National Institute for Health and Care Excellence

Final

Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain

[G] Evidence review for acupuncture for chronic primary pain

NICE guideline NG193

Intervention evidence review underpinning recommendation 1.2.5 and the research recommendation in the NICE guideline

April 2021

This evidence review was developed by the National Guideline Centre based at the Royal College of Physicians

Disclaimer

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or service users. The recommendations in this guideline are not mandatory and the guideline does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and, where appropriate, their carer or guardian.

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1.1 Review question: What is the clinical and cost effectiveness of acupuncture or dry needling for the management of chronic primary pain?

1.2 Introduction

Acupuncture is one of the treatment modalities many pain sufferers seek or get in contact with whilst living with pain and seeing a variety of healthcare professionals in both publicly funded and private settings. Reasons for getting in contact with an acupuncture therapist may include the quest for alternative formulations and treatment strategies for chronic pain, the desire to have temporary or even persistent relief from pain, being dissatisfied with what has already been tried or the lack of treatments that have not been tried before.

There are wide variations in what people associate with the term “acupuncture”. From a simplistic sense, all acupuncture treatments have in common the placement of needles in various parts of the body. The depth of needle penetration ranges from just touching the skin to penetration of deeper body layers, such as bones and deep muscle tissues. In the majority of cases the needles are placed in muscle tissue close to nerve endplates. The placement of needles depends on the theoretical framework therapists apply. Therapists trained in traditional Chinese medicine operate under the assumption of optimising the flow of the vital energy “Qi” in the body. Western approaches in contrast locate their strategy in a neurobiological paradigm and have somatosensory stimulation as the concept underpinning their therapeutic strategies.

Dry needling is a concept aimed at the treatment of painful areas in striated muscle, myofascial trigger points. In this concept therapists aim to needle “as close to where it hurts without making it worse”. In contrast protagonists of traditional Chinese medicine (TCM) choose distant points in their attempts to harmonise the perceived misbalance of body functions and emotions.

Recent research demonstrated that contextual factors, such as therapeutic setting, interpersonal skills of the therapist or even the therapist themselves (“practitioner-effect”) have a significant influence on the outcome of the intervention. In the context of chronic pain, acupuncture treatments are often delivered in sequences of several sittings over time, which can facilitate building a therapeutic relationship. Acupuncture treatments offer the opportunity to treat several painful places and affected body functions at one time, which makes it an attractive option for people with many ailments and emotional components to their predicament. Acupuncture is often delivered in individually tailored one-to-one-settings, but some service providers have moved to deliver acupuncture therapy in group settings.

This review intends to determine the effectiveness of acupuncture and electroacupuncture in people with chronic pain.

1.3 PICO table

For full details see the review protocol in appendix A.

Table 1: PICO characteristics of review question

Population	People, aged 16 years and over, with chronic primary pain (whose pain management is not addressed by existing NICE guidance) (chronic widespread pain, complex regional pain syndrome, chronic visceral pain, chronic orofacial pain, chronic primary musculoskeletal pain other than orofacial)

	Chronic pain in one or more anatomical regions that is characterized by significant emotional distress (anxiety, anger/frustration or depressed mood) and functional disability (interference in daily life activities and reduced participation in social roles). The diagnosis is appropriate independently of identified biological or psychological contributors unless another diagnosis would better account for the presenting symptoms.
Interventions	Interventions: • acupuncture/dry needling • electro acupuncture.
Comparisons	Comparators: • placebo/sham • usual care.
Outcomes	CRITICAL: • pain reduction (any validated scale) • health related quality of life (including meaningful activity) • physical function (5 minute walk, sit to stand, Roland Morris Disability Questionnaire, Oswestry Disability Index, Canadian Occupational Performance Measure) • psychological distress (depression/anxiety) (preferably Hospital Anxiety and Depression Scale) • pain self-efficacy • pain interference. IMPORTANT: • use of healthcare services • sleep • discontinuation. Outcomes will be extracted at the longest time point up to 3 months and at the longest time point after 3 months.
Study design	Randomised controlled trials (RCTs) and systematic reviews of RCTs Cross-over RCTs will be considered if no non-cross-over RCT evidence is identified.

1.4 Clinical evidence

1.4.1 Included studies

32 studies were included in the review[5, 7, 10, 16, 28, 32, 33, 42, 49, 55, 82, 85, 86, 93, 101, 111, 126, 131, 136, 139, 143, 150, 152, 168, 175, 176, 183, 201, 208, 211, 216, 220, 232] and these are summarised in Table 2 below. Evidence from these studies is summarised in the clinical evidence summary tables below (Table 3, Table 4 and Table 5).

See also the study selection flow chart in appendix C, study evidence tables in appendix D, forest plots in appendix E and GRADE tables in appendix F.

1.4.2 Excluded studies

One Cochrane review was identified but did not match the PICO characteristics of this review (Deare 2013[47]), due to differences in the population, outcomes and comparisons. All included studies were cross-checked for inclusion in this review as relevant.

See the excluded studies list in appendix I.

1.4.3 Summary of clinical studies included in the evidence review

Table 2: Summary of studies included in the evidence review

Study	Intervention and comparison	Population	Outcomes	Comments
Aranha 2015[5]	**Intervention (n=25): Acupuncture (traditional).** Duration: Twice a week for 4 weeks, total of 8 sessions. Duration of sessions not specified. **Intervention (n=24): Electro-acupuncture (traditional).** Duration: Twice a week for 4 weeks, total of 8 sessions. Duration of sessions not specified. **Comparison (n=23): Sham acupuncture.** Identical treatment but needles inserted only 1cm distally	Head and neck pain for at least 6 months (n=72) Mean(SD) age 27.33(4.95) Females only Mean duration of pain not reported	Discontinuation at 1 month (post-intervention)	
Assefi 2005[7]	**Intervention (n=25): Acupuncture (traditional)** Duration: Twice weekly for 12 weeks. Duration of sessions 30 minutes. **Comparison (n=25): sham acupuncture (non-traditional; sham needling).** Needles inserted into points not recognised as acupoints or meridians Duration: Twice weekly for 12 weeks. Duration of sessions not specified **Comparison (n=24): sham acupuncture (simulated acupuncture).** Needle replaced with toothpick with fake needle insertion Duration: Twice weekly for 12 weeks. Duration of sessions not specified	Fibromyalgia (n=98) Mean(SD) age 46.8(11.4) Mean duration of pain 10.65 years	At 6 months (follow-up, including 12 week intervention): • Pain • Quality of life • Sleep • Discontinuation	For analysis sham needling, simulated acupuncture and unrelated acupuncture were combined In Cochrane review (Deare 2013)

Study	Intervention and comparison	Population	Outcomes	Comments
	Comparison (n=24): sham acupuncture (Traditional, unrelated condition: involved acupuncture typically used to treat irregular menses). Duration: Twice weekly for 12 weeks. Duration of sessions not specified			
Birch 1998[10]	**Intervention (n=15): acupuncture (traditional)** With infrared lamp to warm needle area Twice weekly for 14 weeks, each session 30 minutes. **Comparison (n=16): sham acupuncture.** Identical treatment but needles not fully inserted and normal lamp with no heat used Twice weekly for 14 weeks, each session 30 minutes. **Comparison (n=15): usual care** Medication without acupuncture, trilisate 500mg per day All participants were offered 500mg per day of trilisate (NSAID), and discouraged from using other medications.	Chronic myofascial neck pain for >6 months (n=46) Mean age 39 years Mean duration of pain 86 months	At 3 months (post-intervention): • Pain • Discontinuation	
Casanueva 2014 [16]	**Intervention (n=60): Dry needling (not traditional, on tender points)** Once weekly for 6 weeks, each session 1 hour. **Comparison (n=60): usual care (current medical treatment).** Participants maintained current medical treatment.	Fibromyalgia (n=120) Mean age 53.54 years Mean duration of pain not reported	At 3 months (follow-up, including 6 week intervention): • Pain • Health related quality of life • Physical function • Psychological distress • Pain interference • Discontinuation • Sleep	

