Table 3.1.4 *Systematic reviews and new identified RCT's.*

Author Year Reference Country Study design	**Population characteristics**	**Intervention Method Number individuals**	**Control Number individuals**	**Results**	**Withdrawal Drop outs**	**Study quality and relevance** **Comments**
Jensen 2005 [8] Sweden RCT	Chronic non-specific spinal pain, sick-listed for spinal pain 1–6 months, 214 randomised Female/male: 117/97 *Mean age* Female: 42 years (SD 10) Male: 45 years (SD 11) Outpatient setting. Follow-up: 3 years post intervention	I1. Behaviour-oriented physio-therapy 20 hours/ week, (individually tailored program, aerobic training, relaxation, endurance exercises, body awa-reness), n=54 I2. Cognitive behaviour therapy 13–14 hours/ week (activity planning, problem solving, applied relaxation, coping), n=49 I3. Behaviour medicine rehabilitation included physiotherapy and cognitive behaviour therapy, n=63 All interventions: 3 professions, 4 weeks, groups 4–8 patients, workplace visits, 6 booster sessions/ 1 year after treatment	C: Treatment as usual n=48	*Total absence from work, days (sick-leave + disability pension), ITT* Females I1: 522 (SD 386) I2: 542 (SD 446) I3: 439 (SD 329) C: 572 (SD 424) Males I1: 541 (SD 446) I2: 629 (SD 379) I3: 494 (SD 375) C: 479 (SD 408) I3 sign improvement vs C –201.3 days (CI –403.9 to 1.3) ns *Mean difference, days (per protocol analysis)* Females I1 vs C: –39.9 (CI –225.4 to 145.6) I2 vs C: –53.3 (CI –263.9 to 157.2) I3 vs C: –134.2 (CI –327.5 to 59.1) Males I1 vs C: –12.6 (CI –273.2 to 247.9) ns I2 vs C: 105.6 (CI –124.9 to 336.1) ns I3 vs C: –65.1 (CI –290.3 to 160.2) *Return to work* Females I3 vs C sign faster, p=0.05, HR 1.9 (CI 1.1 to 3.5) Males No sign difference *Quality of life (SF-36, global scale)* Females I3 vs C sign improvement 7.3 (CI 0.6 to 14.0)	Drop outs n=28, non responders n=43, deceased n=6	High Full time C strongest effect on women. SF-36 males 50% non-responders in C no statistical testing performed

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Table 3.1.4 *continued*

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number individuals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Kääpä [10] 2006 Finland RCT	Chronic low back pain, 132 randomised, Female/male: 98%/2% *Mean age* I: 46 years (SD 7.9) C: 46.5 years (SD 7.0) Employed in health and social service, outpatient setting. Follow-up: 6, 12, 24 months	I: Multidisciplinary rehabilitation program. Group format 6–8 pts, 70 hours 8 week team 4 professions Physical training, workplace interventions, cognitive-behavioural stress management, relaxation, back school, n=59	C: Individual physiotherapy 10 x 1 hour 6–8 weeks. Passive pain treatment (massage, spine traction, mobilisation, TNS/ultrasound), light active exercise, home exercise, n=61	*Pain intensity (I)* Baseline 4.6 (SD 1.9) 6 months: 3.3 (SD 2.5,) 12 months: 3.6 (SD 2.7) 24 months: 3.5 (SD 2.6) *ODI (I)* Baseline: 25.4 (SD 10.6) 6 months: 20.4 (SD 11.6) 12 months: 18.9 (SD 12.8) 24 months: 19.7 (SD 14.3) 24 months I sign improvements ($p<0.05$) in ODI *Pain intensity (C)* Baseline: 5.0 (SD 2.6) 6 months: 3.4 (SD 2.5) 12 months: 3.4 (SD 2.5) 24 months 4.0 (SD 2.9) *ODI (C)* Baseline: 23.8 (SD 11.7) 6 months: 18.0 (SD 11.5) 12 months: 18.5 (SD 12.4) 24 months: 19.3 (SD 13.1) C sign improvements ($p<0.05$) in ODI, pain intensity. No sign difference I vs C *Subjective working capacity, depression (DEPS) general well-being beliefs of working ability after treatment* 24 months I sign improvements ($p<0.05$) subjective working ability now, beliefs in future working ability No sign differences I vs C 6, 12, 24 months ($p>0.05$)	2 withdraw from the study *Excluded after randomisation* I: n=5 C: n=5 *At follow-up 24 months* I: 17% C: 25%	High No sign differences between I and C in main outcomes. Selected population

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Table 3.1.4 continued

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number individuals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Linton [12] 2005 Sweden RCT	Non-specific back or neck pain, employed sick leave <4 months during past year for spinal pain, no physical therapy during past year, 229 randomised 185 participated *Female/male* I1: 81%/19% I2: 80%/20% *Mean age* I1: 49.1 years (SD 6.8) I2: 48.7 years (SD 7.3) Follow-up: 1 year	I1: Cognitive behaviour therapy + minimal treatment 6–8 pts 2 hours/ week 6 times (problem solving, coping), n=69 I2: Cognitive behaviour therapy + preventive physical therapy + minimal treatment and physical training (individual tailored), n=69 At least 2 professions	C: Minimal treatment (medical examination, information, booklet), n=47	*Sick absenteeism (self-report items + data from National Insurance Authory) previous 6-month period, % on sick leave/month* I1: 6–8% I2: 2–5% C: 9–14% *Risk of sick leave >15 days* Sign higher in C than I1 OR=6.10 (CI 1.29 to 28.77). Sign higher in C than I2 OR=4.80 (CI 1.19 to 19.32) *Pain intensity, Function ADL, Disability (RMDQ), Fear (TSK), Catastrophising (PCS), Depression/Anxiety (HAD)* All groups improved from pre-test follow-up 1 year, I1 best results 5/20 variables I2 on 15/20 variables. No sign differences between groups	Declined participation before treatment n=44. At follow-up 1 year, n=27 (I1: 21.7%, I2: 11.6%, C: 8.5%)	High I1 and I2 had fewer days on sick leave during 12-month follow-up than C. Risk for sick disability higher in C

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Table 3.1.4 continued

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number individuals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Niemistö 2003 [15] Finland RCT Niemistö 2005 [16] RCT Finland	LBP >3 months Age 24–46 years, employed, ODI at least 16%, hospital outpatient setting, 204 randomised, Female/male: 110/94 *Mean age* I: 37.3 years (SD 5.6) C: 36.7 years (SD 5.6)	I: Combination group. Included manipulation, muscle stabilising exercises, evaluation treatment sessions once a week during 4 weeks educational booklet, information, individual instructions, n=102	C: Physicians consultation group. Educational booklet, information, individual instructions, n=102	*Pain intensity (VAS)* I: VAS Baseline: 59.5 (SD 21.2) 5 months: 25.2 (SD 23.3) 12 months: 25.7 (SD 23.3) 24 months: 30.7 (SD 4.4) C: VAS Baseline: 53.3 (SD 21.2) 5 months: 36.1 (SD 23.3) 12 months: 32.2 (SD 24.9) 24 months: 33.1 (SD 24.9) *ODI* Intervention Baseline: 29.5 (SD 9.7), 5 months: 14.7 (SD 11.6) 12 months: 13.7 (SD 11.6) 24 months: 12.0 (SD 11.6) Control Baseline: 28.8 (SD 9.7) 5 months: 18.6 (SD 11.6) 12 months: 16.5 (SD 11.6) 24 months: 14.0 (SD 9.9) Sign improvement over time up to 12- and 24 months follow-up in VAS and ODI. 5 months: I sign better than C VAS ($p<0.001$) and ODI ($p=0.002$) 12 months: I sign better than C VAS ($p< 0.01$), 24 months: No sign difference ODI ($p=0.020$) Depression (Finnish depression questionnaire, DEPS), health-related quality of life (HRQoL), days on sick leave 12 months: I improved sign in DEPS and HRQoL over time C improved sign in DEPS and HRQoL over time No sign difference between groups	8 patients (6 from I, 2 from C)	High Sign decreased pain intensity in I compared to C 12 months, 24 months and decreased disability 12 months

