PICO 5: NKR 40 Lænderygsmerter

Characteristics of studies

Characteristics of included studies

CruserdA 2012

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Intervention Kontrol **Included criteria:** Soldiers presenting with a new complaint of ALBP, defined as a minimum of 30 days hiatus of pain from previous LBP episodes, were recruited daily at the MAMC clinics. The CRC verified that a soldier met the first level screening criteria. To pass the first screening level, a soldier had to be male or female, of any racial or ethnic origin, and between 18 and 35 years old. If a woman’s onset of her last menstrual cycle was 28 days prior to enrollment, she was given a urine pregnancy test, and excluded from the study if pregnant. **Excluded criteria:** A soldier could not enroll in the study ifthe SEP found evidence of a serious neurological,rheumatologic, or orthopedic condition present onexamination, including spondylolysis, spondylolisth-esis, fracture, nerve impingement, tumors, or infec-tions. Also, soldiers were not eligible if there wasclinical evidence of a leg length discrepancy greaterthan 13 mm or if their leg pain was worse than theirback pain indicating possible radiculopathy. Soldierscould not have had manual therapy for this episodeof ALBP. Last, they could not enroll in the study ifthere was any known inability to give informedconsent or the soldier knew at that time that he or shewould be unable to stay in the study for the four weekprotocol and participate in the end-point outcomesmeasures for the tri **Pretreatment:** Comparable at baseline
Interventions	**Intervention Characteristics** Intervention ● *Osteopathisk ledbehandling + sædvanlig behandling (OMT)*: OMT protocol Fig. 2. p. 9. ● *Sædvanlig behandling (UCO)*: DoD LBp guidelines p. 7

	Kontrol ● *Osteopathisk ledbehandling + sædvanlig behandling (OMT)*: ● *Sædvanlig behandling (UCO)*: x
Outcomes	*Funktionsevne 0-12 uger (Disability)* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: Roland Morris ● **Range**: 0-24 ● **Direction**: Lower is better ● **Data value**: Endpoint *Smerteniveau 0-12 uger (Pain)* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: NRS ● **Range**: 0-10 ● **Direction**: Lower is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** This work was supported by a grant from the SamueliInstitute for Information Biology (SIIB) through anaward from the Uniformed Services University ofthe Health Sciences (USUHS) under Award No.MDA905-03-C-0003. **Country:** USA **Setting:** Militærhospital **Comments:** NB militær personale **Authors name:** Cruser, des Anges **Institution:** University of North Texas Health Science Center, Texas College of Osteopathic Medicine, Fort Worth, TX, USA **Email:** desAnges.Cruser@unthsc.edu **Address:** Dr des Anges Cruser, University of North TexasHealth Science Center, Texas College of Osteopathic Medicine, 3500Camp Bowie Boulevard, PCC-463, Fort Worth, TX 76107, USA. E
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Incomplete outcome data	Low risk	
Blinding of outcome assessors	Unclear risk	No
Sequence Generation	Low risk	
Allocation concealment	Low risk	
Other sources of bias	Low risk	
Blinding of participants and personnel	High risk	
Selective outcome reporting	Low risk	

Hancock 2007

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Intervention Kontrol **Included criteria:** All patients with low back pain (with or without leg pain)of less than 6 weeks duration presenting to any of40 participating GPs in Sydney, Australia, were invited toparticipate. The inclusion criterion was a complaint ofpain in the area between the 12th rib and buttock creasecausing moderate pain and moderate disability (measuredby adaptations of items 7 and 8 of SF-367) **Excluded criteria:** Exclusioncriteria were: present episode of pain not preceded by apain-free period of at least 1 month, in which care was notprovided; known or suspected serious spinal pathology;nerve root compromise (with at least two of these signs:myotomal weakness, dermatomal sensory loss, orhyporefl exia of the lower limb refl exes); presently takingNSAIDs or undergoing spinal manipulation; any spinalsurgery within the preceding 6 months; andcontraindication to paracetamol, diclofenac, or spinalmanipulative therapy.

