McGregor, A.H., Probyn, K,, Cro, S., Doré, C.J., Burton, A.K., Balagué, F. Pincus T. & Fairbank, J.

Rehabilitation following surgery for lumbar spinal stenosis.

Cochrane Database of Systematic Reviews 2013, Issue 12. Art. No.: CD009644.

DOI: 10.1002/14651858.CD009644.pub2.

Included studies

Aalto 2011 *{published data only}*

Aalto, T.J., Leinonen, V., Herno, A., Alen, M., Kroger, H., Turunen, V., et al.
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):1331-40.

Mannion 2007 {*published and unpublished data}*

Mannion, A.F., Denzler, R., Dvorak, J., Muntener, M. & Grob, D.
A randomised controlled trial of post-operative rehabilitation after surgical decompression of the lumbar spine.
European Spine Journal 2007;**16**(8):1101-17.

McGregor 2010 {*published and unpublished data}*

McGregor, A.H., Dore, C.J., Morris, T.P., Morris, S. & Jamrozik, K.
ISSLS Prize paper: "Function after spinal treatment, exercise and rehabilitation (FASTER): a factorial randomised trial to determine whether the functional outcome of spinal surgery can be improved".
Spine 2011;**36**(21):1711-20.

Types of participants

Adults 18 years of age or older who had spinal decompression surgery for central or lateral stenosis at single or multiple levels were included in this review. Stenosis had to be confirmed through imaging and clinical assessment, and the surgery performed had to be primary decompression surgery for stenosis (as distinct from surgery for disc herniation). We included all surgical decompression procedures, with or without vertebral fusion.

Dealing with missing data

We contacted authors of original trials to request additional unpublished data as required. In two of the papers selected (Mannion et al. 2007; McGregor et al. 2010), only subgroups were suitable for inclusion in the review; relevant data from these subgroups were not published in the papers but were retrieved directly from the authors.

In total, three studies (N = 373 participants) met the inclusion criteria and were considered in this review.

SummaryX 17.4.2020

(9) Aalto, T.J., Leinonen, V., Herno, A., Alen, M., Kroger, H., Turunen, V., et al.
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):1331-40.

SummaryX: 2.3.1 Laadunarviointi (sivut 7-8)

Kaksi tutkijaa arvioi itsenäisesti kuuden kirurgista hoitoa tai kuntoutusta konservatiiviseen hoitoon vertaavan tutkimuksen (harhan riskin (RoB, risk of bias) käyttäen Furlanin ym. työkalua (15).

- Kaksi tutkimusta (Aalto ym. 2011, Malmivaara ym. 2007) täytti kahdeksan kolmestatoista kriteeristä, ja niiden voidaan katsoa olevan kohtalaisen hyvin toteutettuja. Näistä Aalto ym. 2011 tutkimuksessa oli muita mahdollisia uhkia tutkimuksen validiteetille, esim. ennen interventiota potilailla oli keskimäärin melko vähän selästä johtuvaa toiminnallista haittaa (Oswestry-haittaindeksi, ODI <30) ja suhteellisen lievä selkäkipu.

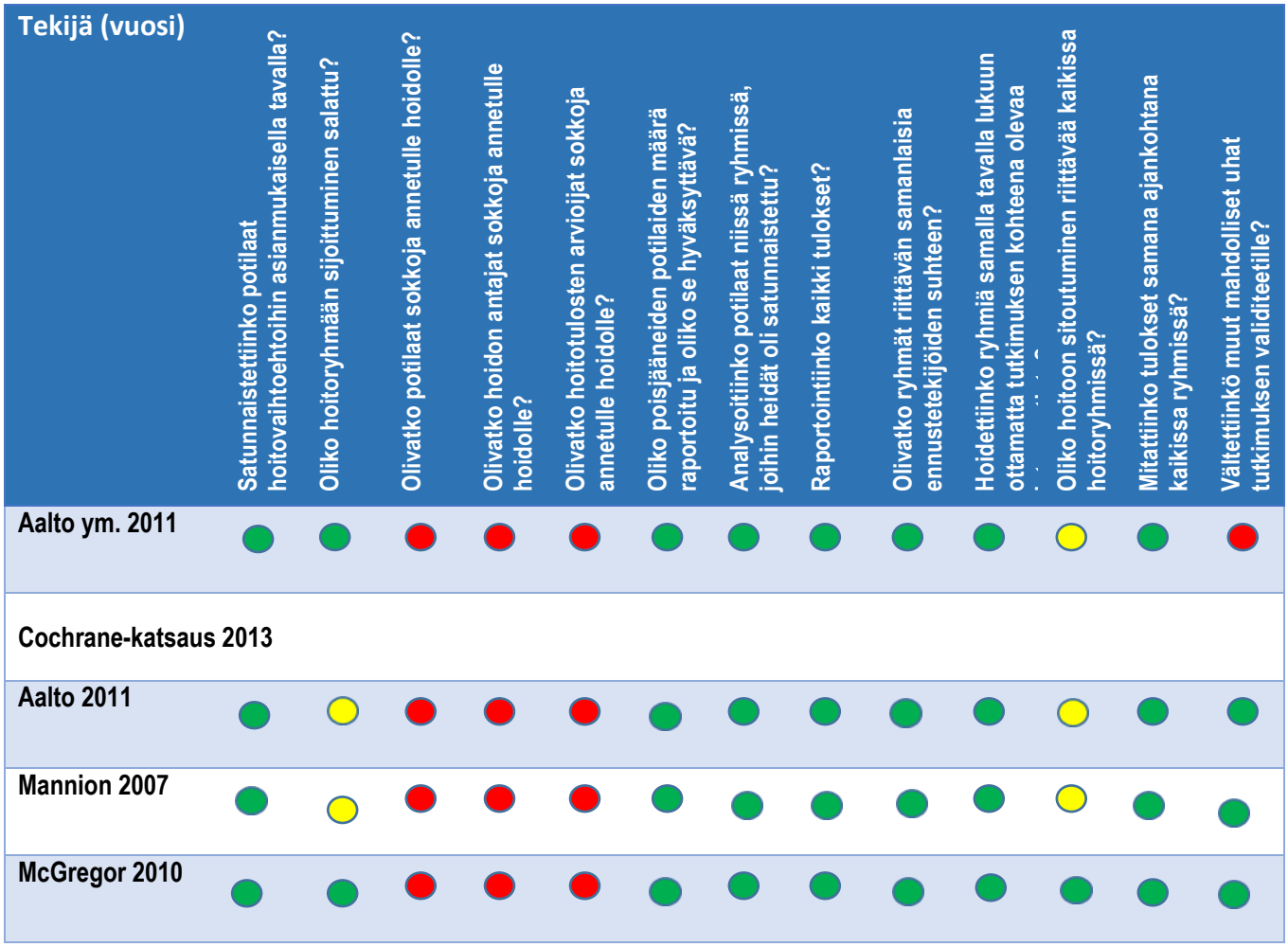
Cochrane-katsaus: Assessment of risk of bias in included studies (pages 12-14)