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Table 3.1.4 continued

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number individuals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Scascighini 2008 [29] Switzerland Systematic review	35 RCT (27 studies, 6 follow-up protocol studies, 2 additional) 21 included chronic low back pain or back pain, 9 included fibromyalgia, 9 included mixed chronic pain 1990–2006 >18 years old, 2 407 patients. No data on sex, 18/27 programmes outpatient setting. Follow-up: At least 3 months	I: Multidisciplinary treatment: At least 3 out of psychotherapy, physiotherapy, relaxation techniques, medical treatment or patient education, vocational therapy	C: Waiting list or treatment as usual	15 studies (multiple high quality RCTs with consistent findings) found that multidisciplinary treatment was superior to C (3 of 5 studies showed better results of I vs C for fibromyalgia). Authors conclusions: I more effective than C, limited evidence for mixed chronic pain. No difference other treatment strategies		

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Table 3.1.4 *continued*

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number individuals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Smeets 2008 [17] The Nether-lands RCT	Low back pain >3 months RDQ >3, ability to walk at least 100 m. Age 18–65 years, rehabilitation centre outpatient setting, 172 randomised, Female/male: 95.9%/4.1% Mean age: 41.91 years (SD 9.65). Follow-up: Post treatment, 6 and 12 months	I1: Graded activity with problem solving training consisted of graded activity training 3 group sessions, max 17 individual sessions/30 minutes and problem solving training 10 sessions 11/2 hours group 4 pts, 3 professions, n=58 I2: Combined treatment C + I1, 3–4 professions, n=61	C: Active physical treatment (aerobic training, strength endurance training) group 4 patients 3 times/week 10 weeks, 1 profes-sion, n=53	*Disability (RDQ)* I1: Mean improvement 6 months: 3.65 (CI 2.40–4.90) 12 months: 3.74 (95% CI 2.48–5.01) I2: Mean improvement 6 months: 2.54 (CI 1.31–3.76) 12 months: 2.12 (CI 0.89–3.36) No sign difference between I1 and I2 12 months 1.62 (CI –0.06 to 3.31) C: Mean improvement: 6 months: 3.15 (CI 1.88–4.43) 12 months: 3.28 (CI 2.0–4.58) No sign difference between C and I2 12 months 1.16 (95% CI –0.52 to 2.84)	12 m n=16 (I1 n=2, I2 n=6 I3 n=8)	High Single treatments were at least equally effective as I2

C = Control group; CI = Confidence interval; DEPS = Depression questionnaire score; h = Hour; HR = Hazard ratio; HRQoL = Health-Related Quality of Life; I = Intervention group; n = Number of patients; ODI = Oswestry disability index; OR = Odds ratio; p = Probability; QoL = Quality of life; RCT = Randomised controlled trial; RDQ = Roland disability questionnaire; SD = Standard deviation; SF-36 = Short form 36 (quality of life instrument); sign = Significant; TNS = Transcutaneous neurostimulator

Table 3.1.5 *Health economy.*

Author Year Reference Country	Study question Study design	Patient population	Intervention	Outcome	Costs	Results	Study quality and relevance Comments
Niemestö 2005 [16] Finland	Cost-effectiveness of combined manipulation, stabilising exercises and physician consultation compared to physician consultation alone Prospective CEA, along RCT	204 patients with chronic low back pain	I: Combination (98) C: Consultation (100)	Pain (VAS) Disability (ODI) Quality of life	Mean annual total costs decreased during the 2-year follow-up compared to baseline. I: – $288 C: – $1370	Significant improvements in both groups on every outcome. I sign better in VAS with a ICER=$512 per unit. C more cost-effective in terms of health care use and work absenteeism	High

C = Control group; CEA = Cost-effectiveness analysis; I = Intervention group;
ICER = Incremental cost effectiveness ratio; ODI = Oswestry disability index;
RCT = Randomised controlled trial; VAS = Visual analogue scale

Table 3.2.2 *Neck pain.*

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Chiu 2005 [8] China RCT	Individuals with chronic neck pain (n=218) Outpatient setting. Mean age 43 years. Female/male: 68%/32%	I1: TENS over acupuncture points in the neck region. Stimulation in continuous trains of 150 micro seconds square pulses at 80 Hz (30 minutes) + infrared irradiation (20 minutes) + neck advice, n=73 I2: Intensive neck exercise programme. Two 35 minutes sessions a week for six weeks. Exercises were activation of deep neck muscles for active stabilisation of the spine. Neck extension and flexion 8–12 repetitions, load about 30% of peak isometric muscle strength + infrared irradiation (20 minutes) + neck advice, n=67	C: Infrared irradiation over the C4 region + advice. Twice a week, 20 minutes a session for 6 weeks, n=78	*Pain (Verbal numerical pain scale)* I1: Baseline mean 4.7 (SD 1.8), 6 months mean 3.4 (SD 2.4) I2: Baseline mean 4.6 (SD 1.9), 6 months mean 3.1 (SD 2.1) C: Baseline mean 4.3 (SD 2.1), 6 months mean 3.6 (SD 2.1) No significant difference between any of the 3 groups *Disability (Northwick Park Neck Pain Questionnaire)* I1: Baseline mean 1.6 (SD 0.4), 6 months mean 1.2 (SD 0.5) I2: Baseline mean 1.4 (SD 0.6), 6 months mean 1.0 (SD 0.6) C: Baseline mean 1.4 (SD 0.5), 6 months mean 1.2 (SD 0.6) I2 had significantly better improvement compared to controls at 6 months *Neck muscle strength* I1: Baseline mean 8.9 (SD 3.9), 6 months mean 10.0 (SD 4.7) I2: Baseline mean 9.1 (SD 4.3), 6 months mean 11.0 (SD 5.0) C: Baseline mean 8.7 (SD 4.1), 6 months mean 9.8 (SD 4.7) No significant difference between any of the 3 groups	16.5%. ITT analyses	High No complications reported. I1 and I2 were effective for improvements in neck pain, disability, and neck muscle strength. Improvements were maintained up to 6 months Advice + infrared radiation (control group) showed significant change only in neck strength over time but to lower degree compared to I1 and I2

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Table 3.2.2 continued

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Chiu (cont.) 2005 [8] China	Individuals with chronic neck pain (n=218). Outpatient setting. Mean age: 43 years. Female/male: 68%/32%	I1: TENS over acupuncture points in the neck region. Stimulation in continuous trains of 150 micro seconds square pulses at 80 Hz (30 minutes) + infrared irradiation (20 minutes) + neck advice, n=73 I2: Intensive neck exercise programme. Two 35 minutes sessions a week for six weeks. Exercises were activation of deep neck muscles for active stabilisation of the spine. Neck extension and flexion 8–12 repetitions, load about 30% of peak isometric muscle strength + infrared irradiation (20 minutes) + neck advice, n=67	C: Infrared irradiation over the C4 region + advice. Twice a week, 20 minutes a session for 6 weeks, n=78	*Medication* I1: Medication decreased significantly from baseline to 6 months. Baseline 26% (SD 35.6), 6 months 17% (SD 23.3) I2: Medication decreased significantly from baseline to 6 months. Baseline 20% (SD 30), 6 months 12% (SD 17.9) C: No significant change. No significant differences between any of the groups *Sick leave* I1: Sick leave decreased significantly from baseline to 6 months. Baseline 11% (SD 15.5), 6 months 4% (SD 5.5) I2: Sick leave decreased significantly from baseline to 6 months. Baseline 11% SD 16.5, 6 months 2% (SD 3) C: No statistically significant difference within the control group over the 6 months. No statistically significant difference between any of the 3 groups	16.5%. ITT analyses	High No complications reported. I1 and I2 were effective for improvements in neck pain, disability, and neck muscle strength. Improvements were maintained up to 6 months Advice + infrared radiation (control group) showed significant change only in neck strength over time but to lower degree compared to I1 and I2