	Pretreatment: none
Interventions	**Intervention Characteristics** Intervention ● *SMT + placebo NSAID + advice*: x ● *Placebo SMT + placebo NSAID + advice*: ● *Back book*: Kontrol ● *SMT + placebo NSAID + advice*: ● *Placebo SMT + placebo NSAID + advice*: x ● *Back book*:
Outcomes	*Smerteniveau 0-12 uger (Pain)* ● **Outcome type**: ContinuousOutcome *Funktionsevne 0-12 uger (disability)* ● **Outcome type**: ContinuousOutcome
Identification	**Sponsorship source:** The trial was mainly funded by Australia's National Health and MedicalResearch Council. The active diclofenac was donated by Alphapharm. **Country:** Australia **Setting:** primary care **Comments:** **Authors name:** Mark Hancock **Institution:** University of Sydney, Back Pain Research Group **Email:** M.Hancock@usyd.edu.au **Address:** PO Box 170, Lidcombe,NSW 1825, Australia
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Incomplete outcome data	Low risk	
Blinding of outcome assessors	Low risk	
Sequence Generation	Low risk	
Allocation concealment	Low risk	
Other sources of bias	Low risk	
Blinding of participants and personnel	High risk	
Selective outcome reporting	Low risk	

Hsieh 2002

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Intervention Kontrol **Included criteria:** The inclusion criteria required an age of 18 years of age or older, LBP duration of more than 3 weeks and less than 6months for the current episode or a pain-free period of at least 2 months in the preceding 8 months for recurrent LBP, agreement for randomization, and consent for treatment. **Excluded criteria:** The exclusion criteria specified pregnancy; serious Medical problems (e.g., advanced cancer, heart failure); definable neurologic abnormalities in the lower extremities (e.g., peripheral neuropathy, multiple sclerosis, hemiplegia, myelopathy); spinedisorders with bony lesions (e.g., osteoporosis, fracture, unstable spondylolisthesis, multiple myeloma), with radiographswere taken as clinically indicated; significant mental disorders(e.g., psychosis, mania, major depression), as indicated by tele-phone inquiry and clinical interview; obesity (a Davenport body mass index exceeding 33 kg per meter of height 1); leg painwith positive nerve root tension test results; litigation; automobile injuries; work injuries; inappropriate illness behavior (positive Wadell’s sign);29 anticoagulant therapy; history of lumbar surgery; and use of the study treatments for the current episode. **Pretreatment:** Baseline variables controlled by the adjusted randomization scheme are shown in Table 1. Other

	baseline variables are shownin Table 2. There were no significant important differences between the four groups in terms of these variables.
Interventions	**Intervention Characteristics** Intervention ● *Joint manipulation + myofacial therapy*: The patients received both joint manipulation and myofascialtherapy treatments three times per week for 3 weeks. Cliniciansin the three manual treatment groups were not allowed to offerany recommendations for home exercises or self-care exceptsome ice if the pain flared up after treatment. ● *Myofacial therapy*: The myofascial therapy pro-gram included intermittent Fluori-Methane sprays 25,26and5to 10 stretches after 3 to 5 seconds of each isometric contraction at 50% to 70% of their maximal effort, ischemic compressions using a massagefinger, stripping massage along the orientation of the taut bands by the two thumbs for 3 to 5 strokes, and hot packs for 10 minutes at the completion of therapy. The involved lumbarparaspinal or gluteal muscles, as indicated by the examiner on the Assessment Recommendation form, were treated. Additional muscles also could be treated if the clinician believed that it wasclinically necessary. ● *Back book*: Each patient received the intervention once per week for a total of 3 weeks. During the first treatment visit, the patient watched three videos about spine anatomy, common causes of LBP, and body mechanics for daily activities.23 Subsequently, the patients received individual instructions and supervised practice of their home program by experienced licensed physical therapists at UCIMC and trained experienced licensed chiropractors at LACC. These programs included recommended sitting and standing neutral postures,body mechanics, and home exercises (lumbar flexion, exten-sion, stretching, and stabilization). The programs were divided into three sessions with different content to maintain the patient’s interest and compliance with the program. Duration of daily walking was 20, 30, and 30 minutes for the first, secondand third weeks. The patients were provided with three weeklylogs to record their compliance with the daily exercise programs. Kontrol ● *Joint manipulation + myofacial therapy*: ● *Myofacial therapy*: x ● *Back book*: x
Outcomes	*Smerteniveau 0-12 uger (Pain)* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: VAS ● **Range**: 0-10