We assessed the risk of bias in included RCTs using the 12 criteria recommended by the CBRG, along with the additional item, 'Other sources of bias' (Appendix 6; Furlan 2009; Higgins 2011). For each study, each criterion was rated as 'low risk', 'high risk' or 'unclear risk.

- All included studies were rated as having low risk of bias because they fulfilled six or more of the risk of bias criteria and had no serious flaws. No study had unacceptably high dropout rates, and no unacceptably unbalanced dropout rates, unacceptably low adherence rates or total or nearly total non-adherence to the protocol was noted; clearly significantly unbalanced baseline differences for the primary outcome (functional status) were not accounted for in the analysis. The main risk of bias within all of the included studies was lack of blinding, which could not be which could not be avoided because of the nature of the intervention under study (Figure 2, page 13).

Tutkimusten laadunarviointi (yhdistetty SummaryX ja Cochrane katsausten tulokset).

Valmistelumuistion liite 1



Harhan riski: Vähäinen Epäselvä Suuri

Aalto ym. 2011 (9) [SummaryX]			
Harhan riskin lähde:	**Kysymys**	**Vastaus**	**Kommentteja**
Potilasvalinta:	(1) Satunnaistettiinko potilaat hoitovaihtoehtoihin asianmukaisella tavalla?	Kyllä	
Potilasvalinta:	(2) Oliko hoitoryhmään sijoittuminen salattu?	Kyllä [a]	
Tutkimuksen toteutus:	(3) Olivatko potilaat sokkoja annetulle hoidolle?	Ei	Intervention luonne estää potilaiden sokkouttamisen
Tutkimuksen toteutus:	(4) Olivatko hoidon antajat sokkoja annetulle hoidolle?	Ei	Intervention luonne estää hoidon antajien sokkouttamisen
Tulosten mittaaminen:	(5) Olivatko hoitotulosten arvioijat sokkoja annetulle hoidolle?	Ei	Potilaat eivät olleet sokkoja annetulle hoidolle, potilaat raportoivat kaikki hoitotulokset
Kato:	(6) Oliko poisjääneiden potilaiden määrä raportoitu ja oliko se hyväksyttävä?	Kyllä	Kato 2 v kohdalla: 2 % (1/50, postoperative rehabilitation) / 6 % (3/50 controls)
Kato:	(7) Analysoitiinko potilaat niissä ryhmissä, joihin heidät oli satunnaistettu?	Kyllä	Lisäksi tehtiin ja raportoitiin erikseen "kuntoutusaikeen mukainen" analyysi
Raportointi:	(8) Raportointiinko kaikki tulokset?	Kyllä	
Potilasvalinta:	(9) Olivatko ryhmät riittävän samanlaisia ennustetekijöiden suhteen?	Kyllä	Kuntoutus- ja tavanomaisen hoidon ryhmien välillä ei tilastollista eroa. Kuntoutusjakson onnistuneesti läpikäyneillä vähemmän aiempia selkäleikkauksia kuin kaikilla kuntoutusryhmän potilailla ja tavanomaisen hoidon potilailla