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Table 3.2.2 continued

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Dziedzic 2005 [9] United Kingdom RCT	Patients with non-specific neck pain (n=350). Out-patient setting. Pain duration >3 months 77%. Mean age: 50.6. Female/male: 74%/26% Follow-up: 6 months	I1: Advice and exercises. Home exercises (active and resisted neck movements in sitting, active coping ie stay active despite pain, n=115 I2: Advice and exercise with the addition of manual therapy. Hands-on passive or active assisted movements, mobilisations, or manipulations to the joints and soft tissue, n=114 I3: Advice and exercise with the addition of pulsed shortwave diathermy. Pulsed shortwave diathermy without prescriptive exact dosage, n=121		*Disability (Northwick Park Neck Pain Questionnaire)* I1: Mean reduction of disability 10.2 (SD 14.1) I2: Mean reduction of disability 10.2 (SD 14.1) I3: Mean reduction of disability 10.3 (SD 15.0) No statistically significant differences between treatment groups *Participants' global assessment of change, pain intensity, severity of patient-nominated main problem; days off work; quality of life (SF-12)* No statistically significant differences between treatment groups reported	7%. ITT analyses	High No serious adverse events reported. Conclusion: The addition of manual therapy or pulsed shortwave did not provide any additional benefits to advice and exercises in patients with chronic neck pain

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Table 3.2.2 *continued*

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Ylinen 2003 [11] RCT 2006 [12] 2007 RCT [10] RCT Finland	Constant or frequent neck pain >6 months Female/male: 180/0 Mean age: 46 years Follow-up: 6, 12 and 36 months	Both training groups I1: Endurance, 10 supervised training sessions, n=60 I2: Strength, 10 supervised training sessions, n=60 I1, I2 had also a 12-day program including relaxation, fear of pain reducing and exercise motivating behavioural support, 4 individual sessions of massage and mobilisation by physiotherapy. Home aerobic exercise 3 times a week	C: 3 days at the rehabilitation centre for tests and for 1 advice session of stretching exercises to be done at home 3 times a week, n=60	*Neck disability index 12 months, median difference* I1 compared to baseline: –8 (CI –11 to –6) sign. I2 compared to baseline: –9 (CI –11 to –7) sign. C compared to baseline: –3 (CI –6 to –0) I1 vs C: –5 sign, I2 vs C: –6 sign *Modified neck/shoulder pain disability index 12 months, median difference* I1 compared to baseline: –22 (CI –26 to –19) sign I2 compared to baseline: –23 (CI –27 to –20) sign C compared to baseline: –12 (CI –15 to –8) I1 vs C: –10 sign, I2 vs C: –11 sign *Pain intensity (VAS) 12 months, median difference* I1 compared to baseline: –35 (CI –42 to –28) sign I2 compared to baseline: –40 (CI –48 to –32) sign C compared to baseline: –16 (CI –22 to –9) I1 vs C: –19 sign, I2 vs C: –24 sign The results in I1 and I2 were maintained at 3 years follow-up. There were no results at 3 years for C *Isometric neck strength and neck muscle endurance* I2 increased most in strength compared to C. I1 was also better in all these measures compared to C. I1, I2 sign better at 3 years follow-up in strength in several muscles when compared to 12 months follow-up	3 patients	High I1 and I2 have long term effects and decrease disability and pain intensity better than C

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Table 3.2.2 *continued*

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Stewart 2007 [13] RCT Australia	134 patients with chronic (>3 months) whiplash associated disorders, WAD grade I–III. Female/male 89/45 Mean age: 43.3 (SD 14.7) Follow-up: Post-treatment and 12 months	I: Advice and 6-week individualised, graded exercise designed to improve the ability to complete functional activities that the patient considered being difficult due to the whiplash associated disorder Exercises included such as aerobic, functional activities, endurance, coordination, strengthening. The principles of cognitive behavioural therapy were used. Home exercise was also included. Mean nr of sessions=9.9 (range 0–12), n=66	C: Advice included standardised education, reassurance and encouragement to resume activities. Cognitive principles were applied in discussions. One consultation and two telephone contacts mean 2.9 contacts, n=68	*Pain intensity (0–10 box scale), 12-months* I vs C: Mean difference in pain intensity –0.2 (CI –1.0 to 0.6) *Bothersomeness (0–10 box scale), 12-months* I vs C: 0.3 (CI –0.6 to 1.3) *Functional ability (Patient Specific Scale) 12-months* I vs C: 0.6 (CI -0.1 to 1.4) Improvement in all primary measures but not as much as in intervention group at 6-week follow-up. No significant differences between groups at 12 months follow-up *Disability (Neck Disability Index), global perceived effect (11-point scale), health related quality of life (SF-36)* Intervention group decreased significantly more in disability and increased more in health related quality of life and in global improvement compared to control group Controls became better but not as much as intervention group	9 patients (6 in the control and 3 in the intervention group)	High I were more effective post-treatment but not in long term (12 months) compared to C

C = Control group; CI = Confidence interval; I = Intervention group; ITT = Intention-to-treat analysis; n = Number of patients; SD = Standard deviation; SF-36 = Short form 36 (quality of life); TENS = Transcutaneous electric nerve stimulation

Table 3.2.3 *Low back pain.*

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Cairns 2006 [16] United Kingdom RCT	Patients with recurrent and persistent low back pain (n=97). Mean age: 38 years Female/male: 52%/48%. 21% on sick leave. Out-patient setting (primary care) Follow-up: 12 months	I: Specific spinal stabilisation. Standardised educational information (normal activities, avoiding rest) Manual and exercise treatments currently used in UK practice (Maitland mobilisation, physical exercises and advice). Specific intervention components: endurance training for the deep abdominal and back extensor muscles, diagnostic ultrasound if needed. Maximum of 12 treatment sessions over 12 weeks, n=47	C: Conventional treatment. Standardised educational information (normal activities, avoiding rest). Manual and exercise treatments currently used in UK practice (Maitland mobilisation, physical exercises and advice). Exercises using low load, high repetition muscle activity were excluded, n=50	*The Roland Morris Disability Questionnaire (RMQ)* I: Improvement –5.1 (CI –6.3 to –3.9). C: Improvement –5.4 (CI –6.5 to –4.2). Disability improvements did not differ between treatment groups –0.4 (CI –2.0 to 1.3) Mean changes exceeded the a priori criteria for minimal clinically significant change in both groups. Findings from 12-month follow-up were similar to 6 months *McGill Pain Questionnaire* I: –1.4 (CI –3.7 to 0.9) C: –3.1 (CI –5.3 to –0.8) *Psychologic distress (Modified Zung, Modified Somatic Perception Questionnaire)* I: –2.7 (CI –5.5 to 0.2) (Modified Zung); 0.6 (CI –0.7 to 1.9) (Modified Somatic Perception Questionnaire) C: Distress –3.2 (CI –6.0 to –0.5) (Modified Zung); 0.7 (CI –0.6 to 1.9) (Modified Somatic Perception Questionnaire) *Quality of life;SF-36* I: –36 8.8 (95% CI 4.9–12.7) Mental component SF-36 –3.7 (95% CI –2.9 to –1.4) C: 8.5 (95% CI 4.7–12.3) Mental component SF-36 –3.4 (95% CI –6.0 to –0.8) No significant differences in any of the secondary outcomes	23% ITT analysis	High Patients with chronic low back pain had long-term improvements with both treatment packages comprising education, physical exercises and mobilisation. No additional effect was seen adding specific spinal stabilisation exercises

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Table 3.2.3 continued

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Critchley 2007 [24] United Kingdom RCT	Chronic low back pain (n=212). Hospital physiotherapy department with outpatient visits. Mean age: 44 years (SD 12). Female/male: 64%/36%. Follow-up: 18 months post randomisation	I1: The pain management program – combination of back education and group general strengthening, stretching, light aerobic exercises progressed by pacing principles. Cognitive-behavioural components included goal setting, graded return to normal activities and use of coping strategies. A maximum of 8 session's à 90 minutes, n=62 I2: Spinal stabilisation physiotherapy. Individual transversus abdominis and lumbar multifidus muscle training followed by group exercises challenging spinal stability. A maximum of 8 sessions of 90 minutes, n=71	C: Usual individual physiotherapy management combination of joint mobilisation and manipulation, massage, trunk muscle retraining, stretches, and general spinal mobility exercises. A maximum of 12 sessions of 30 minutes, n=59	*The Roland Morris Disability Questionnaire (RMQ)* I1: Reductions from mean 11.5 (CI 9.8 to 13.1) to 6.5 (CI 4.5 to 8.6) I2: Reductions from mean 12.8 (CI 11.4 to 14.2) to 6.8 (CI 4.9 to 8.6) C: Reduction from mean 11.1 (CI 9.6 to 12.6) to 6.9 (CI 5.3 to 8.4). There were no significant differences between treatment groups *Pain, health-related quality of life (EQ-5D); days off work; treatment satisfaction* All groups: Pain and number off days work decreased. HRQL increased There were no significant differences between treatment groups	25% ITT analysis	Usual individual physiotherapy, spinal stabilisation training, and pain management program including cognitive-behavioural components were all equally safe and effective Pain management with cognitive-behavioural components was associated with least health service consumption and costs