	● **Unit of measure**: cm ● **Direction**: Lower is better ● **Data value**: Endpoint *Smerteniveau 6-18 måneder* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: VAS ● **Range**: 0-10 ● **Unit of measure**: cm ● **Direction**: Lower is better ● **Data value**: Endpoint *Funktionsevne 0-12 uger* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: Roland Morris ● **Range**: 0-24 ● **Direction**: Lower is better ● **Data value**: Endpoint *Funktionsevne 6-18 måneder (Disability)* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: Roland Morris ● **Range**: 0-24 ● **Direction**: Lower is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** Supported by the Human Resources and Service Administration, thePublic Health Service, the Department of Health and Human Services(Grant 1 R18 AH10004), the Foundation for Chiropractic Educationand Research, Leander Health Technologies, and the Lloyd TableCompany. **Country:** USA **Setting:** The study was conducted at the Outpatient Physical Therapy Clinic at the University of California Irvine Medical Center (UCIMC) located in Orange, California, and the Center for Research and Spinal Care at the Los Angeles College

	of Chiropractic (LACC) located in Anaheim, Calif. **Comments:** The recruitment methods included public announcements and advertisements in major local newspapersand local radio stations as well as distribution of study brochures. **Authors name:** Hsieh, C-Y J. et al **Institution:** Research Division and †Professional Affairs, Los Angeles College of Chiropractic, Southern California University of Health Sciences, Whittier, **Email:** jhsieh@ix.netcom.com **Address:** John Hsieh, MS, PT, DC, CA84 South Palm AvenueAlhambra, CA 91801
Notes	*Jan Nordsteen* on 19/02/2016 03:52 **Select** Pain duration ?!

Risk of bias table

Bias	Authors' judgement	Support for judgement
Incomplete outcome data	High risk	
Blinding of outcome assessors	Unclear risk	No
Sequence Generation	Low risk	
Allocation concealment	Unclear risk	No
Other sources of bias	High risk	
Blinding of participants and personnel	High risk	
Selective outcome reporting	Unclear risk	No

Hurley 2004

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Intervention Kontrol **Included criteria:** All patients 18to 65 years of age referred by general practitioners (GPs) fortreatment of LBP with or without pain radiation into the buttockand/or one or both lower limbs, of between 4 and 12weeks' duration were invited to participate **Excluded criteria:** Previous spinal surgeryRecent motor vehicle accidentSystemic diseaseConcurrent medical or musculoskeletal conditionsContraindications to manipulative therapy or interferential therapyReflex and/or motor signs of nerve root, spinal cord, or cauda equinacompressionEpisodes of LBP in the previous 6 monthsPhysiotherapy treatment for LBP in the previous 12 monthsHistory of psychological or psychiatric illnessLack of fluency in EnglishRoland Morris Disability Questionnaire score 4 pointsPregnancy **Pretreatment:** No statistical significant differences between groups at baseline. Table 2.
Interventions	**Intervention Characteristics** Intervention ● *Manual therapy (MT) + interferential therapy (IFT)*: MT Group.Subjects assigned to this group were treated bythe MT protocol, which was defined as any "mobilization" or"manipulation" techniques' for the lumbar spine that passivelymove an intervertebral joint within or beyond its existing rangeof movement, respectively, described by Maitland10orCyriax.9Maitland mobilization (Grade I, II, III, or IV) andmanipulation (Grade V) techniques refer to the application ofoscillatory or glide techniques, while Cyriax mobilization(Grade A or B) and manipulation (Grade C) techniques refer tothe application of rotational and extension maneuvers; bothapproaches use short- and long-lever arms. On the basis ofnormal clinical practice, each physiotherapist had free choiceof which mobilization and manipulation techniques to use andwhen, and the spinal levels to which they were applied on thebasis of the initial and progressive assessment of each patient'slumbar joint dysfunction.IFT Group.Study participants assigned to this group weretreated by the IFT protocol based on the results of a previousstudy by the researchers.22OmegaInter4150 portable IFTunits (TensCare Ltd, London) were used to deliver standard-ized IFT stimulation parameters (i.e., carrier frequency 3.85kHz; beat frequency 140 Hz constant; pulse duration 130 mi-croseconds; treatment time 30 minutes) using the spinal nerveroot electrode placement method via two Reply 658 carbonsilicone self-adhesive electrodes (50100 mm) (Figure 1).Combined Therapy (CT) Group.Both the MT