Tutkimuksen toteutus:	(10) Hoidettiinko ryhmiä samalla tavalla lukuun ottamatta tutkimuksen kohteena olevaa interventiota?	Kyllä	
Tutkimuksen toteutus:	(11) Oliko hoitoon sitoutuminen riittävää kaikissa hoitoryhmissä?	Epäselvä	14 % kuntoutusryhmän potilaista osallistui alle puoleen ryhmäkuntoutuskerroista.
Tulosten mittaaminen:	(12) Mitattiinko tulokset samana ajankohtana kaikissa ryhmissä?	Kyllä	
Muuta:	(13) Vältettiinkö muut mahdolliset uhat tutkimuksen validiteetille?	Ei [b]	Tavanomaisen hoidon ryhmään satunnaistetuilla potilailla oli mm. vähemmän fysioterapiaa ennen leikkausta ja korkeampi ODI kuin kuntoutus-ryhmän potilailla. Lisäksi tutkimuksessa potilailla oli keskimäärin melko vähän selästä johtuvaa toiminnallista haittaa (ODI <30)

[a] Cochrane Unclear risk: Two trial authors were present when participants were allocated to groups; unclear whether authors were aware of subsequent group allocation.
[b] Cochrane Low risk: No other biases

Mannion ym. 2007 [Cochrane]			
Harhan riskin lähde:	**Kysymys**	**Vastaus**	**Kommentteja**
Potilasvalinta:	(1) Satunnaistettiinko potilaat hoitovaihtoehtoihin asianmukaisella tavalla?	Kyllä	Yes, a restricted randomisation procedure with blocks of 12, as prepared by the lead author in advance; participants were prestratified by age (under/over 60) and gender
Potilasvalinta:	(2) Oliko hoitoryhmään sijoittuminen salattu?	Epäselvä	Unclear whether authors were aware of subsequent group allocation
Tutkimuksen toteutus:	(3) Olivatko potilaat sokkoja annetulle hoidolle?	Ei	It was indicated that participants were partially 'blinded' to control for expectation bias by being informed that the study sought to compare three popular approaches to postoperative rehabilitation; however, we do not judge this to be adequate blinding because of the nature of the intervention
Tutkimuksen toteutus:	(4) Olivatko hoidon antajat sokkoja annetulle hoidolle?	Ei	Not possible because of the nature of the intervention
Tulosten mittaaminen:	(5) Olivatko hoitotulosten arvioijat sokkoja annetulle hoidolle?	Ei	Participant-reported outcomes; participants were not adequately blinded because of the nature of the intervention
Kato:	(6) Oliko poisjääneiden potilaiden määrä raportoitu ja oliko se hyväksyttävä?	Kyllä	Dropout rates for full study were described and acceptable
Kato:	(7) Analysoitiinko potilaat niissä ryhmissä, joihin heidät oli satunnaistettu?	Kyllä	ITT analysis was used
Raportointi:	(8) Raportointiinko kaikki tulokset?	Kyllä	No protocol was found; however, all expected outcomes were reported
Potilasvalinta:	(9) Olivatko ryhmät riittävän samanlaisia ennustetekijöiden suhteen?	Kyllä	Groups were similar at baseline It must be noted, however, that baseline imbalances between rehabilitation and control groups were noted for the outcome of "leg pain"; because the trial was adequately randomised, this is likely to be a chance imbalance
Tutkimuksen toteutus:	(10) Hoidettiinko ryhmiä samalla tavalla lukuun ottamatta tutkimuksen kohteena olevaa interventiota?	Kyllä	No co-interventions
Tutkimuksen toteutus:	(11) Oliko hoitoon sitoutuminen riittävää kaikissa hoitoryhmissä?	Epäselvä	No specific mentions
Tulosten mittaaminen:	(12) Mitattiinko tulokset samana ajankohtana kaikissa ryhmissä?	Kyllä	Yes
Muuta:	(13) Vältettiinkö muut mahdolliset uhat tutkimuksen validiteetille?	Kyllä	No other biases

Valmistelumuistion liite 1

McGregor ym. 2010 [Cochrane]			
Harhan riskin lähde:	**Kysymys**	**Vastaus**	**Kommentteja**
Potilasvalinta:	(1) Satunnaistettiinko potilaat hoitovaihtoehtoihin asianmukaisella tavalla?	Kyllä	**Yes, randomisation was stratified by surgeon, and surgical procedure was performed** using random permuted blocks
Potilasvalinta:	(2) Oliko hoitoryhmään sijoittuminen salattu?	Kyllä	Yes, allocation to study group was performed by central telephone randomisation
Tutkimuksen toteutus:	(3) Olivatko potilaat sokkoja annetulle hoidolle?	Ei	Not possible because of the nature of the intervention
Tutkimuksen toteutus:	(4) Olivatko hoidon antajat sokkoja annetulle hoidolle?	Ei	Not possible because of the nature of the intervention
Tulosten mittaaminen:	(5) Olivatko hoitotulosten arvioijat sokkoja annetulle hoidolle?	Ei	Participant-reported outcomes; participants could not be blinded because of the nature of the intervention
Kato:	(6) Oliko poisjääneiden potilaiden määrä raportoitu ja oliko se hyväksyttävä?	Kyllä	Dropout rates for full study were described and acceptable
Kato:	(7) Analysoitiinko potilaat niissä ryhmissä, joihin heidät oli satunnaistettu?	Kyllä	ITT analysis was used
Raportointi:	(8) Raportointiinko kaikki tulokset?	Kyllä	Protocol was assessed, and all expected outcomes were reported
Potilasvalinta:	(9) Olivatko ryhmät riittävän samanlaisia ennustetekijöiden suhteen?	Kyllä	Groups were similar at baseline
Tutkimuksen toteutus:	(10) Hoidettiinko ryhmiä samalla tavalla lukuun ottamatta tutkimuksen kohteena olevaa interventiota?	Kyllä	Co-interventions were the same in both groups
Tutkimuksen toteutus:	(11) Oliko hoitoon sitoutuminen riittävää kaikissa hoitoryhmissä?	Kyllä	Yes, compliance described and acceptable
Tulosten mittaaminen:	(12) Mitattiinko tulokset samana ajankohtana kaikissa ryhmissä?	Kyllä	Yes
Muuta:	(13) Vältettiinkö muut mahdolliset uhat tutkimuksen validiteetille?	Kyllä	No other biases