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Table 3.2.3 continued

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Ferreira 2007 [25] Australia RCT	Individuals with low back pain (n=240). Hospitals with out-patient setting. Mean age: 53.5 years Female/male: 69%/31%	I1: General exercise. Supervised exercise in group. Strengthening and stretching for main muscle groups and cardiovascular fitness. Individual maintenance session, n=80 I2: Motor control exercise. Aimed at improving function of specific trunc muscles. Progression with functional tasks. I1 and I2 included 12 sessions a 60 minutes. Cognitive-behavioural principles (skill acquisition by modelling, pacing, progressive goal setting, self-monitoring of progress and positive reinforcement), n=80	I3: Spinal manipulative therapy. Joint mobilisation or manipulation of the spine. No exercises or home exercise programs. Therapy was discontinued if participant recovered before the 12 sessions were completed, n=80	*Function (Patient-Specific Functional Scale PSFS)* 6 months, mean difference I2 vs I1: 1.1 (CI –1.0 to 3.1). I3 vs I1: 1.7 (CI –0.4 to 3.8). I2 vs I3: –0.7 (CI –2.7 to 1.3) 12 months, mean difference I2 vs I1: 1.1 (CI –1.0 to 3.2) I3 vs I1: 0.3 (CI –1.7 to 2.3) I2 vs I3: 0.8 (CI –1.2 to 2.9) *Global perceived effect* 6 months I2 vs I1: 0.5 (CI –0.3 to 1.3) I3 vs I1: 0.3 (CI –0.5 to 1.1) I2 vs I3: 0.2 (CI –0.6 to 1.0) 12 months I2 vs I1: 0.7 (CI –0.2 to 1.6) I3 vs I1: 0.1 (CI –0.8 to 1.0) I2 vs I3: 0.6 (CI –0.3 to 1.5) There were no significant differences between groups. I3 showed similar changes over time as did I1 and I2	22%	Similar treatment effects in PSFS for all groups at 6 and 12 months

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Table 3.2.3 continued

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Friedrich 2005 [6] Austria RCT	Patients with low back pain (n=93), duration over 4 months. Out-patient setting. Age 44.1 years (SD 10.7). Female/male: 51%/49%	I: Standard exercise program combined with motivational program. Individual, sub maximal, gradually increased exercises including spinal mobility, trunk and lower limb muscle length, force, endurance, coordination. 10 training session's à 25 minutes, 2–3 times per week. Motivation program including counselling and information, enhancement of internal locus of control, reinforcement techniques, treatment contracts, cues for exercises, and exercise diaries, n=44	C: Standard exercise program. Content and dosage see intervention group, n=49	*Disability; Pain intensity; Working ability* I: 5-year follow-up: Decreases in disability with a cumulative effect from 12 months to 5 years effect parameter (Linear Parial-Credit model)=2.34. Decreases in pain intensity. Increased working ability. Statistically significant difference at 5 years in disability, pain intensity, and working ability in favour for the intervention group C: Decreases in disability with a cumulative effect 12 months to 5 years effect parameter=1.1 *Low back pain episodes* Differences in number of low back pain episodes 1.75 (intervention), 5.7 (control)	40% at 5-year follow-up. ITT-analyses	High A program combining exercise therapy with motivation enhancing strategies was twice as effective in the long-term compared to exercises only
Frost 2004 [19] United Kingdom RCT	Patients with low back pain (n=286). 75% duration of >3 months. 25% duration between 6 weeks and 3 months. Out-patient setting. Mean age: 40.8 years. Female/male: 61%/39%. Follow-up: 2, 6 and 12 months	I: Advice only. One session a 60 minutes with a physiotherapist including physical examination and general advice to remain active. Advice book, n=142	C: Therapy group. Physical examination by physiotherapist. Any combination of joint mobilisation and manipulation, soft tissue techniques including stretching, spinal mobility, strengthening exercises, het or cold, and advice. Up to 5 additional treatments of around 30 minutes, n=144	*Disability (Oswestry disability Index; ODI) 6 months, mean change* I: –1.83 (SD 10.6) C: –2.89 (SD 11.6) *ODI at two and six months. Roland Morris Disability Questionnaire (RMQ) at 2, 6, and 12 months. General Health (SF-36); Patient perceived benefit of treatment* Main statistical analyses showed no statistically significant differences between groups. Patients in the therapy group were more likely to report benefits from treatment at all time points than patients in the advice group	30% at 12 months. ITT	High Routine physiotherapy seamed to be no more effective than one session of assessment and advice from a physiotherapist

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Table 3.2.3 continued

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Goldby 2006 [17] United Kingdom RCT	Patients with chronic low back pain with a duration for >12 weeks (n=213), Hospital out-patient setting. Mean age: 42 years (SD 11.8). Female/male: 68%/32%. Follow-up: 12 months	I1: Spinal stabilisation program. Group format. Exercises for selective training of transversus abdominis, multifidus, the pelvic floor muscles and diaphragm. Video. 10 1-hour classes. Back school ie 3-hour session including anatomy, biomechanics and lifting, pathologies, advice on general exercises and fitness, n=84 I2: Manual therapy. No permission of specific stabilisation exercises or electro physical methods. Any other form of manual or exercise therapy was allowed. Maximum of 10 sessions. Back school, n=89	C: Minimal intervention, education. Educational booklet "Back in action". Back school, n=40	*Disability (Oswestry disability Index; ODI)* Significant reductions in both intervention groups. I1: Baseline 40.5 (SD 15.6), 12 months 24.8 (SD 17.5) I2: Baseline 39.2 (SD 13.7), 12 months 29.6 (SD 20.5) C: Baseline 33.5 (SD 12.2), 12 months 27.0 (SD 19.6), ns *Pain* Significant reductions in both intervention groups. I1: Baseline 45.8 (SD 27.5), 12 months 29.3 (SD 28.1) I2: Baseline 55.7 (SD 28.3), 12 months 35.2 (SD 31.0) C: Baseline 37.6 (SD 34.0), 12-months 30.0 (SD, 35.0) *Quality of life (Nottingham Health Profile)* Significant reductions in both intervention groups I1: Baseline 162.2 (SD 105.5), 12 months 70.1 (SD 78.5) I2: Baseline 163.2 (SD 119.0), 12 months 103.6 (SD 110.2) C: Baseline 139.6 (SD 89.0), 12 months 87.5 (SD 107.1), ns	9% of those who attained treatment, 46% of those randomised. ITT with LVCF	High Stabilisation exercises are more effective than manual therapy or controls (education) regarding disability, pain intensity, and dysfunction outcomes. No significant differences between groups at 12 months follow-up