	and IFTprotocols were provided to subjects assigned to the CT group ateach treatment session with the MT protocol preceding the IFTprotocol ● *Interferential therapy*: IFT Group.Study participants assigned to this group weretreated by the IFT protocol based on the results of a previousstudy by the researchers.22OmegaInter4150 portable IFTunits (TensCare Ltd, London) were used to deliver standard-ized IFT stimulation parameters (i.e., carrier frequency 3.85kHz; beat frequency 140 Hz constant; pulse duration 130 mi-croseconds; treatment time 30 minutes) using the spinal nerveroot electrode placement method via two Reply 658 carbonsilicone self-adhesive electrodes (50100 mm) (Figure 1) ● *Back book*: Back Book.Following assessment, all subjects received theBack Bookfrom their treating physiotherapist, who reinforcedits positive messages during the first visit, by encouraging earlyreturn to normal activities and participation in low impactactivities such as walking, swimming, and cycling.31The UKClinical Guideline recommendations regarding physical reacti-vation are encompassed in theBack Book,31which has beenshown to be readily acceptable and understandable and to createa positive shift in beliefs about LBP.32It is reported to be morelikely to have an impact as part of a treatment package33; thus, itwas an appropriate standardized cointervention for the RCT. Kontrol ● *Manual therapy (MT) + interferential therapy (IFT)*: ● *Interferential therapy*: x ● *Back book*: x
Outcomes	*Funktionsevne 0-12 uger (disability)* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: Roland Morris ● **Range**: 0-24 ● **Direction**: Lower is better ● **Data value**: Change from baseline *Funktionsevne - 6-18 måneder (Disability)* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: Roland Morris ● **Range**: 0-24 ● **Direction**: Lower is better

	● **Data value**: Change from baseline *Smerteniveau 0-12 uger (Pain)* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: VAS ● **Range**: 0-100 ● **Direction**: Lower is better ● **Data value**: Change from baseline *Smerteniveau 6-18 måneder (Pain)* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: VAS ● **Range**: 0-100 ● **Direction**: Lower is better ● **Data value**: Change from baseline *Livskvalitet 6-18 måneder (Quality of life)* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported ● **Scale**: EQ-5D ● **Range**: 0-1 ● **Direction**: Higher is better ● **Data value**: Change from baseline
Identification	**Sponsorship source:** Supported by the Society of Orthopaedic Medicine (UK and Republicof Ireland) Project Grants, Manipulation Association of CharteredPhysiotherapists Churchill Livingstone Award and Research PresentationAward, and TensCare Ltd, London, for loan of interferential therapyOmega Inter 4150 portable units. This work was completed as partof a PhD thesis (D.A.H.) at the University of Ulster RehabilitationSciences Research Group. **Country:** Ireland **Setting:** NHS - hospitals, physiotherapy departments **Comments:** **Authors name:** Hurley, Deirdre et al. **Institution:** School of Physiotherapy, University College Dublin, Mater Misericordiae Hospital, Dublin, Republic of Ireland