Cochrane-katsaus:

- A total of three studies (N = 373 participants) were included in the review and meta-analysis.
- huom. alkuperäistutkimuksista poimittuna lannerangan ahtauma potilaiden (leikattujen) n = 397; ilmeisesti poissuljettuja, mutta aika ei riittänyt tarkistamaan katsauksen kirjoittajilta

Ryhmien alkutilanne

Tutkimus, maa	Vertailu I vs C	Otoskoko spinaali-stenoosi	Ikä, ka (v) Miehiä (%) (I / C)	Ryhmä (I / C)	Toimintakyky ka (SD)		Kipu ka (SD)	
					Ostwestry (0-100)	Roland-Morris (0-24)	alaselkä VAS (0-100)	alaraaja VAS (0-100)
Aalto et al. 2011 (Cochrane) Suomi	Fysioterapia vs preoperatiivi-nen ohjaus	n=102	ikä (vuotta) 62.5 (34-86; 11.1) naisia 59 % / miehiä 41 % BMI: 29.5 (4.0)	I alku	24.3 (15.9)		16 (19)	27 (26)
				C alku	29.7 (20.5)		20 (26)	32 (28)
Mannion et al. 2007 [a] (Cochrane) Sveitsi	Fysioterapia (a ja B ryhmät yhdistetty) vs omatoiminen harjoittelu	n = 107	ikä (vuotta) 67.1 (10.6) naisia 41 % / miehiä 59 % BMI: 27 (4.5)	I alku		10.9 (4.9)	25 (20)	30 (23)
				C alku		10.6 (4.7)	29 (21)	22 (24)
McGregor et al. 2010[b] (Cochrane) Englanti	Fysioterapia vs tavanomainen hoito	n = 188	ikä (vuotta) 62 (15) naisia 51,5 % / miehiä 49,5 % BMI: 27 (5)	I alku	30 (18)		35 (26)	33 (27)
				C alku	32 (21)		35 (29)	32 (28)

[a] This study included spinal stenosis and herniated disc participants For this review, only lumbar spinal stenosis participants who met the inclusion criteria for this meta-analysis were included; herniated disc participants were excluded. Data from the relevant subgroup were gathered directly from the trial authors and were not published.

[b] This trial also included herniated disc participants, who were excluded for this analysis. Only the subgroup that met the inclusion criteria for this analysis was included. Combined groups data were gathered directly from the trial authors and were not published.

Interventiot ja tulosmuuttujat:

Tutkimus	Vertailu		Intervention toteutus	Tulosmuuttujat
Aalto et al. 2011 [a] (Cochrane) Suomi **n = 102** 100 % dekompres-sio	Fysioterapia aloitus 3 kk postoperatiivisesti n = 50		krt/vko 90 min fysioterapeutin ohjaamaa harjoittelua ryhmässä 12 viikon ajan 12 x 90 min ohjattu harjoittelu krt/vko toistettiin 1 vuoden jälkeen kotiharjoittelu 3-24 kk sis. venyttely päivittäin ja voimaharjoittelu 3 x vko	postoperatiivisesti 3 kk, 6 kk, 12 kk ja 24 kk • Haitta-aste: Ostwestryn indeksi (ODI) (0-100%) [d] • Kipu (NRS): lepokipu selässä (0-10) [d] ja jalkakipu kävellessä (0-10) [d] viimeisen viikon aikana • Yleinen selkä- ja jalakipu tutkimushetkellä intervention alussa (VAS 0 to 100 mm) [d]
	Kontrolli n = 52		preoperatiivinen ohjaus sairaalassa (ei hoitoa tai itsehoito)[a].	
Mannion et al. 2007 [b] (Cochrane) Sveitsi	Interventio n = 105, joista stenoosi	Fysioterapia (PTStabEx) n = 56, joista 66 % stenoosi	Fysioterapia 2 x 30 min / viikko sis. selän stabiloivia harjoituksia 12 viikon ajan	preoperatiivisesti ja postoperatiivisesti 2 kk, 5 kk, 12 kk ja 24 kk