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Table 3.2.3 continued

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Niemistö 2003 [20] RCT Niemistö 2005 [21] RCT Riipinen 2005 [22] Finland RCT	Low back pain >3 months, inclusion age 24–46 years, n=204. Female/male: 110/94. Age m=37 (SD 5.6) Follow-up: 5, 12 and 24 months	I: Combination group, included manipulation, exercise (stabilising exercises in lying down and during activities), information once a week during 4 weeks, n=102	C: Physician consultation group, information and educational booklet, posture instructions, 3–4 individual exercises aimed at increasing mobility and stability. Reinforcement at 5 months, n=102	*Pain intensity VAS, mean* I: 5 months 25.3 (SD 22.8) 12 months 26.0 (SD 21.9) 24 months 30.7 (SD 24.4) C: 5 months 35.7 (SD 23.6) 12 months 32.3 (SD 24.9) 24 months 33.1 (SD 24.9) *Disability (Oswestry Disability Index, ODI), mean*: I: 5 months 15.0 (SD 12.4) 12 months 13.9 (SD 11.3) 24 months 12.0 (SD 11.6) C: 5 months 18.5 (SD 10.6) 12 months 16.2 (SD 12.0) 24 months 14.0 (SD 9.9) *Frequency of LBP 24-months* I: Decreased from 58% to 37%. C: Decreased from 62% to 39% ns compared to controls Significant improvement over time up to in every measure. *Depression (Finnish Depression Questionnaire, DEPS), Health-Related Quality of Life (HRQoL 15D)* The intervention and control groups improved significantly in both secondary measures over time but there were no significant differences between groups	8 patients (6 from intervention group and 2 from control group)	High Combination group decreased significantly more in disability and pain intensity compared to physician consultation group measured at 5, 12 months. At 24 months follow-up combination group decreased significantly more only in pain intensity compared to physician consultation group

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Table 3.2.3 continued

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Petersen 2002 [14] RCT 2007 [15] RCT Denmark	Low back pain patients (n=260), 85% had had pain >3 months. Mean age: 35,8 years (23–52,1) Female/male: 118/142. Follow-up: 2, 8 and 14 months after treatment	I: McKenzie therapy. Self-mobilising, mobilisation by the therapist. Max 15 sessions during 8 weeks + instructions to continue 2 months home exercises, n=132	C: Strengthening training, start. Stationary bike, intensive dynamic back strengthening in flexion and extension. Max 15 sessions during 8 weeks + instr to continue 2 months home exercises, n=128	*Disability* I: 8 months 30.8 (CI 10.1 to 76.9), mean change in disability from baseline to 14 months 7 points (CI 4.3 to 10.1) C: 8 months 33.3 (CI 7.1 to 70), mean change in disability from baseline to 14 months 9 points (CI 5.4 to 12.5) *Pain variables* I: 8 months 14.0 (CI 2 to 54) mean change in pain intensity, from baseline to 14 months 5 points (95%CI 2.9 to 7.9) C: 8 months 18 (CI 2.9 to 36) mean change in pain intensity, from baseline to 14 months 8 points (CI 5.7 to 9.9) No differences between the groups at 14 months follow-up *Return to work (sick leave days), pain medication use, global change (5-point scale)* No significant differences in any of the measures	I: 38 pts 29% C: 42 pts 33%	High McKenzie treatment was slightly better at 2 months follow-up but not at 8 or 14 months follow-up compared to strengthening group

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Table 3.2.3 *continued*

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Sherman 2005 [23] USA RCT	Chronic low back pain (n=101). Mean age: 44 (13). Female/male: 66/35. Follow-up: 3 months	I1: Yoga (viniyoga), 12 weekly sessions and home practicing, n=36 I2: Aerobic and strengthening exercises including short education in body mechanics, exercise benefits and goal setting. 12 weekly sessions and home practicing, n=33	C: Self-care book emphasising self-care strategies, adoption of fitness training program, lifestyle modification, guidelines for flare-ups, n=30	*Disability (Roland Disability Scale; RDS)* 3 months I1 vs C: Mean difference –3.6 (CI –5.4 to –1.8) sign. I2 vs C: Mean difference –2.1 (CI –4.1 to –0.1) p=0.035 >50% decrease in RDS score: I1: 69% I2: 50% C: 30% No sign difference between I1 and I2 *Bothersomeness of back pain.* I1 vs C: Mean difference –2.2 (CI –3.2 to –1.2) sign I2 vs C: No sign difference –0.8 (CI –2.1 to 0.5). I1 vs I2: Mean difference –1.4 (CI –2.5 to –0.2) sign *Health related quality of life (SF-36), degree of restricted activity, medication use, and home practise logbooks* Medication use decreased most in I1. There were no differences in SF-36 between the groups	At 3 months follow-up there were 6 drop outs totally	High Yoga and exercise is better in disability than self-care book in short term

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Table 3.2.3 *continued*

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Smeets 2008 [26] RCT The Netherlands	Chronic low back pain. Mean age: 41.9 (±9.65). Female/male: 79/93. Follow-up: 6 and 12 months	I: Combination treatment; included active physical treatment aimed to increase aerobic capacity and muscle reconditioning, graded activity with problem solving training, totally 30 sessions including 19 graded activity sessions during 10 weeks, n=61	C1: Active physical treatment aimed to increase aerobic capacity and muscle reconditioning, 3 times a week during 10 weeks, n= 53 C2: Graded activity based on operant behavioural theory and problem solving training, 11 sessions during 10 weeks, n=58	*Disability (Roland Disability Questionnaire RDQ)* 6 months, mean improvement from baseline I: 2.54 (CI 1.31-3.76) C1: 3.15 (CI 1.88-4.43) C2: 3.65 (CI 2.40-4.90) C1 vs I: 0.62 (CI –1.06 to 2.30), ns C2 vs I: 1.11 (CI –0.56 to 2.79), ns 12 months follow-up, mean improvement from baseline I: 2.12 (CI 0.89-3.36) C1: 3.28 (CI 2.00-4.58) 53% could be classified as having clinically relevant reduction in disability. C2: 3.74 (CI 2.48-5.01) 58% could be classified as having clinically relevant reduction in disability C1 vs I: 1.16 (CI –0.52 to 2.84) C2 vs I: 1.62 (CI –0.06 to 3.31) 51% could be classified as having clinically relevant reduction in disability *3 individual main complaints regarding activities, current back pain (VAS, Pain Rating Index), perceived improvement of disability (7-point scale), depression (Beck depression inventory), 6 functional performance tests* No other significant differences in any of the measures was seen except in self-perceived improvement were both C1 and C2 were better than I at 12 months follow-up	Totally 16 participants up to 12 months follow-up, 8 from I, 2 from C1, 6 from C2	High All three treatments had positive effects and were equal in their effect

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Table 3.2.3 continued

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Von Korff 2005 [7] USA RCT	Back pain patients (n=240). Female/male: 150/90. Mean age: 49 (SD 9.4) Follow-up: 6, 12 and 24 months	I: Four individual sessions addressing pain related fears, goal setting for activities and action plan, teaching exercises relevant to action plan, managing flare-ups. Additional 1–3 bonus visits, book and video about self-management of back pain, n=119	C: Usual care including pain medication prescription, primary care visits, and minority visited physiotherapist, n=121	*Disability (Roland Disability Questionnaire, (RDQ), mean* I: Baseline: 12.3 (SD 5.5) 6 months: 9.2 (SD 6.6) 24 months: 8.1 (SD 6.5). At 24 month 49.4% of the patients had a clinically relevant change (>30% reduction) in RDQ. C: Baseline: 11.4 (SD 5.7) 6 months: 10.1 (SD 6.4) 24 months: 9.1 (SD 7.2). At 24 month 37% of the patients had a clinically relevant change (>30% reduction) in RDQ. I decreased significantly more in disability from baseline to 24-months follow-up compared to C *Pain intensity, mean* I: Baseline: 5.7 (SD 1.8) 6 months: 4.2 (SD 2.0) 24 months: 4.3 C: Baseline: 5.8 (SD 1.8) 6 months: 4.7 (SD 2.2) 24-months: 4.6 (SD 2.5) Sign difference between groups at 6 and 12 months but not 24 months follow-up (SD 2.1) *Fear-avoidance beliefs (modified Tampa scale of Kinesiophobia, TSK), Back pain worry (NRS), mental health and social functioning (SF-36)* Intervention group showed significantly greater reductions in fear-avoidance and back pain worry. There were no differences between groups in SF-36	n=53 I: 25 pts 21% C: 28 pts 23%	High An activating intervention with cognitive and behavioural components decreased disability and pain intensity at short and long-term when compared to usual care