Study	Intervention and comparison	Population	Outcomes	Comments
Cho 2014 [28]	**Intervention (n=15): Acupuncture (traditional)** Three times a week, totalling 9 sessions over 3 weeks (duration not specified, needles left in for 15mins). Plus NSAIDs (zaltoprofen 80mg 3 times daily) **Comparison (n=15): Acupuncture only.** Three times a week, totalling 9 sessions over 3 weeks (duration not specified, needles left in for 15mins). **Comparison (n=15): Usual care** NSAIDs, zaltoprofen 80mg 3 times daily	Chronic neck pain (n=45) Mean age 38.68 years Mean duration of pain not reported	At 7 weeks (follow-up, including 3 week intervention): • Pain • Physical function • Psychological distress • Discontinuation	For the analysis acupuncture + NSAIDs and acupuncture only groups were combined
Chou 2011[32]	**Intervention (n=15): Acupuncture (traditional).** Traditional sites but needles moved in and out at different directions plus rotations for 15 seconds, followed by no movement for 3 minutes, repeated multiple times for each acupoint. Three to 4 times per week for 4 weeks, duration of sessions not specified **Comparison (n=15): Acupuncture (traditional)** Traditional sites but needles maintained without movement. Three to 4 times per week for 4 weeks, duration of sessions not specified **Comparison (n=15): Sham acupuncture** Identical sessions but needles made contact with skin without penetration of the skin	Chronic pain on one side of the shoulder because of active myofascial trigger points (n=45) Mean age 34 years Duration of pain (months): modified acupuncture 6.1 (2.2); simple needling 6.1 (2.3); placebo 6.2 (2.2)	At 4 weeks (post-intervention): • Pain • Discontinuation	For the analysis, the traditional acupuncture and simple needling acupuncture groups were combined
Coan 1981[33]	**Intervention (n=15): Acupuncture (Traditional).** Sessions 3-4 times per week for 2-3 weeks, session duration not specified **Comparison (n=15): Usual care (waiting list).**	Neck and/or radicular arm and hand pain for at least 6 months (n=30) Mean age 49 years	Pain at 12 weeks post-intervention	

Study	Intervention and comparison	Population	Outcomes	Comments
		Duration of pain (years): acupuncture 7.8; sham 8.3		
Couto 2014[42]	**Intervention (n=26): Acupuncture (non-traditional, trigger points)** Multiple deep intramuscular stimulation therapy. 2 Sessions per week for 4 weeks. Session duration not specified. **Comparison (n=26): Sham electro-acupuncture** Electro-acupuncture device used without a passing current (participants told they would not feel anything due to the high frequency current) 2 Sessions per week for 4 weeks. Session duration not specified.	Myofascial pain syndrome for >3 months (n=52) Mean age 34 years Mean duration of pain not reported Females only	At 4 weeks (post-intervention): • Pain • Health related quality of life • Sleep • Discontinuation	
Deluze 1992 [49]	**Intervention (n=36): Acupuncture (electro-acupuncture, traditional).** Six sessions over 3 weeks, session duration not specified **Comparison (n=34): Sham (sham electro-acupuncture, non-traditional points).** Different points (not traditional, random and close to the traditional sites), with a slightly weaker voltage used Six sessions over 3 weeks, duration not specified	Fibromyalgia N=70 Mean age 48 years Duration of pain (years), mean (SE): acupuncture 14.4 (3.7); sham 6.9 (1.3)	At 3 weeks (post-intervention): • Pain • Sleep • Discontinuation	In Cochrane (Deare 2013)
Edwards 2003 [55]	**Intervention (n=14): Acupuncture (Non-traditional, trigger points).** Plus active stretching exercise. Three weeks (number of sessions and length of sessions were dependent on severity) **Comparison (n=13): Usual care?** (active stretching exercise). Three weeks.	Chronic musculoskeletal pain (myofascial pain) with active trigger points (n=40) Mean age 56.5 years Mean duration of pain (months): acupuncture 16 (23); usual care 10 (12)	At 3 weeks (post-intervention): • Pain • Discontinuation	For the analysis, active stretching exercise group and no treatment group were combined

Study	Intervention and comparison	Population	Outcomes	Comments
	Comparison (n=13): Usual care (no treatment). Three weeks.			
Harris 2005 [82]	**(n=29) Intervention: Acupuncture (traditional)** Total of 18 treatments over 9 weeks (3 weeks of 1 treatment per week, 2 treatments per week and 3 treatments per week, session length not specified). **(n=85) Comparison: Sham acupuncture** (identical duration). 3 different interventions for 9 weeks (pooled in the analysis): Non-traditional points with stimulation; no further (n=28) Traditional points without stimulation (n=30) Non-traditional points without stimulation (n= 27).	Fibromyalgia (n=114) Mean age 46 years Mean pain duration 5.5 years	At 9 weeks (post-intervention) and 15 weeks (follow-up): • Quality of life • Pain • Discontinuation (9 weeks only)	
He 2004 [86], He 2005 [85]	**Intervention (n=14): electroacupuncture (traditional)** (combination of body acupuncture, body electroacupuncture and ear acupressure). Three times a week for 3-4 weeks, 45 minute sessions (total of 10 treatments). **Comparison (n=10): Sham (sham electro-acupuncture).** Identical treatment but no voltage Three times a week for 3-4 weeks (total of 10 treatments).	Chronic pain in the neck and shoulder (n=24) Mean age 46.5 years Duration of pain (years): acupuncture 12 (8); placebo 12 (10) Females only	• Pain (at 3-4 weeks post-intervention and 3 years follow up) • Discontinuation (3-4 weeks)	Downgraded for indirectness as includes body acupuncture and ear acupressure
Ilbuldu 2004 [93]	**Intervention (n=14): Dry needling (non-traditional, trigger points)** Once a week for 4 weeks, session duration not specified **Comparison (n=10): Placebo (placebo laser).** Probe placed on trigger points but no beam applied Three times a week.	Myofascial pain syndrome with trigger points in the upper trapezius muscle (n=24) Mean age 33.82 years Mean duration of pain (months): dry needling 38.48 (31.94); placebo 36.95 (33.65)	Pain at 4 weeks (post-intervention) and 6 months (follow-up)	

Study	Intervention and comparison	Population	Outcomes	Comments
	All participants were given muscle stretching exercises and were required to exercise regularly during the 4 week treatment period. Paracetamol was prescribed when participants had pain.	Females only		
Itoh 2014 [101]	**Intervention (n=8): Acupuncture (Non-traditional, trigger point).** Five treatments over 5 weeks, each lasting 30 minutes. **Comparison (n=7): sham (sham acupuncture).** Identical treatment, needles did not penetrate the skin.	Myofascial pain (n=16) Mean age 57.15 years Duration of pain (years): acupuncture 2.1 (1.6); sham 2.2 (1.6)	Discontinuation at 5 weeks post-intervention	
Karatay 2018 [111]	**Intervention (n=25): Acupuncture (traditional)** Semi-weekly for four weeks, for a total of 8 sessions, each session lasting 30 minutes. **Comparison (n=25): sham (sham acupuncture).** Identical treatment but incorrect points used (not acupoints or meridians) **Comparison (n=25): sham (simulated acupuncture).** Identical treatment but needles made contact with skin and not inserted	Fibromyalgia (n=75) Age range 20-50 years Duration of pain (years): acupuncture 4.4 (3.99); sham 3.94 (3.30); simulated 5.09 (3.39) Females only	At 3 months (follow-up, including 4 week intervention): • Pain • Health related Quality of life • Psychological distress • Sleep • Discontinuation	For the analysis, sham acupuncture and simulated acupuncture groups were combined
Lee 2011 [126]	**Intervention (n=45): Acupuncture (traditional)** Two treatments a week for 10 weeks, totalling 20 treatments. **Comparison (n=45): sham acupuncture.** Identical treatment but needles not fully inserted	Chronic prostatitis/chronic pelvic pain syndrome for >3 months (n=90) Mean age 41.8 years Mean duration of pain (months): acupuncture 22.4 (28.4); sham 27.5 (26.9)	At 10 weeks (post-intervention): • Pain • Discontinuation	
Liang 2011 [131]	**Intervention (n=88): Acupuncture (traditional).**	Neck or shoulder pain or stiffness for ≥6 months (n=178)	At 3 months (follow-up, including 3 week intervention):	