(n = 159, joista stenoosi 65 – 71 %) **n = 107**	➔ **n = 72**	➔ n=37		• Haitta-aste: Roland Morris Disability (RDQ) kysely (0-24) [d] • Kipu (NRS): selkä ja jalkakipu (0-10) [d] viimeien viikon aikana • FABQ (Fear Avoidance Beliefs Questionnaire) kysely (0-24) [d]
		Fysioterapia (PT-Mixed) n = 49, joista 71 % stenoosi ➔ n = 35	Fysioterapia 2 x 30 min / viikko nykykäytännön mukaan 12 viikon ajan	
	Kontrolli n = 54, joista 65 % stenoosi ➔ **n = 35**		Omatoiminen harjoittelu 12 viikkoa: Potilaita ohjattiin olemaan mahdoll. aktiivisia ja tekemään itselleen sopivaa liikuntaa/harjoittelu (pitivät päiväkirjaa)	
McGregor et al. 2011 [c] (Cochrane) Englanti (n = 338, joista 56 % dekompres-sio) **n = 188**	Interventio n = 98 Fysioterapia aloitus 6- 8 viikkoa postoperatii visesti	Fysioterapia n = 49	yhteensä 12 standardisoitua fysioterapiakertaa ryhmässä 2 x 60 min / viikko; kesto 6 viikkoa (aerobinen kunto, venyttely, stabilisoivat harjoitukset, selkä-, vatsa- ja jalkalihasten voima- ja kestävyysharjoitukset, nosto-ohjeet, motivointi)	postoperatiivisesti 6 viikkoa sekä 3 kk, 6 kk, 9 kk ja 12 kk • Haitta-aste: Ostwestryn indeksi (ODI) (0-100%) [d] • Kipu: Selkä- ja jalkakipu (VAS 0-100) [d] • HADS (Hospital anxiety and depression) kysely (0-21) [d] • FABQ (Fear Avoidance Beliefs Questionnaire) kysely (0-24) [c] • EQ-5D elämänlaatu (0-100) [e]
		Fysioterapia ja ohjekirja n = 49	Kuntoutus kuten edellä ja selkäleikkaus ohjekirja kotiutusvaiheessa	
	Kontrolli n = 90	Ohjekirja n = 39	Selkäleikkaus ohjekirja kotiutusvaiheessa	
		Tavanomai-nen hoito n = 51	Leikanneen kirurgin käytännön mukainen tavanomaisen hoito	

[a] Usual care therefore consisted of no treatment or self management. However, no restrictions were placed on prohibiting rehabilitation; therefore, treating surgeons and GPs if required could prescribe other treatments (e.g. physiotherapy, analgesics) (Cochrane page 23)
[b] The two intervention groups in this trial were combined into a single group, using methods as described in the Cochrane Handbook for Systematic Reviews of Interventions, as interventions were homogeneous enough and both interventions met the inclusion criteria for this analysis. (page 26)
[c] This trial included four treatment arms; it used a 2 × 2 factorial design and randomly assigned participants to four groups: rehabilitation-only, booklet-only, rehabilitation-plus-booklet and usual care only. For this review, the four groups were combined into two groups—only booklet and no booklet; rehabilitation-only and rehabilitation-plus-booklet versus booklet-only and usual care only—to contrast rehabilitation with usual care. (page 28)
[d] lower scores representing lower levels of disability / pain / anxiety / fear avoidance beliefs
[e] higher scores representing a perfect health state

The analysis was carried out using two comparisons.

1) Effect of rehabilitation within six months postoperatively (short term).
2) Effect of rehabilitation at 12 months postoperatively (long term).

- The decision to consider only the 12 months postoperative outcome (for long-term follow-up) was a reflection of the data available because only two of the included studies provided further postoperative follow-up data.

1) **Primary outcomes** considered by this review was functional status as measured by a back-specific scale (Roland Morris Disability Questionnaire (RMDQ) or Oswestry Disability Index (ODI)).
2) **Secondary outcomes** included measures of pain severity (and location, i.e. back pain/leg pain) and global improvement/overall health.

- joissakin tutkimuksissa mukana ollut terveydentila (elämänlaatu) tai ahdistuneisuus / masentuneisuus jätetty pois analyysista.

Aalto et el. 2011

Tulosmuuttuja, Päätulosmuuttujat lihavoituna	**Mittaus-ajankohta**	**Potilaita (I/C)**	**Interventio ka (SD)**	**Kontrolli ka (SD)**	**Std. Mean Difference**
Toimintakyky Oswestryn indeksi (skaala 0–100, pienempi parempi)	Ennen kuntoutusta	50/52	24,3 (15,9)	29,7 (20,5)	
	6 kk	50/52	22,5 (17,8)	26,4 (19,1)	-0.28 [-0.67, -0.11]
	1 v	49/51	24,8 (19,1)	31,0 (20,1)	-0.44 [-0.83, -0.04]
Selkäkipu levossa edeltävän viikon aikana: NRS (muutettu skaala VAS 0–100, pienempi parempi)	Ennen kuntoutusta	50/52	16 (19)	20 (26)	
	6 kk	50/52	14 (18)	20 (26)	-0.35 [-0,73, 0.03]
	1 v	49/51	1,6 (2,0)	24 (26)	-0.49 [-0,85, -0.12]
Alaraajakipu kävellessä edeltävän viikon aikana: NRS (muutettu skaala VAS 0–100, pienempi parempi)	Ennen kuntoutusta	50/52	27 (26)	32 (28)	
	6 kk	50/52	24 (24)	35 (29)	-0.46 [-0.77, -0.16]
	1 v	49/51	28 (29)	35 (31)	-0.30 [-0.62, 0.02]

