grupper.Data er sendt fra forfatteren</p>

## Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	High risk	

Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

## Footnotes

## References to studies

## Included studies

**Aalto 2011**

Aalto, T. J.; Leinonen, V.; Herno, A.; Alen, M.; Kroger, H.; Turunen, V.; Savolainen, S.; Saari, T.; Airaksinen, O.. Postoperative rehabilitation does not improve functional outcome in lumbar spinal stenosis: a prospective study with 2-year postoperative follow-up. *European Spine Journal* 2011;20(8):1331-1340. [DOI: ]

**McGregor 2011**

McGregor, Alison H.; Dore, Caroline J.; Morris, Tim P.; Morris, Steve; Jamrozik, Konrad. ISSLS prize winner: Function After Spinal Treatment, Exercise, and Rehabilitation (FASTER): a factorial randomized trial to determine whether the functional outcome of spinal surgery can be improved.. *Spine* 2011;36(21):1711-1720. [DOI: <http://dx.doi.org/10.1097/BRS.0b013e318214e3e6>]

## Excluded studies

**Ilves 2016**

Ilves, Outi; Hakkinen, Arja; Dekker, Joost; Pekkanen, Liisa; Piitulainen, Kirsi; Jarvenpaa, Salme; Marttinen, Ilkka; Vihtonen, Kimmo; Neva, Marko H.. Quality of life and disability: can they be improved by active postoperative rehabilitation after spinal fusion surgery in patients with spondylolisthesis? A randomised controlled trial with 12-month follow-up.. *European Spine Journal* 2016;(Journal Article). [DOI: <http://dx.doi.org/10.1007/s00586-016-4789-5>]

**Marchand 2015**

Marchand, Andree-Anne; Suitner, Margaux; O'Shaughnessy, Julie; Chatillon, Claude-Edouard; Cantin, Vincent; Descarreaux, Martin. Effects of a prehabilitation program on patients' recovery following spinal stenosis surgery: study protocol for a randomized controlled trial.. *Trials [Electronic Resource]* 2015;16(Journal Article):483. [DOI: <http://dx.doi.org/10.1186/s13063-015-1009-2>]

**McGregor 2010**

McGregor, A. H.; Dore, C. J.; Morris, T. P.; Morris, S.; Jamrozik, K.. Function after spinal treatment, exercise and rehabilitation (FASTER): improving the functional outcome of spinal surgery.. *BMC Musculoskeletal Disorders* 2010;11(Journal Article):17. [DOI: <http://dx.doi.org/10.1186/1471-2474-11-17>]

**Traistaru 2013**

Traistaru M.R.; Rogoveanu O.; Popescu, R.. Benefits of rehabilitation program in patients with l5-s1 degenerative foraminal stenosis.. *Annals of the Rheumatic Diseases* 2013;72 (no pagination(Journal Article)). [DOI: <http://dx.doi.org/10.1136/annrheumdis-2013-eular.2147>]