Study	Intervention and comparison	Population	Outcomes	Comments
	For 3 weeks with a total of 9 sessions, session duration not specified **Comparison (n=90): Sham acupuncture.** Identical treatment but needles only shallowly inserted and at incorrect points.	Mean age 37 years Duration of pain (unit not reported): acupuncture 50.43 (49.61); control 44.89 (36.78)	• Pain • Health related quality of life • Discontinuation	
Lopez-Martos 2018 [136]	**Intervention (n=20): dry needling (non traditional, trigger points).** Once per week, for 3 weeks (session duration not specified). **Comparison (n=20): electro-acupuncture (non traditional, trigger points).** Once per week, for 3 weeks (session duration not specified). **Comparison (n=20): Sham electro-acupuncture** Identical treatment but needles not injected and no voltage Two weeks after each procedure, all subjects were instructed to perform concentric exercises with the masticatory muscles.	Myogenic pain in the temporomandibular area (myofascial pain) for at least 6 months (n=60) Mean age 39 years Mean duration of pain not reported	Discontinuation (3 weeks post-intervention)	
MacPherson 2015[139] (Essex et al 2017 [60]	**Intervention (n=173): Acupuncture (traditional)** Up to 12 fifty minute treatments delivered once per week and then once every 2 weeks. Plus usual care. **Comparison (n=172): Usual care.** General neck pain specific treatments such as prescribed medications and visits to physical therapists	Chronic neck pain (n=345) Mean age 52.9 years Mean duration of neck pain (median), months: acupuncture 60 (5-600); usual care 96 (5-600)	At 3 months post-intervention and 12 months (follow-up, including intervention): • Pain • Quality of life • Pain self-efficacy • Discontinuation	
Martin 2006 [143]	**Intervention (n=25): Electro-acupuncture (traditional)**	Fibromyalgia (n=50) Mean age 49.9 years	At 1 month post-intervention and 7 months (follow-up, including intervention):	In Cochrane (Deare 2013)

Study	Intervention and comparison	Population	Outcomes	Comments
	Treatments were every 2-4 days during 2-3 weeks for a total of 6 sessions (session duration not specified) **Comparison (n=25): Sham (sham eletro-acupuncture).** Identical treatment but needle not inserted and current applied to the skin only. All patients had completed a fibromyalgia treatment programme including 1.5 days of education, counselling and group discussion about symptom management.	Duration of pain not reported	• Pain • Health related quality of life • Pain interference • Discontinuation	
Mist 2018 [150]	**Intervention (n=16): Acupuncture (traditional).** Twice weekly, each session lasting 40 minutes for 10 weeks. **Comparison (n=14): Usual care (education).** Participants had group discussion on chapters from a fibromyalgia book.	Fibromyalgia (n=30) Mean age 54.5 years Mean duration of pain not reported. Females only	Discontinuation (10 weeks post-intervention)	
Molsberger 2010 [152]	**Intervention (n=154): Acupuncture (traditional)** One to three times a week, totalling 15 treatments, each treatment lasting 20 minutes **Comparison (n=135): Sham (sham acupuncture).** Identical treatment but non-traditional acupoints without full needle insertion.	One sided shoulder pain for at least 6 weeks (n=424) Mean age 50.8 years Duration of pain (months): acupuncture 10.7 (9.7); 11.6 (11.4)	At 3 months (post-intervention): • Pain • Discontinuation	
Qin 2018 [168]	**Intervention (n=34): Acupuncture (traditional)** Three times a week for 8 weeks, for a total of 24 sessions. Each session lasted 30 minutes. **Comparison (n=34): Sham acupuncture.** Identical treatment but needles did not penetrate the skin	Chronic prostatitis/chronic pelvic pain syndrome (n=68) Mean age 34.5 years Males only	At 8 weeks (post-intervention): • Pain • Health related quality of life • Discontinuation	

Study	Intervention and comparison	Population	Outcomes	Comments
	Participants were allowed to ingest celecoxib 200 mg in the event of intolerable pelvic pain	Mean duration of pain (years): acupuncture 2 (0.7); sham 2.2 (1)		
Sahin 2010 [175]	**Intervention (n=15): Electroacupuncture (traditional).** Three times a week for 3-4 weeks, with a total of 10 sessions, each lasting 30 minutes. **Comparison (n=16): Sham electroacupuncture.** Identical treatment but needles inserted 1-2cm away from correct points at a reduced depth, and current was switched off after the patient perceived it.	Chronic mechanical neck pain for ≥3 months (n=31) Mean age 36.9 years Mean duration of pain not reported	At 3 months (follow-up, including 3-4 week intervention): • Pain • Discontinuation	
Sahin 2015 [176]	**Intervention (n=50): Acupuncture (non-traditional; points selected based on the theory of neuroanatomy and myofascial pain syndrome).** Once a week for 6 weeks, sessions lasted 20 minutes **Comparison (n=50): Sham acupuncture.** Identical treatment but needles inserted 1cm away from the correct points.	Chronic prostatitis/chronic pelvic pain syndrome with symptoms for at least 3 of the last 6 months (n=100) Age 20-50 years Duration of pain (months): acupuncture 9.6 (3.5); sham 9.5 (2.3) Males only	At 8 weeks post-intervention and 6 months (follow-up, including 6 week intervention): • Pain • Health related quality of life • Discontinuation	
Schlaeger 2015 [183]	**Intervention (n=18): Acupuncture (traditional)** Twice weekly for 5 weeks, totalling 10 sessions. Session duration not stated **Comparison (n=18): Usual care.** No further details	Vulvodynia (generalised vulvodynia or localised vestibulodynia) (n=36) Aged >18 years Duration of pain (years): acupuncture 5.4 (5.3); usual care 4.83 (3.2) Females only	At 5 weeks (post-intervention): • Pain • Discontinuation	