Mannion et al. 2007

Tulosmuuttuja, Päätulosmuuttujat lihavoituna	Mittaus-ajankohta	Potilaita (I/C)	Interventio ka (SD)	Kontrolli ka (SD)	Std. Mean Difference
Toimintakyky Roland-Morris (skaala 0–124, pienempi parempi)	Ennen kuntoutusta	72/35	10.9 (4.9)	10. (4.7)	
	6 kk	72/35	8.6 (5.3)	8.7 (5.8)	0.02 [-0.38, 0.42]
	1 v	72/35	8.9 (6.0)	9.1 (5.7)	-0.07 [-0.48, -0.33]
Selkäkipu levossa edeltävän viikon aikana: VAS (0–100, pienempi parempi)	Ennen kuntoutusta	72/35	25 (20)	29 (21)	
	6 kk	72/35	29.5 (29)	23.5 (26.0)	0.05 [-0.25, 0.36]
	1 v	72/35	28.6 (25.5)	32.0 (27.0)	-0.14 [-0.44, 0.11]
Alaraajakipu kävellessä edeltävän viikon aikana: VAS (skaala 0–100, pienempi parempi)	Ennen kuntoutusta	72/35	30 (23)	22 (24)	
	6 kk	72/35	29.0 (24.8)	24.0 (25.0)	0.21 [-0.12, 0.54]
	1 v	72/35	32.5 (28.3)	33.0 (30.0)	0.00 [-0.31, 0.31]

McGregor et al. 2010

Tulosmuuttuja, Päätulosmuuttujat lihavoituna	Mittaus-ajankohta	Potilaita (I/C) [a]	Interventio ka (SD)	Kontrolli ka (SD)	Std. Mean Difference
Toimintakyky Oswestryn indeksi (skaala 0–100, pienempi parempi)	Ennen kuntoutusta	98/90	30 (18)	32 (21)	
	6 kk	70/61	27 (18)	32(19)	-0.35 [-0.69, -0.00]
	1 v	90/76	29 (21)	34 (22)	-0.25 [-0.56, 0.05]
Selkäkipu levossa edeltävän viikon aikana: VAS (0–100, pienempi parempi)	Ennen kuntoutusta	98/90	35 (26)	35 (29)	
	6 kk	70/61	33.0 (26.0)	41.0 (29.0)	-0.26 [-0.48 , -0.03]
	1 v	90/76	38.0 (30.0)	42.0 (29.0)	-0.15 [-0.35, 0.05]
Alaraajakipu kävellessä edeltävän viikon aikana: VAS (skaala 0–10, pienempi parempi)	Ennen kuntoutusta	98/90	33 (27)	32 (28)	
	6 kk	70/61	32.0 (27.0)	38.0 (28.0)	-0.22 [-0.46, 0.01]
	1 v	90/76	33.0 (31.0)	42.0 (20.0)	-0.38 [-0.60, -0.17]

[a] as not all of the participants attended the short-term follow-up assessment in McGregor 2010, fewer participants are included in the meta-analysis of the short-term follow-up outcomes than were included for the long-term follow-up outcomes.. Although McGregor 2010 had greater follow-up at 12 months (the study's primary endpoint) than at three months, sensitivity analyses conducted by McGregor et al verified consistent findings with different missing data assumptions, giving us no reason to exclude this study. (page 12)

1) Outcomes in the short term (within six months)

In the short term, moderate-quality evidence from three RCTs (340 people) indicate that active rehabilitation is more effective than usual care for functional status (log SMD -0.22, 95% CI -0.44 to 0.00, corresponding to an average percentage improvement (reduction in standardised functional score) of 20%, 95% CI 0% to 36%; Figure 3), and moderate quality evidence (from three RCTs, 340 people) suggest that rehabilitation is more effective than usual care for reported low back pain (log MD -0.18, 95% CI -0.35 to -0.02, corresponding to an average percentage improvement (reduction in VAS score) of 16%, 95% CI 2% to 30%; Figure 4).

Figure 3. Forest plot of comparison: 1 Short term, outcome: 1.1 Functional status short term on log-scale.