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Table 3.2.3 continued

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Yeung 2003 [18] China RCT	Chronic low back pain (n=52). Mean age: 53.0 (13.4). Female/male: 43/9. Follow-up: 3 months	I: Back exercise and electro acupuncture; strengthening and stretching exercises hourly session once a week during 4 weeks, advice and home exercise. Electro acupuncture 3 times a week for 4 weeks, n=26	C: Back exercise; same as in intervention group, n=26	*Pain intensity (NRS), mean* I: Change from pre treatment: 6.38 (SD 1.77) to 3.46 (SD 2.18) C: Change from pre treatment: 5.88 (SD 1.84) to 5.27 (SD 2.31) Significant interaction effect in pain, I significantly lower scores at each follow-up *Disability (The Aberdeen LBP scale)* I: Change from pre treatment m=35.32 (SD=11.72) to m=19.86 (SD=10.12) C: Change from pre treatment m=32.49 (SD=13.79) to m=25.82 (SD=13.11) Significant interaction effect in disability, I had significantly lower scores at each follow-up *Back ROM, isokinetic trunk flexor and extensor strength* I had significantly better ROM compared to C No significant differences in strength	3 patients during follow-up	High Back exercise + electro acupuncture has better effect in pain and disability compared to back exercises only

C = Control group; CI = Confidence interval; DEPS = Finnish depression questionnaire; EQ-5D=EuroQual five dimension; HRQoL = Health-related quality of life; I = intervention group; ITT = Intention-to-treat analysis; IQR = Interquartile range; LVCF = Last value carried forward; n = Number of patients; NRS = Numeric rating scale; ns = non-significant; ODI = Oswestry disability index; PSFS = Patient specific functional scale; RDS = Roland disability scale; ROM = Range of movement; RMQ = Roland Morris Questionnaire; SD = Standard deviation; SF-36 = Short form 36 (quality of life); TSK = Tampa scale of kinesiophobia; VAS = Visual analogue scale

Table 3.2.4 *Musculoskeletal pain.*

Author Year Reference Country Study design	Population Characteristics	Intervention Method Number individuals	Control No indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Åsenlöf 2005 [3] RCT 2006 [4] RCT 2009 [5] RCT Sweden	Chronic musculoskeletal pain in 82% resp 90%, sub acute 18% respective 10% of patients. Mean age: 42,5 years. Female/male: 75/22. Mostly >2 pain sites. Follow-up: 3 and 24 months	I: Individually tailored behavioural medicine program. Aimed to guide patients towards important and frequent daily activities through individually selected goals and strategies. 8–10 supervised sessions, n=45	C: Physical exercise program according to best possible standard physical therapy. Individually adapted according to physical impairment (strength, mobility, endurance) goals. 8–10 supervised sessions, n=52	<u>*Disability (Pain Disability Index)*</u> I: Mean difference between baseline and 3 months follow-up; –15.7 (baseline SD 11.6, 3 month SD 8.4) C: Mean difference between baseline and 3 months follow-up; –10.7 (baseline SD 14.1, 3 month SD 13.2). Treatment effects was maintained at 24 months follow-up I vs C significantly lower disability at 3 months follow-up There were no significant interaction effects between condition and time at 24 months follow-up. However, the groups still differed significantly in disability at this time point, ie the short term effects were maintained. Group mean at 24 months: I: 7.8 (SEM 2.1), C: 12.6 (SEM 1.8) <u>*Pain intensity (NRS), Self-efficacy (The Self-Efficacy Scale), Fear of movement/(re)injury (Tampa Scale of Kinesiophopia), physical performance*</u> Self-efficacy, fear of movement, pain intensity decreased significantly over time. Maximum and average pain intensity, fear of movement were sign lower in I vs C (3 months follow-up). Self-reported max pain intensity, functional self-efficacy differed sign between groups at 24 months follow-up. No other between-group differences. I had higher impact on participants' performance of highest ranked everyday life activities and larger proportions of patients in I had clinically significant outcomes Self-efficacy, fear of movement, pain intensity decreased significantly over time (3 months follow-up)	16 (I: 7, C: 9)	High Individually tailored behavioural medicine program is more effective compared to physical exercise program in short and long term

C = Control group; I = Intervention group; M = Mean; n = Number of patients; NRS = Numeric rating scale; SEM = Standard error of the mean; TSK = Tampa scale of kinesiophobia

Tabell 3.2.5 *Health economy.*

Author Year Reference Country	Study question Study design	Patient population	Intervention	Outcome	Costs	Results	Study quality and relevance Comments
Niemestö 2005 [21] Finland	Cost-effectiveness of combined manipulation, stabilising exercises and physician consultation compared to physician consultation alone Prospective CEA, along RCT	204 patients with chronic low back pain	I: Combination, n=98 C: Consultation, n=100	Pain (VAS) Disability (ODI) Quality of life	Mean annual total costs decreased during the 2-year follow-up compared to baseline I: – $288 C: – $1 370	Significant improvements in both groups on every outcome. I sign better in VAS with an ICER=$512 per unit. C more cost-effective in terms of health care use and work absenteeism	Medium
Critchley 2007 [24] United Kingdom	Cost-effectiveness of three types of physiotherapy for pats with chronic low back pain Pragmatic RCT and economic analysis	212 patients	I1: Individual physiotherapy I2: Spinal stabilisation I3: Pain management	Activity limitations (RDQ) Recent pain (VAS) QoL (EQ-5D) Working participation QALY	Direct health care costs	Similar improvements with all interventions	High
Lewis 2007 [27] United Kingdom	Cost-effectiveness of three physiotherapy treatments for non-specific neck disorders RCT and CEA, CUA	350 patients	I1: Advice and exercise, n=115 I2: Advice and exercise + manual therapy, n=114 I3: Advice and exercise + pulsed shortwave diathermy n=121	NPQ EQ-5D	Direct (health care) as well as direct + indirect (societal)	I2 cost-effective depending on perspective. I3 not cost-effective	Medium
Rivero-Arias 2006 [28] United Kingdom	Cost-utility of routine physiotherapy treatment compared with an assessment session and advice from physiotherapist	286 patients with low back pain >6 weeks	I: Routine physiotherapy C: Assessment session and advice	ODI (12 months) R&M SF-36 EQ-5D; QALY Days off work	Direct costs + societal NHS costs I: £179 C: £159 NS diff Out of pocket cost sign higher (£41) for I	Utility improved for both groups at 12 months, NS diff between groups. Advice should be first-line treatment	Medium

C = Control group; CEA = Cost effectiveness analysis; CUA = Cost utility analysis; EQ-5D = EuroQual five dimension; I=Intervention group; ICER = Incremental cost effectiveness ratio; NHS = National Health Service; NPQ = Northwick park neck pain questionnaire; ODI = Oswestry disability index; QALY = Quality adjusted life years saved; VAS = Visual analogue scale

Table 3.3.1 *Psychologic treatment, one therapeut.*

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Broderick 2005 [5] USA RCT	Fibromyalgia patients (n=92) All female with a mean age of 50 years. Effects were assessed at post-treatment, at a 4 month follow-up and at 10 month follow-up	I: Trauma writing for 20 minutes on 3 days at 1-week intervals, n=31	C1: Control treatment consisted of neutral writing, n=32 C2: Usual care, n=29	Results showed better effect for I compared to C1, C2 at 4 months *Pain* ES=0.49 *Fatigue* ES=0.62 *Psychological well-being* ES=0.47 No significant differences between groups at 10 months	12 out of 92 (13%) did not fulfill the full protocol	High Control groups were combined in the analyses. Primary and secondary outcomes not clearly defined
Gillis 2006 [6] USA RCT	Fibromyalgia patients (n=83) Mean age: 50.3 years (range 23–72). Female/male: 97.2%/2.8% Follow-up: 1 month and 3 month post treatment	I: Emotional disclosure, n=38	C: Neutral time management, n=34	*Fibromyalgia impact questionnaire* Emotion disclosure better worse than neutral time management at 1 month, but better at 3 month follow-up. Effect sizes not reliable Measures of pain, physical dysfunction, sleep, health care utilisation, negative affect and lack of social support Some effects on sleep and health care utilisation in favour of the disclosure group	13% drop out (11/83)	High Differences at baseline not significant but still as large as the improvement in the intervention group indicating randomisation failure