Study	Intervention and comparison	Population	Outcomes	Comments
Tekin, 2013 [201]	**Intervention (n=23): Dry needling (non-traditional, trigger points)** Six sessions over a period of 4 weeks, duration of sessions not specified **Comparison (n=23): Sham (sham dry needling).** Identical treatment but needles did not penetrate the skin.	Myofascial pain syndrome for ≥6 months (n=46) Age 24-65 years Duration of pain (months): 63.5 (50.7); sham 57.9 (48.3)	At 4 weeks (post-intervention): • Pain • Discontinuation	
Ugurlu, 2017 [208]	**Intervention (n=25): Acupuncture (traditional)** Three sessions in the first week, 2 sessions/week in the following 2 weeks, and 1 session/week in the following 5 weeks, totalling 12 sessions lasting 30 minutes each. **Comparison (n=25): sham acupuncture.** Identical treatment but needles did not penetrate the skin.	Fibromyalgia for ≥6 months (n=50) Mean age 45.44 years Duration of pain (years) (sd): acupuncture 6.28 (4.97); sham 6.32 (2.21)	At 2 months (post-intervention): • Pain • Health related quality of life • Psychological distress • Discontinuation	Also reported but not extracted: Pain: VAS (activity, night)
Vas, 2016[211]	**Intervention (n=82): Acupuncture (non-traditional, individualised acupuncture).** Once per week for 9 weeks, each session 20 minutes. **Comparison (n=82): sham (sham acupuncture).** Stimulation of dorsal and lumbar regions, needles did not penetrate the skin Participants in both groups also received pharmacological treatment prescribed by their GP.	Fibromyalgia (n=164) Aged >17 years Duration of pain (months): acupuncture 70.7 (44.5); sham 69.2 (43.7) Female only	At 10 weeks post-intervention and 12 months (follow-up, including 9 week intervention): • Pain • Health related quality of life • Psychological distress • Discontinuation	
White, 2004 [216]	**Intervention (n=70): Acupuncture (non-traditional)** Twice a week for 4 weeks, duration of sessions not specified **Comparison (n=65): Sham electro-acupuncture.** Different acupuncture points, electrodes fixed in place but current switched off.	Chronic (>2 months) mechanical neck pain (n=135) Age 18-80 years Duration of pain (years): acupuncture 4.81 (7.03); placebo 7.71 (11.39)	At 8 weeks and 12 months (follow-up, including 4 week intervention): • Pain • Physical function • Health related quality of life • Discontinuation	

Study	Intervention and comparison	Population	Outcomes	Comments
	Patients in both groups were instructed to use acetaminophen alone for pain relief and were not given or permitted any other form of treatment, including exercises or stretches, during the study and for 2 months after treatment ended.			
Witt 2006 [220]	**Intervention (n=1880): Acupuncture (non-traditional, individualised)** Up to 15 sessions in 3 months, session duration not specified **Comparison (n=1886): usual care (no acupuncture)** All patients were allowed to use any additional conventional treatments as needed	Chronic neck pain for >6 months (n=3766) Age ≥18 years Mean duration of pain 6 years	At 3 months (post-intervention): • Health related quality of life • Pain • Discontinuation	
Zhang, 2013 [232]	**Intervention (n=103): Acupuncture (electro-acupuncture, traditional).** Three times a week for 3 weeks, session duration 45 minutes **Comparison (n=103): Sham (sham laser acupuncture).** Mock laser light that wasn't active. Each point treated for 2 minutes at a distance of 0.5-1cm from skin. Duration 3 weeks (number of sessions not stated).	Chronic mechanical neck pain (≥3 months) (n=206) Mean age 45.8 years Mean duration of pain 75.4 months	At 3 months post-intervention and 12 months (follow-up, including 3 week intervention): • Pain • Health related quality of life • Discontinuation	

See appendix D for full evidence tables.

1.4.4 Quality assessment of clinical studies included in the evidence review

Table 3: Acupuncture compared to sham acupuncture

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Sham acupuncture	Risk difference with Acupuncture (95% CI)
Pain (VAS/NRS; 0-10; final and change scores; high is poor outcome) at ≤3 months	1230 (13 studies) 3-12 weeks	⊕⊖⊖⊖ VERY LOW1,2,3 due to risk of bias, inconsistency, imprecision		-	The mean pain in the intervention groups was 1.41 lower (2.11 to 0.72 lower)
Pain (NIH-CPSI; 0-21, high is poor outcome, final values) at ≤3 months	159 (2 studies) 8 weeks	⊕⊕⊖⊖ LOW1,3 due to risk of bias, imprecision		The mean pain in the control groups was 8.6	The mean pain in the intervention groups was 2.04 lower (2.83 to 1.26 lower)
Pain (VAS; 0-10; final values and change scores; high is poor outcome) at >3 months	376 (4 studies) 15-52 weeks	⊕⊕⊖⊖ LOW1,3 due to risk of bias, imprecision		-	The mean pain in the intervention groups was 0.81 lower (1.33 to 0.3 lower)
Pain (NIH-CPSI; 0-21; high is poor outcome, final values) at >3 months	159 (2 studies) 24-40 weeks	⊕⊕⊕⊖ MODERATE1 due to risk of bias		The mean pain in the control groups was 9.85	The mean pain in the intervention groups was 2.88 lower (3.74 to 2.03 lower)
Pain (least square mean difference; VAS; 0-10, final values, high is poor outcome) at >3 months	96 (1 study) 6 months	⊕⊕⊖⊖ LOW1,3 due to risk of bias, imprecision		-	The mean pain in the intervention groups was 0.5 higher (0.3 lower to 1.3 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Sham acupuncture	Risk difference with Acupuncture (95% CI)
Health related quality of life (SF12 physical composite; 0-100, final values; high is good outcome) at ≤3 months	210 (2 studies) 4-10 weeks	⊕⊕⊕⊖ MODERATE1 due to risk of bias		The mean health related quality of life in the control groups was 31.5	The mean health related quality of life in the intervention groups was 11.76 higher (6.49 to 17.02 higher)
Health related quality of life (SF12 mental composite; 0-100, final values; high is good outcome) - Fibromyalgia at ≤3 months	158 (1 study) 10 weeks	⊕⊕⊖⊖ LOW1,3 due to risk of bias, imprecision		The mean health related quality of life in the control groups was 29.4	The mean health related quality of life in the intervention groups was 16.1 higher (0.54 lower to 32.74 higher)
Health related quality of life (SF12 mental composite; 0-100, final values; high is good outcome) - Myofascial pain syndrome at ≤3 months	52 (1 study) 4 weeks	⊕⊕⊕⊖ MODERATE1 due to risk of bias		The mean health related quality of life in the control groups was 65.96	The mean health related quality of life in the intervention groups was 15.17 lower (21.45 to 8.89 lower)
Health related quality of life (SF36 physical component summary; 0-100, high is good outcome, final values) at ≤3 months	244 (3 studies) 3-8 weeks	⊕⊖⊖⊖ VERY LOW1,2,3 due to risk of bias, inconsistency, imprecision		The mean health related quality of in the control groups was 40.2	The mean health related quality of life in the intervention groups was 0.27 lower (4.59 lower to 4.05 higher)
Health related quality of life (SF36 mental component summary; 0-100, high is good outcome, final values) at ≤3 months	168 (2 studies) 3-9 weeks	⊕⊖⊖⊖ VERY LOW1,2,3 due to risk of bias, inconsistency, imprecision		The mean health related quality of life in the control groups was 46.2	The mean health related quality of life in the intervention groups was 4.76 higher (0.54 lower to 10.06 higher)
Health related quality of life (SF36 physical functioning subscale; final values, 0-100, high is good	178 (1 study) 12 weeks	⊕⊕⊕⊖ MODERATE1		The mean health related quality of life in the	The mean health related quality of life in the intervention groups was