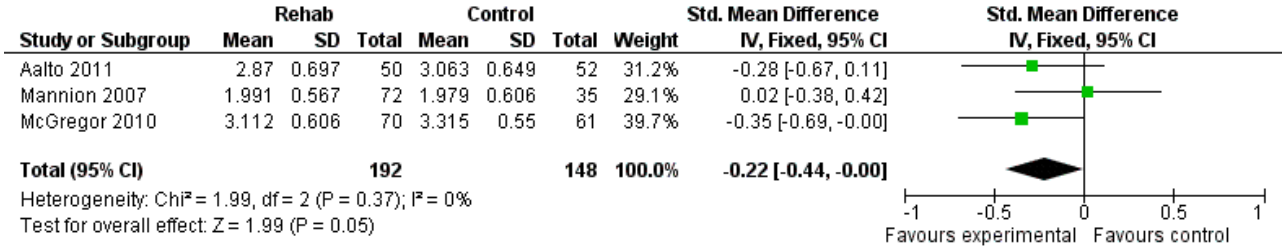
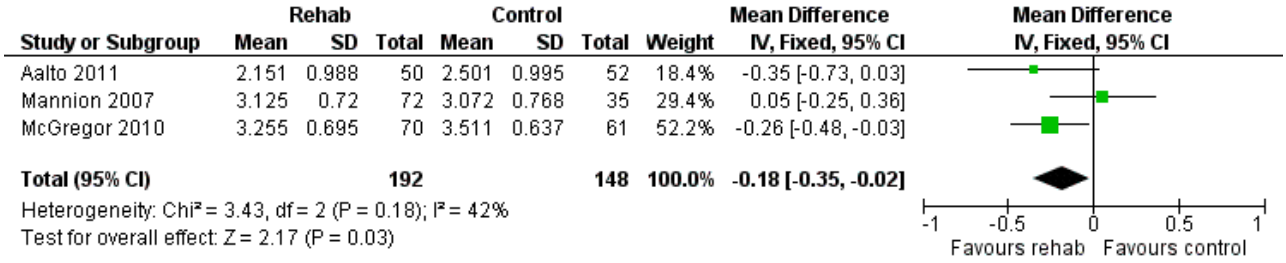
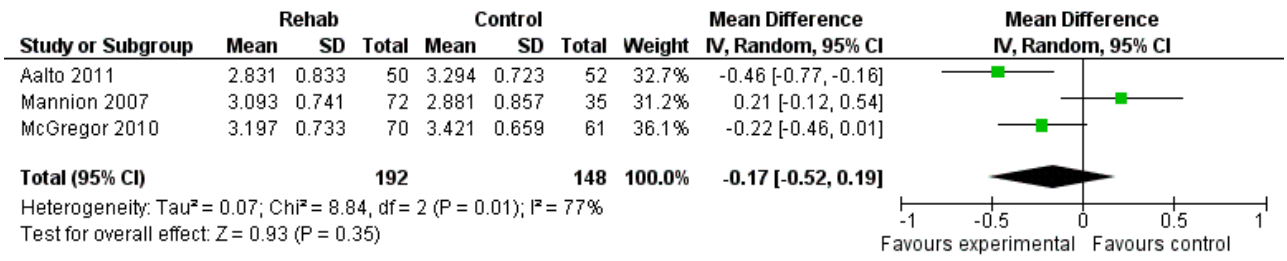


Figure 4. Forest plot of comparison: 1 Short term, outcome: 1.3 Low back pain short term on log-scale.



Low-quality evidence from three RCTs (340 people) show no statistically significant difference in leg pain (log MD -0.17, 95% CI -0.52 to 0.19, corresponding to an average percentage improvement (reduction in VAS score) of 16%, 95% CI 21% worsening (increase in VAS) to 41% improvement (decrease in VAS)) between individuals who received active rehabilitation and those who received usual care (Figure 5).

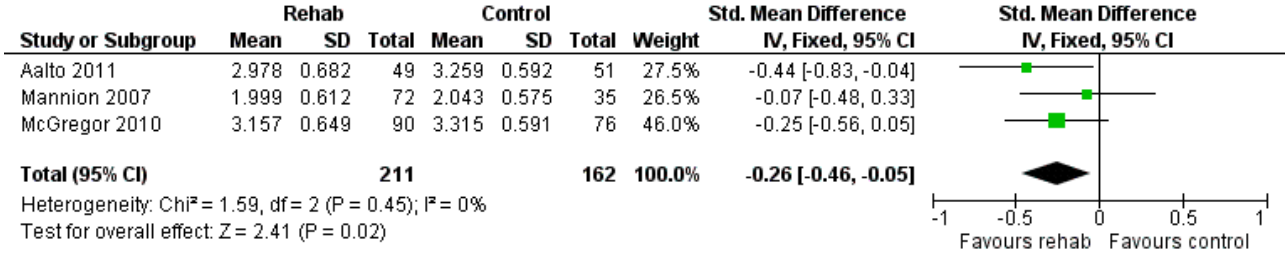
Figure 5. Forest plot of comparison: 1 Short term, outcome: 1.2 Leg pain short term on log-scale.