	Email: deirdre.hurleyosing@ucd.ie **Address:** Deirdre A. Hurley,PhD, School of Physiotherapy, University College Dublin, Mater MisericordiaeHospital, Eccles St, Dublin 7, Rep. Ireland
Notes	

Risk of bias table

Bias	Authors' judgement	Support for judgement
Incomplete outcome data	High risk	
Blinding of outcome assessors	Low risk	
Sequence Generation	Low risk	
Allocation concealment	Low risk	
Other sources of bias	Unclear risk	No
Blinding of participants and personnel	High risk	
Selective outcome reporting	Unclear risk	No

Footnotes

References to studies

Included studies

CruserdA 2012

Cruser dA.; Maurer D.; Hensel K.; Brown SK.; White K.; Stoll ST.. A randomized, controlled trial of osteopathic manipulative treatment for acute low back pain in active duty military personnel.. The Journal of manual & manipulative therapy 2012;20(1):5-15. [DOI: 10.1179/2042618611Y.0000000016]

Hancock 2007

Hancock,M. J.; Maher,C. G.; Latimer,J.; McLachlan,A. J.; Cooper,C. W.; Day,R. O.; Spindler,M. F.; McAuley,J. H.. Assessment of diclofenac or spinal manipulative therapy, or both, in addition to recommended first-line treatment for acute low back pain: a randomised controlled trial. Lancet (London, England)

2007;370(9599):1638-1643. [DOI: S0140-6736(07)61686-9 [pii]]

Hsieh 2002

Hsieh,C. Y.; Adams,A. H.; Tobis,J.; Hong,C. Z.; Danielson,C.; Platt,K.; Hoehler,F.; Reinsch,S.; Rubel,A.. Effectiveness of four conservative treatments for subacute low back pain: a randomized clinical trial. Spine 2002;27(11):1142-1148. [DOI: 00007632-200206010-00003 [pii]]

Hurley 2004

Hurley,D. A.; McDonough,S. M.; Dempster,M.; Moore,A. P.; Baxter,G. D.. A randomized clinical trial of manipulative therapy and interferential therapy for acute low back pain. Spine 2004;29(20):2207-2216. [DOI: 00007632-200410150-00004 [pii]]