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Sham acupuncture	Risk difference with Acupuncture (95% CI)
outcome, final values) at ≤3 months		due to risk of bias		control groups was 85.88	1.62 lower (5.92 lower to 2.68 higher)
Health related quality of life (SF36 physical role subscale, final values and change scores; 0-100, high is good outcome, final values) at ≤3 months	178 (1 study) 12 weeks	⨁⨁⨀⨀ LOW1,3 due to risk of bias, imprecision		The mean health related quality of life in the control groups was 82.22	The mean health related quality of life in the intervention groups was 6.09 lower (15.13 lower to 2.95 higher)
Health related quality of life (SF36 bodily pain subscale, final values; 0-100, high is good outcome, final values) at ≤3 months	178 (1 study) 12 weeks	⨁⨁⨀⨀ LOW1,3 due to risk of bias, imprecision		The mean health related quality of life in the control groups was 66.93	The mean health related quality of life in the intervention groups was 3.16 higher (0.81 lower to 7.13 higher)
Health related quality of life (SF36 general health subscale, final values; 0-100, high is good outcome, final values) at ≤3 months	178 (1 study) 12 weeks	⨁⨁⨀⨀ LOW1,3 due to risk of bias, imprecision		The mean health related quality of life in the control groups was 59.9	The mean health related quality of life in the intervention groups was 0.86 higher (4.12 lower to 5.84 higher)
Health related quality of life (SF36 emotional role subscale, final values; 0-100, high is good outcome, final values) at ≤3 months	178 (1 study) 12 weeks	⨁⨁⨀⨀ LOW1,3 due to risk of bias, imprecision		The mean health related quality of life in the control groups was 71.11	The mean health related quality of life in the intervention groups was 2.37 higher (7.49 lower to 12.23 higher)
Health related quality of life (SF36 vitality subscale, final values; 0-100, high is good outcome, final values) at ≤3 months	178 (1 study) 12 weeks	⨁⨁⨀⨀ LOW1,3 due to risk of bias, imprecision		The mean health related quality of life in the control groups was 60.33	The mean health related quality of life in the intervention groups was 3.93 higher (0.64 to 7.22 higher)
Health related quality of life (SF36 social functioning subscale, final values; 0-100, high is good	178 (1 study) 12 weeks	⨁⨁⨀⨀ LOW1,3 due to risk of		The mean health related quality of life in the control groups was 80.13	The mean health related quality of life in the intervention groups was 3.25 higher (0.61 lower to 7.11 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Sham acupuncture	Risk difference with Acupuncture (95% CI)
outcome, final values) at ≤3 months		bias, imprecision			
Health related quality of life (SF36 mental health subscale, final values; 0-100, high is good outcome, final values) at ≤3 months	178 (1 study) 12 weeks	⊕⊕⊖⊖ LOW1,3 due to risk of bias, imprecision		The mean health related quality of life in the control groups was 61.64	The mean health related quality of life in the intervention groups was 5.49 higher (2.44 to 8.54 higher)
Health related quality of life (NIH-CPSI; 0-12; high is poor outcome, final values) at ≤3 months	159 (2 studies) 8-12 weeks	⊕⊕⊕⊖ MODERATE1 due to risk of bias		The mean health related quality of life in the control groups was 6.2	The mean health related quality of life in the intervention groups was 1.59 lower (2.11 to 1.06 lower)
Health related quality of life (FIQ; 0-100; high is poor outcome final values) at ≤3 months	72 (1 study) 4-12 weeks	⊕⊕⊖⊖ LOW1,3 due to risk of bias, imprecision		The mean health related quality of life in the control groups was 57.05	The mean health related quality of life in the intervention groups was 13.41 lower (22.88 to 3.98 lower)
Health related quality of life (SF36 physical component summary; 0-100, high is good outcome, final values) at >3 months	76 (1 study) 15 weeks	⊕⊖⊖⊖ VERY LOW1,3 due to risk of bias, imprecision		The mean health related quality of life in the control groups was 39.79	The mean health related quality of life in the intervention groups was 5.06 lower (9.55 to 0.57 lower)
Health related quality of life (SF36 physical component summary; change scores; 0-100, high is good outcome) at >3 months	96 (1 study) 6 months	⊕⊕⊖⊖ LOW1,3 due to risk of bias, imprecision		Not reported	The mean health related quality of life in the intervention groups was 0.4 lower (2.3 lower to 1.5 higher)
Health related quality of life (SF36 mental component summary; change scores; 0-100, high is good outcome) at >3 months	96 (1 study) 6 months	⊕⊕⊖⊖ LOW1,3 due to risk of bias, imprecision		Not reported	The mean health related quality of life in the intervention groups was 1.5 lower (4 lower to 1 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Sham acupuncture	Risk difference with Acupuncture (95% CI)
Health related quality of life (SF12 physical component summary; change scores; 0-100, high is good outcome) at >3 months	153 (1 study) 12 months	⊕⊕⊖⊖ LOW1,3 due to risk of bias, imprecision		The mean health related quality of life in the control groups was 11.4	The mean health related quality of life in the intervention groups was 25.8 higher (12.46 to 39.14 higher)
Health related quality of life (SF12 mental component summary; change scores; 0-100, high is good outcome) at >3 months	153 (1 study) 12 months	⊕⊕⊖⊖ LOW1,3 due to risk of bias, imprecision		The mean health related quality of life in the control groups was 9.3	The mean health related quality of life in the intervention groups was 13.6 higher (1.26 to 25.94 higher)
Health related quality of life (NIH-CPSI; 0-12; final values, high is poor outcome) at >3 months	159 (2 studies) 24-40 weeks	⊕⊕⊕⊖ MODERATE1 due to risk of bias		The mean health related quality of life in the control groups was 7.27	The mean health related quality of life in the intervention groups was 2.22 lower (2.84 to 1.61 lower)
Physical function (Neck Pain Questionnaire/Neck Disability Index; 0-100; high is poor outcome, final values) at ≤3 months	118 (1 study) 8 weeks	⊕⊖⊖⊖ VERY LOW1,3 due to risk of bias, imprecision		The mean physical function in the control groups was 12.68	The mean physical function in the intervention groups was 1.7 lower (4.25 lower to 0.85 higher)
Physical function (Neck Disability Index; 0-100;high is poor outcome, final values) at >3 months	106 (1 study) 12 months	⊕⊖⊖⊖ VERY LOW1,3 due to risk of bias, imprecision		The mean physical in the control groups was 10.72	The mean physical function in the intervention groups was 1.83 lower (4.85 lower to 1.19 higher)
Psychological distress (BDI; 0-63; high is poor outcome final values) at ≤3 months	50 (1 study) 8 weeks	⊕⊕⊕⊖ MODERATE1 due to risk of bias		The mean psychological distress in the control groups was 18.76	The mean psychological distress in the intervention groups was 9.28 lower (13.72 to 4.84 lower)
Psychological distress (HDRS; 0-52; high is poor outcome; change	206 (2 studies) 10-12 weeks	⊕⊕⊖⊖ LOW1,3 due to risk of		-	The mean psychological distress in the intervention groups was

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Sham acupuncture	Risk difference with Acupuncture (95% CI)
scores and final values) at ≤3 months		bias, imprecision			20.17 lower (27.1 to 13.24 lower)
Psychological distress (HDRS; change score; 0-52; high is poor outcome) at >3 months	155 (1 study) 12 months	⊕⊕⊖⊖ LOW1,3 due to risk of bias, imprecision		The mean psychological distress change score in the control groups was -5.6	The mean psychological distress in the intervention groups was 15 lower (34.13 lower to 4.13 higher)
Sleep (Visual analogue sleep quality scale; 0-10, final values, high is good outcome) at ≤3 months	52 (1 study) 4 weeks	⊕⊕⊖⊖ LOW1,3 due to risk of bias, imprecision		The men sleep in the control groups was 4.79	The mean sleep in the intervention groups was 1.48 higher (0.78 to 2.18 higher)
Sleep (Nottingham Health Profile sleep subscale; 0-100; final values, high is poor outcome) at ≤3 months	72 (1 study) 12 weeks	⊕⊕⊕⊖ MODERATE1 due to risk of bias		The mean sleep in the control groups was 55.29	The mean sleep in the intervention groups was 45.59 lower (59.25 to 31.93 lower)
Sleep (VAS sleep; 0-10, change scores, high is poor outcome) at >3 months	96 (1 study) 6 months	⊕⊕⊕⊖ MODERATE1 due to risk of bias		-	The mean sleep in the intervention groups was 0.5 lower (1.2 lower to 0.2 higher)
Discontinuation at ≤3 months	1477 (17 studies) 3-12 weeks	⊕⊖⊖⊖ VERY LOW1,2,3 due to risk of bias, inconsistency, imprecision	RD -0.03 (-0.08 to 0.03)	175 per 1000	30 fewer per 1000 (from 80 fewer to 30 more)
Discontinuation at >3 months	360 (3 studies) 6-12 months	⊕⊖⊖⊖ VERY LOW1,3 due to risk of	RR 1.67 (0.78 to 3.56)	80 per 1000	54 more per 1000 (from 18 fewer to 205 more)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Sham acupuncture	Risk difference with Acupuncture (95% CI)
		bias, imprecision			