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Table 3.3.1 continued

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Leeuw 2008 [8] The Nether-lands RCT	Chronic low back pain (n=85). Female/male: 48.2%/51.8%. Mean age: 45.32 years. Follow-up: 6 months	I: Exposure in vivo, n=42	C: Operant graded activity, n=43	Quebec Back Pain Disability Scale, Patient specific complaints No differences between groups Improvements in both groups (within group ES about 0.80) Perceived harmfulness of activities; pain catastrophising; daily activity and pain intensity Difference in favor of exposure in vivo on measures of perceived harmfulness and pain catastrophising	14% (n=12) at 1-month follow-up	High

C = Control group; ES = Effect size; I = Intervention group; n = Number of patients

Table 3.4.5 *Acupuncture for treatment of chronic back pain.*

Author Year Reference Country Study design	**Population characteristics**	**Intervention Method Number individuals**	**Control Number indiviuduals**	**Results**	**Withdrawal Drop outs**	**Study quality and relevance** **Comments**
Brinkhaus 2006 [4] Germany RCT	Chronic low back pain for more than 6 months 301 randomised, 3 excluded (explained). Female/male: 202/96. Mean age: 58.8 years (±9.1) Follow-up: 26 weeks	I1: Acupuncture 12 sessions 30 minutes over 8 weeks, n=146 I2: Minimal acupuncture 12 sessions 30 minutes over 8 weeks, n=73	C: Waitinglist, n=79 (Only results directly after 8 weeks)	*Pain intensity (VAS)* I1: VAS decrease 38.4 mm (±29.8) I2: VAS decrease 42.1 mm (±30.3) No sign difference –3.8 mm (CI –12.4–4.9), p=0.39 *Back function (FFbH-R), Disability (PDI), QoL (SF-36)* I1: FFbH-R 66.0 (±20.1), PDI 19.3 (±13.9), SF-36/physical functioning 40.5 (±9.7), SF-36/mental 49.9 (±10.0), SF-36/pain 53.6 (±22.9). I2: FFBh-R 64.1 (±2.9), PDI 21.4 (±15.6), SF-36/physical functioning 36.2 (±10.3), SF-36/mental 46.8 (±12.9), SF-36/pain 49.6 (±23.6) No sign difference for: FFbH-R, 1.9 (CI –4.2 to 8), p=0.53, PDI, –2.1 (CI –6.3 to –2.1), p=0.33, SF-36/mental 3.1 (CI –0.5 to 6.6), p=0.09, SF-36/pain 3.9 (CI –2.7 to 10.7), p=0.24	14 (5%)	High

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Table 3.4.5 *continued*

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Cherkin 2009 [6] USA RCT	Chronic low back pain >3 months, 641 patients randomised. Female/male: 38%/62%. Mean age: 47 years (SD 13) range 18–70 years Follow-up: 26 and 52 weeks	I1: Individualised acupuncture, traditional Chinese Baseline RMDQ 10.8 (SD 5.2), bothersomeness score 5.0 (SD 2.5), n=157 I2: Standardised acupuncture 8 aku points. Baseline RMDQ 10.8 (SD 5.6), bothersomeness score 5.0 (SD 2.3) Both groups treated twice weekly 3 weeks then weekly for 4 weeks total 10 treatments, n=158	C1: Simulated acupuncture, tooth pick stimulation at 10 and 20 minutes, twice weekly 3 weeks then weekly for 4 weeks total 10 treatments. Baseline RMDQ 9.8 (SD 5.2), bothersomeness score 4.9 (SD 2.4), n=162 C2: Usual care chosen by pts and physicians. Baseline RMDQ 11.0 (SD 5.2), bothersomeness score 5.4 (SD 2.4), n=161	*RMDQ at 26 weeks* I1: 6.8 (SD 5.5) I2: 6.7 (SD 5.8) C1: 6.4 (SD 6.0) C2: 8.4 (SD 6.0) *RMDQ at 52 weeks* I1: 6.0 (SD 5.4) I2: 6.0 (SD 5.8) C1: 6.2 (SD 5.8) C2: 7.9 (SD 6.5) No sign difference between I1, I2, C1 *Bothersomness of pain 0–10 at 26 weeks* I1: 3.8 (SD 2.5) I2: 3.7 (SD 2.6) C1: 3.5 (SD 2.7) C2: 4.4 (SD 2.6) *Bothersomness of pain 0–10 at 52 weeks* I1: 3.7 (SD 2.6) I2: 3.5 (SD 2.7) C1: 3.4 (SD 2.7) C2: 4.1 (SD 2.6) No sign difference between I1, I2, C1	26 and 52 weeks 48 patients (9%)	High RMDQ Roland Morris Disability Questionnaire Adverse events short term pain 11 patients, 1 month of pain 1 patient

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Table 3.4.5 *continued*

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Control Number indiviuduals	Results	Withdrawal Drop outs	Study quality and relevance Comments
Haake 2007 [5] Germany RCT	18 years or older Pain for ≥6 months, 1 162 randomised. Female/male: 692/470. *Age* I: 50 years C1: 49 years, C2: 51 years Follow-up at 1.5, 3 and 6 months	I: Verum acupuncture. Mean 12.5, 30 minutes sessions/patient, n=387	C1: Sham acupuncture. Mean 11.9 sessions/ patient, n=387 C2: Physiotherapy, exercise + pain medication, n=388	*At least 33% better on von Korff Chronic Pain Scale 6 months* I: 47.6% (CI 42.4–52.6) C1: 44.2% (CI 39.2–49.3). C2: 27.4 (95 % CI 23.0–32.1) I sign better than C3, p<0.001, C2 sign better than C3, p<0,001 *Disability (HFAQ), QoL (SF-36), Global assessment at 1.5, 3 and 6 months* I and C1 better than C2. No pair wise comparison analyses were made	45 patients (4 %)	High Adverse events: I: 12, C1: 12, C2: 16. Not related to the intervention
Thomas 2006 [18] United Kingdom RCT	Non-specific low back pain with duration 4–52 weeks mean 4 m 241 patients. Female/male: 99//46. Mean age: 42–44 years (range 18–65) Follow-up: 12 months	I: Acupuncture 10 treatments over 3 months Other treatment during this time was accepted, n=159	C: Usual care only, n=80	*Bodily pain on SF-36* I: 64.0 (SD 25.6) C: 58.3 (SD 22.2) Adjusted for baseline values and other confounder's significant difference between groups *Oswestry pain disability index* I: 20.6 (SD 19.3) C: 19.6 (SD 15.4) No significant difference between groups	24 patients (15%)	Medium

C = Control group; CI = Confidence interval; FFbH-R = Hannover functional ability questionnaire; I = Intervention group; mm = Millimetre; p = Probability coefficient; PDI = Pain disability index; RMD = Roland Morris disability questionnaire; SD = Standard deviation; Sign = Significant; VAS = Visual analogue scale

Table 3.4.6 *Health economy.*

Author Year Reference Country	Study question Study design	Patient population	Intervention Control	Outcome	Costs	Results	Study quality and relevance Comments
Ratcliffe 2006 [19] United Kingdom	Cost-effectiveness of acupuncture care for persistent non-specific low back pain CUA based on a RCT (Thomas, 2006 [18]) Follow-up: 2 years	241 patients with persistent low back pain recruited from 43 general practitioners, were randomly allocated to 10 acupuncture treatments or usual care only	I: Acupuncture, n=161 C: Usual care, n=81	Pain dimension of SF-36 at 12 and 24 months. Incremental cost per QALY	*Direct costs* I: £460 C: £345	ICUR (acupuncture compared with usual care) = £4 241 Acupuncture cost-effective for low back pain	High

C = Control group; CUA = Cost-utility analysis; ICUR = Incremental cost-utiliy ratio; n = Number of patients; QALY = Quality adjusted life years: RCT = Randomised controlled trial