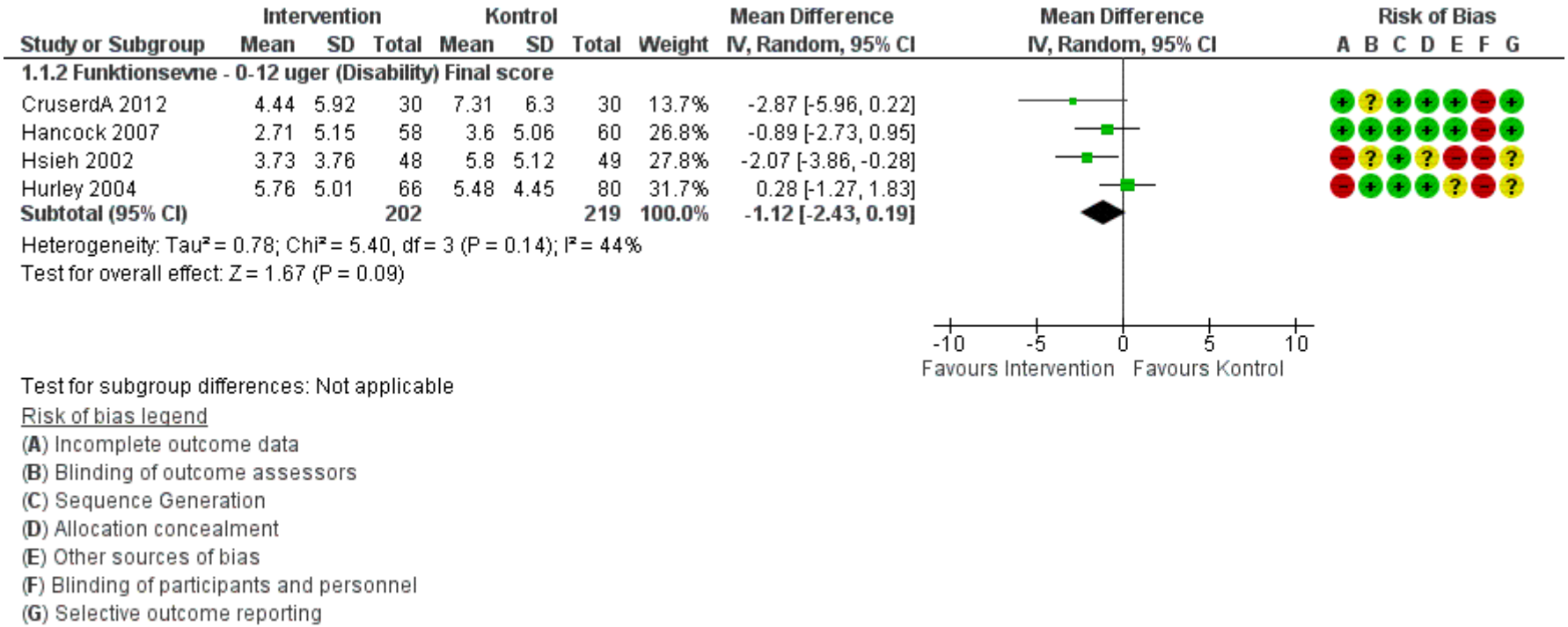
Data and analyses

1 Intervention vs Kontrol

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.4 Smerteniveau 6-18 måneder (Pain)	2		Mean Difference (IV, Random, 95% CI)	Subtotals only
1.4.2 Smerteniveau 6-18 måneder (Pain) Final score	2	256	Mean Difference (IV, Random, 95% CI)	-4.37 [-10.37, 1.63]