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
2 Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis
3 Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs

Table 4: Acupuncture compared to usual care

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with	Risk difference with Acupuncture versus usual care (95% CI)
Pain (VAS; 0-10; final values and change scores; high is poor outcome) at ≤3 months	234 (5 studies) 5-12 weeks	⊕⊕⊖⊖ LOW1,2 due to risk of bias, imprecision		The mean pain in the control groups was 5.68	The mean pain in the intervention groups was 1.46 lower (1.98 to 0.94 lower)
Pain (SF McGill Pain Questionnaire and Northwick pain questionnaire; final values, high is poor outcome) at ≤3 months	384 (2 studies) 6-12 weeks	⊕⊕⊖⊖ LOW1,2 due to risk of bias, imprecision		-	The mean pain in the intervention groups was 0.16 standard deviations lower (0.37 lower to 0.04 higher)
Pain (Neck pain and disability scale; 0-100; change scores, high is poor outcome) at ≤3 months	3162 (1 study) 12 weeks	⊕⊕⊕⊖ MODERATE1 due to risk of bias		The mean in the control groups was 3.9	The mean pain in the intervention groups was 12.3 lower (13.41 to 11.19 lower)
Pain (Northwick park questionnaire; 0-100, final values, high is poor outcome) at >3 months	344 (1 study) 12 months	⊕⊕⊕⊖ MODERATE1 due to risk of bias		The mean pain in the control groups was 40.99	The mean pain) in the intervention groups was 3.92 lower (14.28 lower to 6.44 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with	Risk difference with Acupuncture versus usual care (95% CI)
Quality of life (SF36 physical component; 0-100; change scores; high is good outcome) at ≤3 months	3213 (1 study) 12 weeks	⨁⨁⨁⨀ MODERATE1 due to risk of bias		The mean quality of life in the control groups was 1.2	The mean quality of life in the intervention groups was 4.6 higher (4.1 to 5.1 higher)
Quality of life (SF36 mental component; 0-100; change scores; high is good outcome) at ≤3 months	3213 (1 study) 12 weeks	⨁⨁⨁⨀ MODERATE1 due to risk of bias		The mean quality of in the control groups was 1	The mean quality of life in the intervention groups was 3.2 higher (2.49 to 3.91 higher)
Quality of life (SF36 physical functioning subscale; 0-100; change scores; high is good outcome) at ≤3 months	100 (1 study) 12 weeks	⨁⨀⨀⨀ VERY LOW1,2 due to risk of bias, imprecision		The mean quality of life in the control groups was 28.6	The mean quality of life in the intervention groups was 2.5 higher (4.58 lower to 9.58 higher)
Quality of life (SF36 role limitation subscale; 0-100; change scores; high is good outcome) at ≤3 months	100 (1 study) 6 weeks	⨁⨀⨀⨀ VERY LOW1,2 due to risk of bias, imprecision		The mean quality of life in the control groups was 4.8	The mean quality of life in the intervention groups was 13.8 higher (2.68 to 24.92 higher)
Quality of life (SF36 bodily pain subscale; 0-100; change scores; high is good outcome) at ≤3 months	100 (1 study) 6 weeks	⨁⨁⨀⨀ LOW1 due to risk of bias		The mean quality of life in the control groups was 16	The mean quality of life in the intervention groups was 12 higher (4.44 to 19.56 higher)
Quality of life (SF36 general health subscale; 0-100; change scores; high is good outcome) at ≤3 months	100 (1 study) 6 weeks	⨁⨀⨀⨀ VERY LOW1,2 due to risk of bias, imprecision		The mean quality of life in the control groups was 20.7	The mean quality of life in the intervention groups was 2.9 higher (2.82 lower to 8.62 higher)
Quality of life (SF36 vitality subscale; 0-100; change scores; high is good outcome) at ≤3 months	100 (1 study) 6 weeks	⨁⨀⨀⨀ VERY LOW1,2 due to risk of		The mean quality of life in the control groups was 13.7	The mean quality of life in the intervention groups was 7.4 higher (1.49 to 13.31 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with	Risk difference with Acupuncture versus usual care (95% CI)
		bias, imprecision			
Quality of life (SF36 social functioning subscale; 0-100; change scores; high is good outcome) at ≤3 months	100 (1 study) 6 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean quality of life in the control groups was 34.7	The mean quality of life in the intervention groups was 10.7 higher (0.18 to 21.22 higher)
Quality of life (SF36 role limitation subscale; 0-100; change scores; high is good outcome) at ≤3 months	100 (1 study) 6 weeks	⨁⨁⊖⊖ LOW1 due to risk of bias		The mean quality of life in the control groups was 17.2	The mean quality of life in the intervention groups was 20.9 higher (4.82 to 36.98 higher)
Quality of life (SF36 mental health subscale; 0-100; change scores; high is good outcome) at ≤3 months	100 (1 study) 6 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean quality of life in the control groups was 36.3	The mean quality of life in the intervention groups was 4.7 higher (3.69 lower to 13.09 higher)
Health related quality of life (EQ-5D, -0.594-1, final values, high is good outcome) at >3 months	204 (1 study) 12 months	⨁⨁⊖⊖ LOW1,3 due to risk of bias, imprecision		The mean health related quality of life in the control group was 0.727	The mean health related quality of life in the intervention groups was 0.04 higher (0.01 lower to 0.09 higher)
Physical function (Neck Disability Index; 0-100; final values; high is poor outcome) at ≤3 months	45 (1 study) 7 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean physical function in the control groups was 17.3	The mean physical function in the intervention groups was 0.3 higher (3.12 lower to 3.72 higher)
Physical function (6 minute walk test; metres, change scores) at ≤3 months	100 (1 study) 6 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean physical function in the control groups was 67 metres	The mean physical function in the intervention groups was 39.7 higher (7.29 to 72.11 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with	Risk difference with Acupuncture versus usual care (95% CI)
Psychological distress (BDI depression subscale; 0-62, high is poor outcome, final values) at ≤3 months	145 (2 studies) 6-7 weeks	⨁⨁⨀⨀ LOW1,2 due to risk of bias, imprecision		The mean psychological distress in the control groups was 27.7	The mean psychological distress in the intervention groups was 2.86 lower (5.85 lower to 0.13 higher)
Psychological distress (BDI anxiety subscale; 0-62, high is poor outcome, final values) at ≤3 months	100 (1 study) 6 weeks	⨁⨀⨀⨀ VERY LOW1,2 due to risk of bias, imprecision		The mean psychological distress in the control groups was 35.3	The mean psychological distress in the intervention groups was 5.3 lower (10.5 to 0.1 lower)
Pain self-efficacy (Chronic pain self-efficacy scale, 0-8, high is good outcome) at >3 months	294 (1 study) 12 months	⨁⨁⨁⨀ MODERATE1 due to risk of bias		-	The mean pain self-efficacy in the intervention groups was 2.28 standard deviations higher (0.72 higher to 5.28 higher)
Pain interference (BPI pain interference subscale; 0-10; final and change scores; high is poor outcome) at ≤3 months	100 (1 study) 6 weeks	⨁⨀⨀⨀ VERY LOW1,2 due to risk of bias, imprecision		The mean pain interference in the control groups was 7.8	The mean pain interference in the intervention groups was 1.2 lower (1.91 to 0.49 lower)
Sleep (Pittsbugh Sleep Quality Index; 0-21; final values, high is poor outcome) at ≤3 months	100 (1 study) 6 weeks	⨁⨀⨀⨀ VERY LOW1,2 due to risk of bias, imprecision		The mean sleep in the control groups was 14.25	The mean sleep in the intervention groups was 1.93 lower (3.53 to 0.33 lower)
Discontinuation at ≤3 months	4412 (8 studies) 3-12 weeks	⨁⨁⨀⨀ LOW1,2 due to risk of bias, imprecision	RD --0.01 (-0.02 to 0.01)	102 per 1000	10 fewer per 1000 (from 20 fewer to 10 more)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with	Risk difference with Acupuncture versus usual care (95% CI)
1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias 2 Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs					