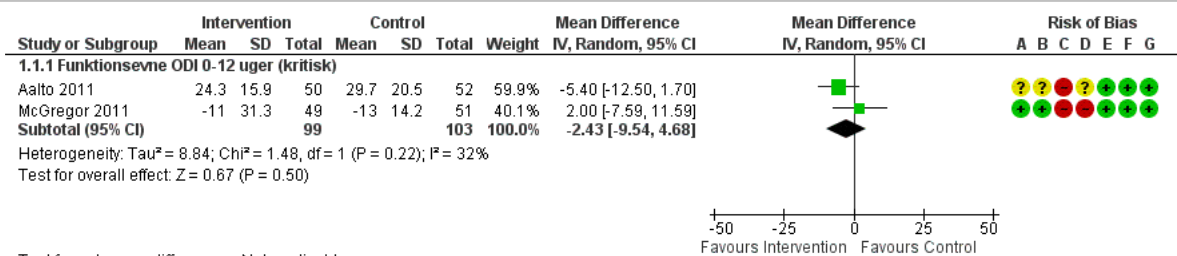
## Data and analyses

## 1 Intervention (post.op. supervised training) vs Control (post.op.training)

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Funktionsevne 0-12 uger (kritisk)	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1.1 Funktionsevne ODI 0-12 uger (kritisk)	2	202	Mean Difference (IV, Random, 95% CI)	-2.43 [-9.54, 4.68]
1.3 Gangdistance 0-12 uger (kritisk)	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.3.1 Gangdistance 0-12 uger (kritisk)	1	102	Mean Difference (IV, Fixed, 95% CI)	44.00 [-109.73, 197.73]
1.4 Smerte 0-12 uger (kritisk)	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.4.1 Smerte, VAS leg pain, 0-12 uger (kritisk)	2	202	Mean Difference (IV, Random, 95% CI)	3.62 [-15.79, 23.04]
1.6 Behov for smertestillende medicin 0-12 uger (vigtigt)	0		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.7 Livskvalitet 0-12 uger (vigtigt)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.7.1 Livskvalitet, 0-12 uger, (Vigtigt)	1	100	Mean Difference (IV, Random, 95% CI)	2.00 [-11.49, 15.49]
1.8 Antal fald 0-12 uger (vigtigt)	0	0	Odds Ratio (M-H, Fixed, 95% CI)	Not estimable
1.9 Funktionsevne 6-18 måneder (vigtigt)	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.10 Gangdistance 6-18 måneder (vigtigt)	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.11 Smerte 6-18 måneder (vigtigt)	0		Mean Difference (IV, Fixed, 95% CI)	Subtotals only

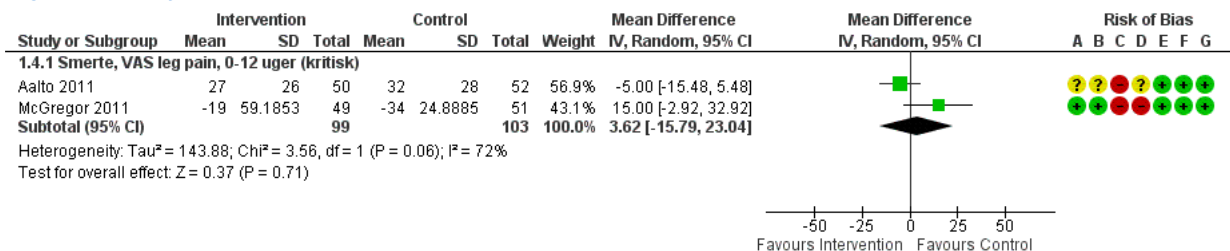
## Figures

## Figure 1 (Analysis 1.1)



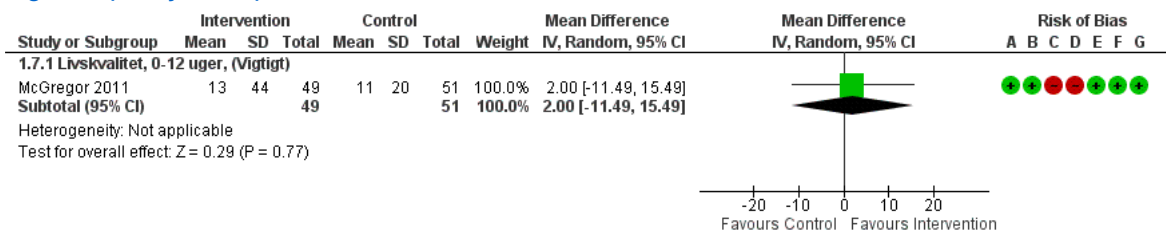
Forest plot of comparison: 1 Intervention (post.op. supervised training) vs Control (post.op.training), outcome: 1.1 Funktionsevne 0-12 uger (kritisk).

Figure 2 (Analysis 1.4)



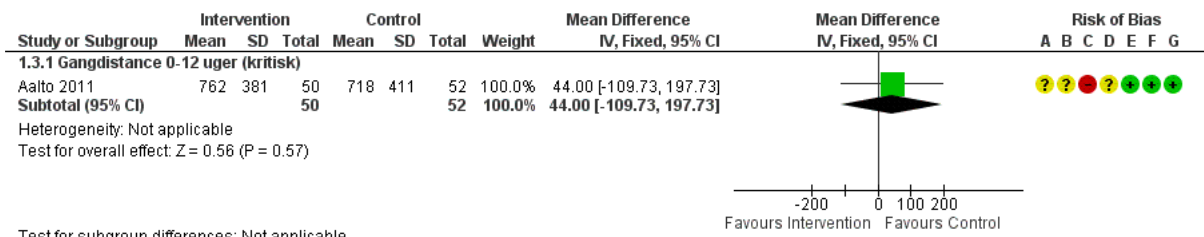
Forest plot of comparison: 1 Intervention (post.op. supervised training) vs Control (post.op.training), outcome: 1.4 Smerte 0-12 uger (kritisk).

Figure 3 (Analysis 1.7)



Forest plot of comparison: 1 Intervention (post.op. supervised training) vs Control (post.op.training), outcome: 1.7 Livskvalitet 0-12 uger (vigtigt).

Figure 4 (Analysis 1.3)



Forest plot of comparison: 1 Intervention (post.op. supervised training) vs Control (post.op.training), outcome: 1.3 Gangdistance 0-12 uger (kritisk).