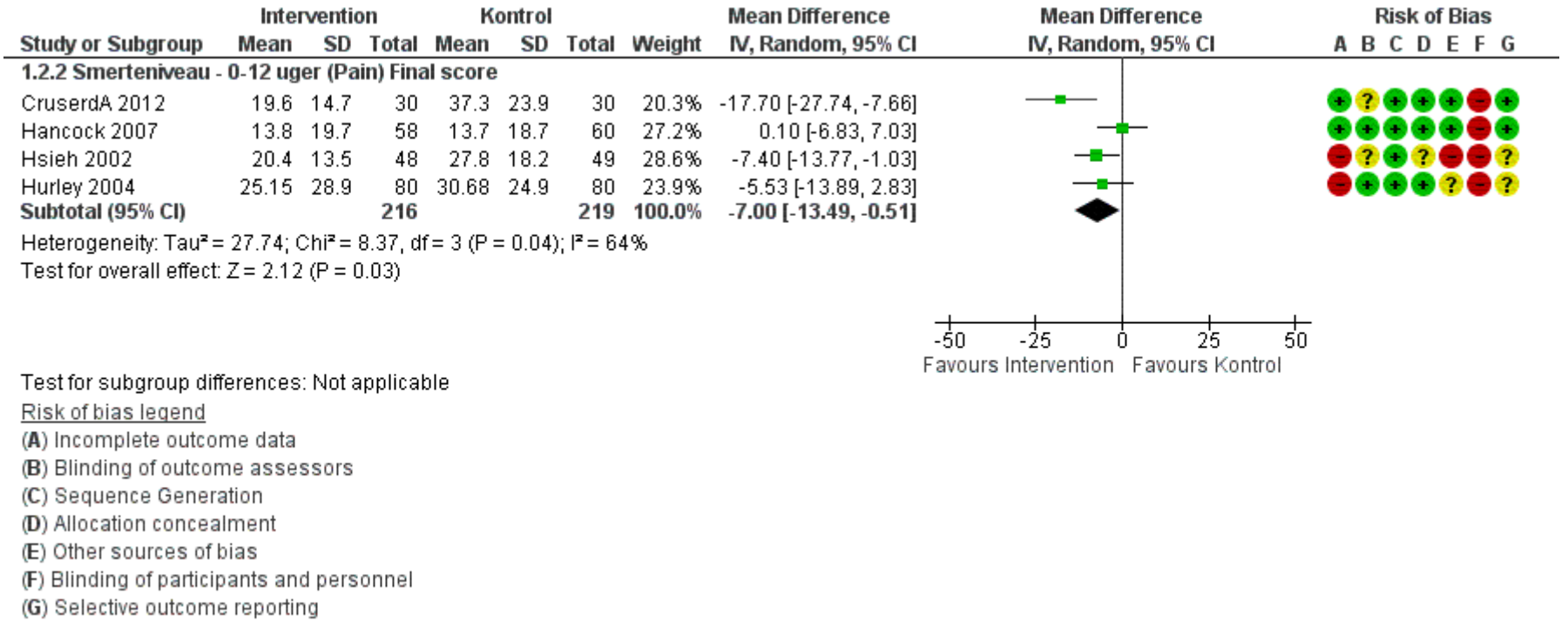
Figures

Figure 1 (Analysis 1.1)



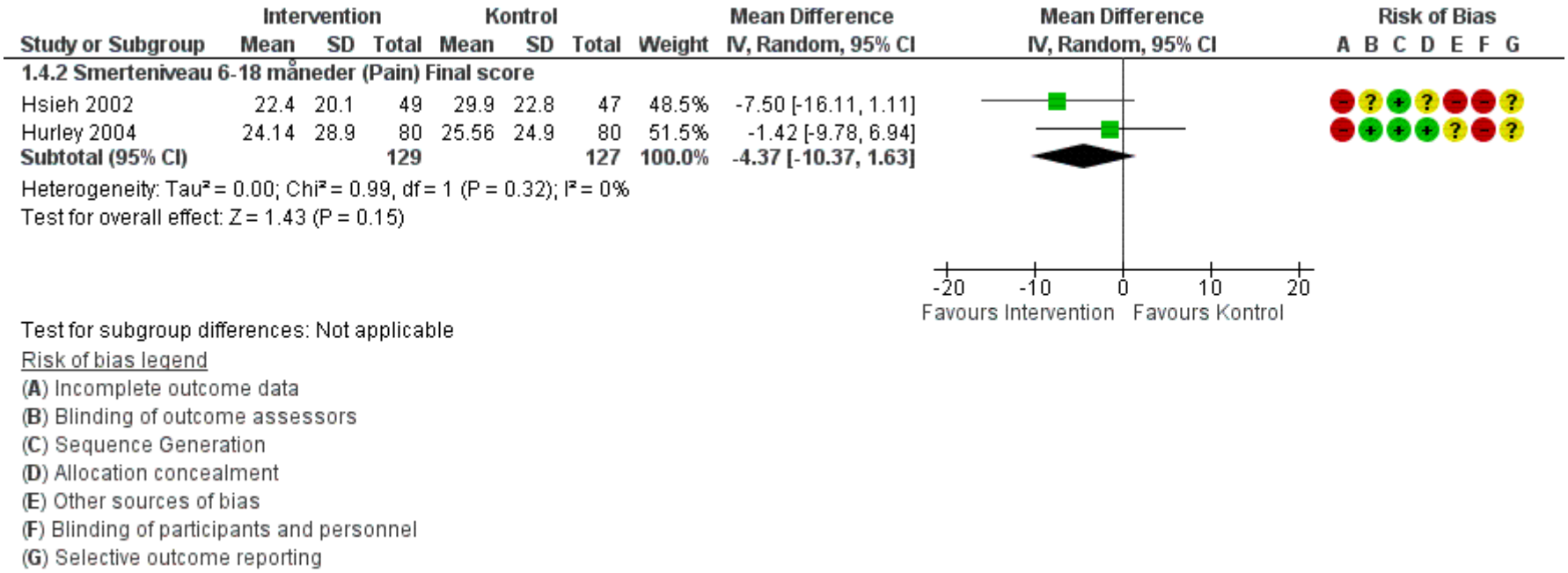
Forest plot of comparison: 1 Intervention vs Kontrol, outcome: 1.1 Funktionsevne - 0-12 uger (Disability).