Table 5: Electro-acupuncture compared to sham electro-acupuncture

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Sham	Risk difference with Electro-acupuncture (95% CI)
Pain (VAS, MPI; 0-10; high is poor outcome; final values) at ≤3 months	320 (5 studies) 4-12 weeks	⨁⊖⊖⊖ VERY LOW1,2,3 due to risk of bias, inconsistency, imprecision		The mean pain in the control groups was 4.88	The mean pain in the intervention groups was 0.83 lower (1.84 lower to 0.17 higher)
Pain (VAS, MPI; 0-10; high is poor outcome; final values) at >3 months	233 (3 studies) 6-36 months	⨁⊖⊖⊖ VERY LOW1,2,3 due to risk of bias, inconsistency, imprecision		The mean pain in the control groups was 4.32	The mean pain in the intervention groups was 0.85 lower (2.41 lower to 0.7 higher)
Quality of Life (SF36 physical component; 0-100; high is poor outcome; final values) at ≤3 months	163 (1 study) 12 weeks	⨁⨁⨁⊖ MODERATE1 due to risk of bias		The mean quality of life in the control groups was 53.3	The mean quality of life in the intervention groups was 0.5 lower (1.75 lower to 0.75 higher)
Quality of Life (SF36 mental component; 0-100; high is good	163 (1 study) 12 weeks	⨁⨁⨁⊖ MODERATE1		The mean quality of life in the control	The mean quality of life in the intervention groups was

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Sham	Risk difference with Electro-acupuncture (95% CI)
outcome; final values) at ≤3 months		due to risk of bias		groups was 45.3	0.6 higher (0.8 lower to 2 higher)
Health related quality of life (FIQ; 0-100; high is poor outcome, final values) at ≤3 months	49 (1 study) 3 weeks	⨁⨁⨀⨀ LOW1,3 due to risk of bias, imprecision		The mean health related quality of life in the control groups was 42.2	The mean health related quality of life in the intervention groups was 7.4 lower (13.66 lower to 1.14 higher)
Quality of Life (SF36 physical component; 0-100; high is good outcome; final values) at >3 months	160 (1 study) 6 months	⨁⨁⨁⨀ MODERATE1 due to risk of bias		The mean quality of life in the control groups was 53.2	The mean quality of life in the intervention groups was 0.2 lower (1.52 lower to 1.12 higher)
Quality of Life (SF36 mental component; 0-100; high is good outcome; final values) at >3 months	160 (1 study) 6 months	⨁⨁⨀⨀ LOW1,3 due to risk of bias, imprecision		The mean quality of life in the control groups was 44.4	The mean quality of life in the intervention groups was 1 higher (0.32 lower to 2.32 higher)
Health related quality of life (FIQ; 0-100; high is poor outcome, final values) at >3 months	49 (1 study) 7 months	⨁⨁⨀⨀ LOW1,3 due to risk of bias, imprecision		The mean health related quality of life in the control groups was 42.7	The mean health related quality of life in the intervention groups was 4.6 lower (10.7 lower to 1.5 higher)
Pain interference (MPI; pain interference; 0-100, high is poor outcome, final values) at ≤3 months	49 (1 study) 4 weeks	⨁⨁⨀⨀ LOW1,3 due to risk of bias, imprecision		The mean pain interference in the control groups was 41.6	The mean pain interference in the intervention groups was 7.4 lower (13.16 to 1.64 lower)
Pain interference (MPI; pain interference; 0-100, high is poor outcome, final values) at >3 months	49 (1 study) 7 months	⨁⨁⨀⨀ LOW1,3 due to risk of bias, imprecision		The mean pain interference in the control groups was 35.5	The mean pain interference in the intervention groups was 2.2 higher (3.94 lower to 8.34 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Sham	Risk difference with Electro-acupuncture (95% CI)
Sleep (VAS sleep quality scale; 0-10, final values, high is good outcome) at ≤3 months	55 (1 study) 3 weeks	⨁⊖⊖⊖ VERY LOW1,3 due to risk of bias, imprecision		The mean sleep score in the control groups was 4.85	The mean sleep score in the intervention groups was 1.11 higher (0.14 lower to 2.36 higher)
Discontinuation at ≤3 months	444 (6 studies) 3-12 weeks	⨁⨁⊖⊖ LOW1,3 due to risk of bias, imprecision	OR 0.62 (0.38 to 1.02)	181 per 1000	65 fewer per 1000 (from 105 fewer to 0 more)

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
2 Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis
3 Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs

See appendix F for full GRADE tables.

1.5 Economic evidence

1.5.1 Included studies

Two health economic studies were identified with the relevant comparison and have been included in this review.[218] These are summarised in the health economic evidence profiles below (**Table 6** and **Table 7**) and the health economic evidence table in appendix H.

1.5.2 Excluded studies

No health economic studies that were relevant to this question were excluded due to assessment of limited applicability or methodological limitations.

See also the health economic study selection flow chart in appendix G.

1.5.3 Summary of studies included in the economic evidence review

Table 6: Health economic evidence profile: Acupuncture in addition to usual care vs. waiting list control

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental QALYs	Cost effectiveness	Uncertainty
Willich et al, 2006[218] [Germany]	Partially applicable[(a)]	Potentially serious limitations[(b)]	• Within-trial analysis based on Witt 2006. [220] • Cost-utility analysis (QALYs) • Population: people aged 18 years and over with a clinical diagnosis of chronic neck pain of at least 6 months duration. • Follow-up: 3 months (post treatment) Comparators: 1. Acupuncture group that received immediate treatment, consisting of 10-15 sessions. 2. Waiting list control, received acupuncture treatment after 3 months.	£274	0.024	£11,430 per QALY gained	Sensitivity analysis was conducted using the societal perspective. • Increasing treatment effects (to 4 years) and lowering acupuncture session payments (£11) increased the probability of acupuncture being cost effective. • Decreasing treatment duration (6 months) and increasing session payments (£41) decreased probability of acupuncture being cost effective.

Abbreviations: ICER: incremental cost-effectiveness ratio; QALY: quality-adjusted life years; RCT: randomised controlled trial

(a) Non-UK paper. Uses SF-6D not EQ-5D for utilities.

(b) German resource use data (2006) and unit costs may not reflect current NHS context. Acupuncture costs arbitrarily derived. Within-trial analysis may not reflect full body of evidence. Discounting for outcomes at 1.5% and costs at 3% rather than NICE reference case of 3.5% in sensitivity analyses. Short follow-up period may not reflect chronic nature of condition and may not be sufficient to capture all benefits and costs. Sensitivity analyses only present results using societal perspective. Unclear how costs related only to condition were separated out.