2) Outcomes over the long term (12 months postoperative)

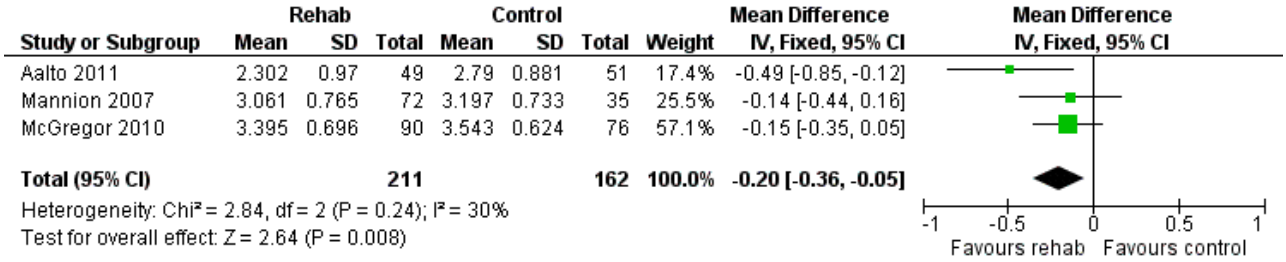
Over the long term, moderate-quality evidence from three RCTs (373 people) indicate that active rehabilitation is more effective than usual care for functional status (log SMD -0.26, 95% CI -0.46 to -0.05, corresponding to an average percentage improvement (reduction in standardised functional score) of 23%, 95% CI 5% to 37%; Figure 7).

Figure 7. Forest plot of comparison: 2 Long term, outcome: 2.1 Functional status long term on log-scale.



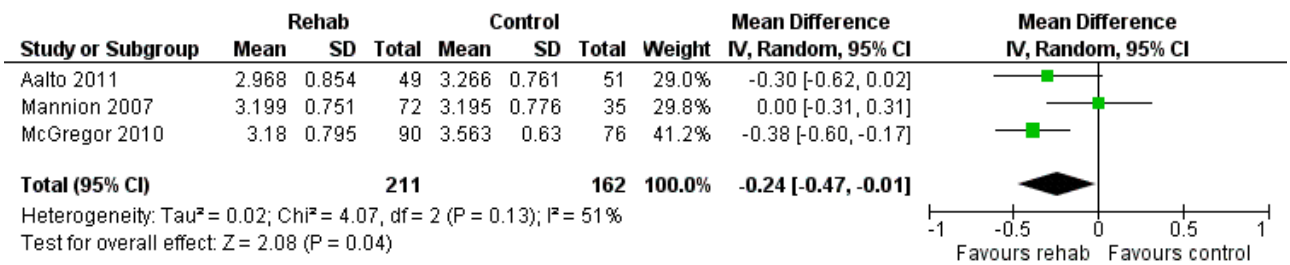
Moderate-quality evidence from three RCTs (373 people) suggest that active rehabilitation is more effective than usual care for low back pain (log MD -0.20, 95% CI -0.36 to -0.05, corresponding to an average percentage improvement (reduction in VAS score) of 18%, 95% CI 5% to 30%; Figure 8).

Figure 8. Forest plot of comparison: 2 Long term, outcome: 2.3 Low back pain long term on log-scale.



Moderate-quality evidence from three RCTs (373 people) also suggest that active rehabilitation is more effective than usual care for leg pain (log MD -0.24, 95% CI -0.47 to -0.01, corresponding to an average percentage improvement (reduction in VAS score) of 21%, 95% CI 1% to 37%; Figure 9).

Figure 9. Forest plot of comparison: 2 Long term, outcome: 2.2 Leg pain long term on log-scale.



Comparison 1. Short term (six months postoperatively)

Outcome or subgroup title	No. of studies	No. of partici-pants	Statistical method	Effect size
1 Functional status short term (log-scale)	3	340	Std. Mean Difference (IV, Fixed, 95% CI)	-0.22 [-0.44, -0.00]
2 Leg pain short term (log-scale)	3	340	Mean Difference (IV, Random, 95% CI)	-0.17 [-0.52, 0.19]
3 Low back pain short term (log-scale)	3	340	Mean Difference (IV, Fixed, 95% CI)	-0.18 [-0.35, -0.02]

Comparison 2. Long term (12 months postoperatively)

Outcome or subgroup title	No. of studies	No. of partici-pants	Statistical method	Effect size
1 Functional status long term (log-scale)	3	373	Std. Mean Difference (IV, Fixed, 95% CI)	-0.26 [-0.46, -0.05]
2 Leg pain long term (log-scale)	3	373	Mean Difference (IV, Random, 95% CI)	-0.24 [-0.47, -0.01]
3 Low back pain long term (log-scale)	3	373	Mean Difference (IV, Fixed, 95% CI)	-0.20 [-0.36, -0.05]

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Table 2| PRISMA-P (preferred reporting items for systematic review and meta-analysis protocols) 2015 checklist: recommended items to address in a systematic review protocol

Section and topic	Item No	Checklist item
Administrative information		
Title:		
Identification	1a	Identify the report as a protocol of a systematic review
Update	1b	If the protocol is for an update of a previous systematic review, identify as such
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number
Authors:		
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments
Support:		
Sources	5a	Indicate sources of financial or other support for the review
Sponsor	5b	Provide name for the review funder and/or sponsor
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol
Introduction		
Rationale	6	Describe the rationale for the review in the context of what is already known
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)
Methods		
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated
Study records:		
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)

Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation
Larissa Shamseer, David Moher, Mike Clarke, Davina Ghersi, Alessandro Liberati (deceased), Mark Petticrew , Paul Shekelle, Lesley A Stewart, the PRISMA-P Group

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