Table 3.4.7 *Acupunture for treatment of fibromyalgia.*

Author Year Reference Country Study design	**Population characteristics**	**Intervention Method Number individuals**	**Control Number indiviuduals**	**Results**	**Withdrawal Drop outs**	**Study quality and relevance Comments**
Assefi 2005 [8] USA RCT	Fibromyalgia 99 patients. Female/male: 94/5 Follow-up: 3 and 6 months post treatment	I: Acupuncture 2 x week/12 weeks, n=25	C1: Acupuncture for unrelated condition, n=25 C2: Sham needling, n=24 C3: Simulated acupuncture, n=25 These groups were pooled	*VAS* Mean between group difference 5 mm (CI –0.3 to –1.2) Not significant	4 patients	High
Martin 2006 [7] USA RCT	Fibromyalgia 50 patients that completed a fibro-myalgia treatment programme before randomisation. Female/male: 49/1. *Mean age* I: 47.9 years (SD 11.2) C: 51.7 years (SD 14.1) Follow-up: 7 months post treatment	I: Acupuncture 6 times during 2–3 weeks, n=25	C: Sham acupunc-ture 6 times during 2–3 weeks, n=25	*Fibromyalgia impact questionnaire* I: 38.1 (SD 12.1) C: 42.7 (SD 9.6) No significant difference *Multi-dimensional pain inventory* I: 37.3 (SD 13.1) C: 41.4 (SD 8.4) No significant difference	1 patient	Medium 1 months post treatment significant differences between groups
Mayhew 2007 [20] United Kingdom Systematic review	5 RCT included. Fibromyalgia according to ACR. Total 364 patients. No data on sex and age. JADAD score = 3 for ingoing studies	I: Acupuncture, n=188	C: Sham-acupuncture Non-acupuncture treatments No treatment, n=176	*Pain reduction* 2 studies reported sign reduction in pain for acupuncture compared to control in the short-term 3 studies reported no sign difference		Medium

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Table 3.4.7 *continued*

Author **Year** **Reference** **Country** **Study design**	**Population characteristics**	**Intervention** **Method** **Number individuals**	**Control** **Number indiviuduals**	**Results**	**Withdrawal** **Drop outs**	**Study quality and relevance** **Comments**
Targino 2008 [21] Brazil RCT	Fibromyalgia ACR classification criteria *Pain duration mean* I: 118.8 months (SD 117.3) C: 93.0 months (SD 75.25) Female/male: 58/0 *Mean age* I: 52.09 (SD 10.97) C: 51.17 (SD 11.20) Follow-up 3, 6, 12 and 24 months after randomisation	I: Acupuncture + standard care 20 sessions 20 minutes 2 x/week, n=34	C: Standard care only (tricyclic antidepressants, exercise, mental relaxation, stretching), n=24	*Pain intensity (VAS); range* I: 3 months VAS 5.0 (0.0–10.0) 6 months VAS 7.0 (2.0–10.0) 12 months VAS 7.0 (0.0–10.0) 24 months VAS 7.0 (0.0–10.0) C: 3 months VAS 8.0 (4.0–7.0) 6 months VAS 7.5 (3.0–10.0) 12 months VAS 7.0 (3.0–10.0) 24 months VAS 8.0 (2.0–10.0) I better than C at 3 months, $p<0.001$ No sign differences at other times *QoL (SF-36)* I sign better than C for 5 out of 8 SF-36 subscales at 3 months. No sign differences at other times	0 after 3, 6 and 12 months. 3 (5%) after 24 months	Medium

C = Control group; CI = Confidence interval; I = Intervention group; mm = Millimetre; p = Probability coefficient; SD = Standard deviation; Sign = Significant; VAS = Visual analogue scale

Table 3.4.8 *Adverse events and complications.*

Author Year Reference Country Study design	Population characteristics	Intervention Method Number individuals	Results	Withdrawals Drop outs	Study quality and relevance Comments
Melchart 2004 [22] Germany Register study	Patients treated with acupuncture i Germany from July 2001 to April 2002	Acupuncture, n=97 733	*Potentially serious adverse events* Exacerbation of depression 1 patient Acute hypertensive crisis 1 patient Vasovagal reaction 1 patient Asthma attack with hypertension and angina 1 patient Pneumothorax 2 patients *Any other adverse event* Needling pain 3 202, 3.28% (99% CI 3.13–3.43) Hematoma 3 114, 3.19% (99% CI 3.04–3.34) Bleeding 1 346, 1.38% (99% CI 1.28–1.48) Orthostatic problem 447, 0.46 (99% CI 0.40–0.52) Forgotten needles 242, 0.25% (99% CI 0.21–0.29) Other 674, 0.69% (99% CI 0.62–0.76)		High quality

CI = Confidence interval; n= Number of patients

Table 3.4.9 *TENS for treatment of chronic neck and back pain.*

Author Year Reference Country Study design	**Population characteristics**	**Intervention Method Number individuals**	**Control Number indiviuduals**	**Results**	**Withdrawals Drop outs**	**Study quality and relevance Comments**
Chiu 2005 [24] China RCT	Neck pain >3 months. Mean age: 43–44 years (range 20–64). Female/male: 70%/30% Follow-up: 6 weeks (pain), 6 months	I1: TENS 80 Hz + infrared radiation, n=73 I2: Exercise + infrared radiation, Pollock's method 35 minutes 2 times a week for 6 weeks, n=67	C: Infrared radiation, n=78	*Verbal pain score 6 weeks, 6 months* No sign differences between the groups *Sick leave 6 months* No sign differences between the groups	36 (16 %)	Medium
Jarzem 2005 [23] Canada RCT	Chronic low back pain >3 months, 350 patients. Mean age: 45.1 years (range 18–70). Female/male: 50%/50% Follow-up directly after 4 weeks of treatment	I1: Conventional TENS, n=84 I2: Acupuncture TENS, n=78 I3: Biphasic TENS, n=79 All stimulators were handed over to the patients after training for 4 weeks self-treatment	C: Sham-TENS The stimulator was handed over to the patients after training for 4 weeks self-treatment, n=83	*McGill activity scale* I1: 37.3(SD 20.6) I2: 32.3 (SD 23.9) I3: 36.5 (SD 23.4) C: 38.0 (SD 20.6) *McGill work scale* I1: 16.6 (SD8.0) I2: 14.8 (SD7.4) I3: 15.6 (SD 7.3) C: 16.8 (SD 6.7) *Roland disability score* I1: 9.9 (SD 5.9) I2: 9.0 (SD 6.1) I3: 9.1 (SD 5.7) C: 9.7 (SD 5.8)	26 (7 %)	Medium
Topuz 2004 [9] Turkey RCT	Chronic low back pain >3 months, 60 patients. Female/male: 41/19 *Mean age* I1: 45.2 years (SD 11.19) I2: 50.13 years (SD 11.97) I3: 37.92 (SD 14.49) C: 41.92 years (SD 7.70) Range 19–70 years	I1: High frequency TENS, n=15 I2: Low frequency TENS, n=15 I3: Percutaneous neuromodulation therapy, n=13 Modalities were administered 20 min, 5 times/week for 2 weeks	C: Placebo TENS administered 20 minutes, 5 times/ week for 2 weeks, n=12	*Pain (VAS)* I1: –2.80 mm (SD 2.0) I2: –2.60 mm (SD 1.40) I3: –3.61 mm (SD 1.98)	5 patients (8%)	Medium

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Table 3.4.9 *continued*

Author **Year** **Reference** **Country** **Study design**	**Population characteristics**	**Intervention** **Method** **Number individuals**	**Control** **Number indiviuduals**	**Results**	**Withdrawals** **Drop outs**	**Study quality and relevance** **Comments**
Weng 2005 [10] Taiwan RCT	Chronic upper back pain >3 months, 30 patients 20–30 years No data on gender	I1: High frequency TENS, n=30 I2: Low frequency TENS, n=30 Treatment were administered 20 minutes 3 times/week for 2 weeks	Sham-TENS 30 patients Treatment were administered 20 minutes 3 times/week for 2 weeks	*Pain (VAS)* I1: –0.61 mm (SD 1.9) I2: –0.65 mm (SD 1.77)	0 patients	Medium Cross over study

C = Control group; CI = Confidence interval; CUA = Cost utility analysis; I = Intervention group; mm = Millimetre; p = probability coefficient; PDI = Pain disability index; pts = Patients; SD = Standard deviation; Sign = Significant; TENS = Transcutaneous electric nerve stimulation; VAS = Visual analogue scale