Figure 2 (Analysis 1.2)



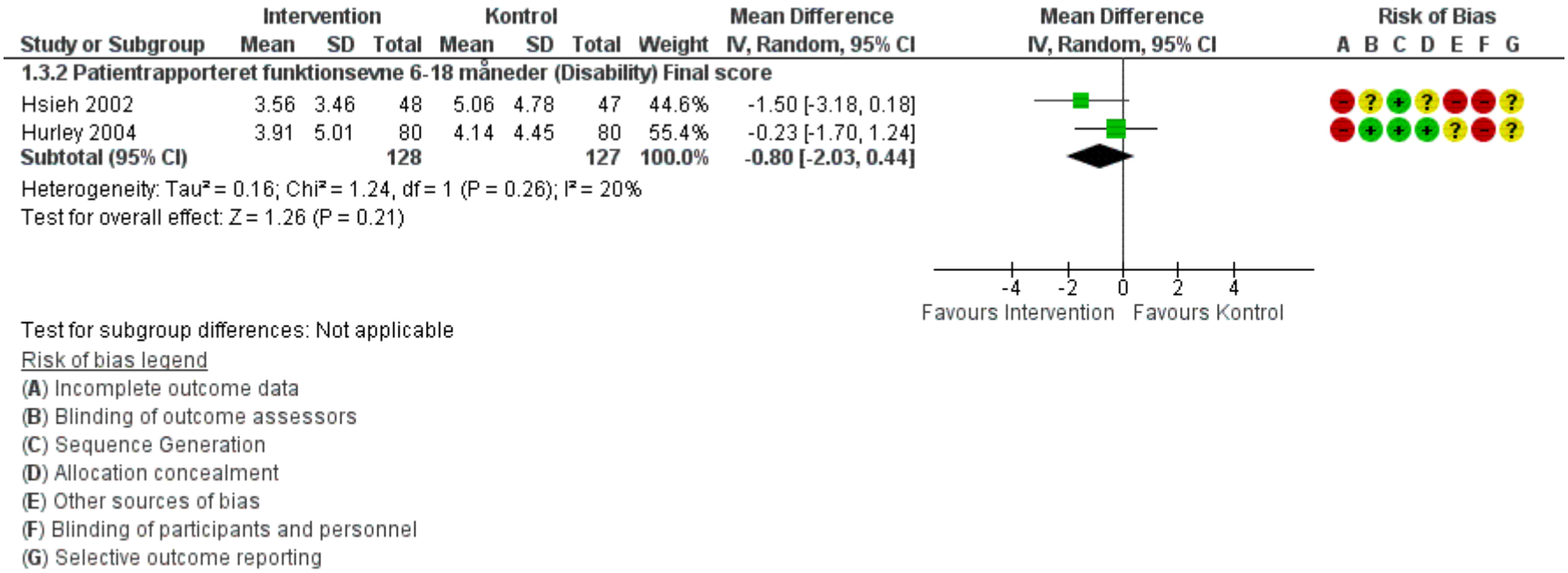
Forest plot of comparison: 1 Intervention vs Kontrol, outcome: 1.2 Smerteniveau - 0-12 uger (Pain).

Figure 3 (Analysis 1.4)



Forest plot of comparison: 1 Intervention vs Kontrol, outcome: 1.4 Smerteniveau 6-18 måneder (Pain).

Figure 4 (Analysis 1.3)



Forest plot of comparison: 1 Intervention vs Kontrol, outcome: 1.3 Funktionsevne - 6-18 måneder (Disability).