Table 7: Health economic evidence profile: Acupuncture in addition to usual care vs. usual care

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental QALYs	Cost effectiveness	Uncertainty
Essex et al 2017[60] [UK]	Directly applicable[(a)]	Potentially serious limitations[(b)]	• Within-trial analysis based on Macpherson 2015.[139] • Cost-utility analysis (QALYs) • Population: People with chronic, non-specific neck pain for 3 months or more • Follow-up: 1 year, but intervention was around 5 months long. Comparators: 1. Acupuncture, Up to 12 fifty-minute treatments delivered once per week and then once every 2 weeks usually over a 5 month period. 2. Usual care	Complete case data: £451 Missing data imputed: £690	Complete case data: 0.032 Missing data imputed: 0.019	Complete case data: £18,767 per QALY gained (95% CI: £,4,426 to £74,562) Missing data for the EQ-5D and costs were imputed: £43,838 per QALY gained (95% CI: –£216,427 to £395,047)	Probabilistic sensitivity analyses was conducted for complete case analysis. Probability of being cost effective at £20,000 = 71% Sensitivity analyses: • Healthcare resources not relating to neck pain were excluded (ICER of £15,364, 95% CI: £4,156 to £56,763)

Abbreviations: ICER: incremental cost-effectiveness ratio; QALY: quality-adjusted life years; RCT: randomised controlled trial

(a) UK paper. Uses EQ-5D for utilities.

(b) Within-trial analysis may not reflect full body of evidence. Costs of providing acupuncture would be higher based on current staff costs. Self-reported resource use, people may not be accurate or also be confused between reporting resource use for neck pain and overall resource use leading to large amount of missing data or double counting, so pre-specified assumptions were made such as if neck pain part was filled in then answers to overall resource use would be replaced with neck pain value. 40% had missing data in the acupuncture arm.

1.5.4 Health economic modelling

This area was prioritised for new economic modelling. The rationale, methods and results are summarised below. Full details are available in the 'Acupuncture modelling report'.

The clinical evidence showed a benefit of acupuncture compared to both sham acupuncture and usual care, in reducing pain and improving quality of life.

Two economic evaluations were identified for this review comparing acupuncture to treatment as usual. One UK-based within-trial economic analysis compared acupuncture in addition to usual care with usual care. This was in people with chronic neck pain, and had a 1 year follow up, although the intervention itself was around 5 months long. Resource use included all appointments and prescriptions. The study found that acupuncture was cost effective (using complete case analysis). The 95% confidence interval was very wide (95% CI: £,4,426 to £74,562). However, a sensitivity analysis where missing data was imputed (40% of data was missing in the acupuncture arm) showed an ICER of £43,838, again with a very large confidence interval (-£216,427 to £395,047). The committee opinion was that the confidence interval led to uncertainty around cost effectiveness, although this would be the more relevant study as it is from a UK perspective. The costs of providing acupuncture (£35 per session) are likely to be lower than current staff costs that might provide acupuncture in the NHS. This might be because of the date of the costs (2012/13) or also because the costs of the sessions were based on the level of practitioner delivering the intervention in the trial, which was unclear. The second study was a German within-trial analysis, comparing acupuncture to a waiting list control in people with chronic neck pain, with a three month follow-up. People in the acupuncture group received between 10 to 15 sessions of acupuncture over the three months. The study considered costs of acupuncture as well as physician visits, medication and hospital stays in both groups. This paper suggested that acupuncture is cost effective compared to waiting list control (ICER: £11,430 per QALY gained). Although acupuncture costs per session used in the analysis (€35/£28) seem lower than current UK costs. Both studies had limitations regarding intervention costs potentially being underestimated, and uncertainty remained around cost effectiveness.

Uncertainty remained about the cost effectiveness of acupuncture from the included studies. Also, acupuncture for chronic primary pain is not currently used in the NHS, therefore, a recommendation could have a resource impact to the NHS in England given the large size of the population living with chronic primary pain. For the above reasons, a probabilistic lifetime cost-utility analysis was undertaken, from the NHS perspective, that compared acupuncture with no acupuncture (both groups had usual care therefore this was not included in the model).

The analysis was based on studies from the clinical review that were compared to usual care (not sham), as the committee agreed usual care was the most appropriate comparator for the economic analysis as would give the full benefit likely to be achieved in a real world scenario and sham would not be used in the NHS except in research (for a more detailed rationale for this decision see the full technical report). Studies were included in the analysis if they reported utilities (EQ-5D), or measures that could be mapped to utilities like QoL measures (the SF-36), and pain scales (this was 7 out of 9 usual care comparison studies). All acupuncture types were pooled. For each study, the difference between EQ-5D outcomes (whether this was during treatment, at the end of treatment or later) and the baseline EQ-5D was taken for the intervention and usual care group, to take account of any baseline differences between the two groups. The difference in EQ-5D was then taken between the intervention and usual care group for each study. Therefore, the treatment benefit is the EQ-5D gain from acupuncture compared to usual care, taking into account baseline differences.

In the economic analysis, the EQ-5D data from different time points (meta-analysed if there was more than one study with a measurement at a particular time point) were used to

estimate QALY gain with acupuncture. Looking at the pattern of the QoL improvement from acupuncture over time plotted graphically showed that there was an increasing QoL trend up to 12 weeks in the data. It was also noted that in studies that measured QoL at the end of the intervention and then again at a later follow-up point, the QoL gain at the follow point was lower, but a difference remained. It was agreed that the analysis should be split into two parts for the economic analysis: the first analysing the data up to 12 weeks and a second looking at how treatment effect changed over time after the end of the intervention. A trend line was estimated using all observed data points up to and including 12 weeks. The linear trend line was generated using weighted least squares regression to apply a higher weight to the treatment effect from timepoints that had smaller variance. In addition, the average change per week was estimated after the end of the intervention using studies that reported at least 2 time points after the end of the intervention (for example one post intervention and a follow-up a number of weeks later). In the economic analysis QOL gain over time was initially modelled using the ≤12 weeks trend line. A linear increase in EQ-5D from zero difference at time zero to the point estimated by the trend line at the first trial observation was also assumed. After 12 weeks the change per week from the follow-up analysis was applied up to 18 weeks (6 weeks follow-up data from studies included) in the base case. Analyses were included with and without further extrapolation of treatment effect beyond this point. . Extrapolation assumptions were based on committee opinion, and different assumptions were needed for different scenarios that occurred in probabilistic analyses. Note the treatment effect was extrapolated only until there was no additional quality of life benefit from acupuncture. QALY gain with acupuncture was estimated by calculating the area under the curve.

The key difference in costs was agreed to be those related to delivering acupuncture. No other costs were incorporated in the analysis. The average resource use from the interventions in each study were identified and costed, and a weighted average cost calculated, weighting by the number of participants in the studies. The committee agreed that in the base case a band 6 staff member should be used for costing purposes. Use of other staff bands and other cost assumptions were tested in sensitivity analyses.

Results

The probabilistic and deterministic base case results can be seen in the table below. Results are presented for both base cases. Both analyses show the ICER is below the NICE threshold of £20,000, and therefore acupuncture would be considered cost effective. The probability of acupuncture being cost effective is also high.

Table 8: Base case results (discounted)

Base case	Analysis	Incremental cost	Incremental QALYs	Cost per QALY gained	Probability cost effective at £20k
Lifetime	Probabilistic	£350	0.058	£5,710	90%
	Deterministic	£350	0.038	£9,113	NA
No extrapolation beyond last trial observation (12 weeks + 6 weeks post-intervention)	Probabilistic	£350	0.024	£14,552	88%
	Deterministic	£350	0.024	£14,310	NA

Abbreviations: QALYs: quality adjusted life years, £20k: £20,000.

The deterministic results are somewhat different to the probabilistic in the lifetime analysis as there is a larger incremental QALY gain in the probabilistic analysis because the QALY gains

have a skewed distribution. This occurs because there are some simulations in the probabilistic model where the post intervention QOL is a shallow downward slope which leads to a large QALY gain in the lifetime analysis because the point at which there is no longer a difference in treatment effect from acupuncture are far into the future. This was visualised by reviewing the patterns of the regression lines graphically and summarising the distribution of QALY gains. In the first base case, where no extrapolation of the data is modelled, then the probabilistic and deterministic results are very close, proving that the extrapolation assumptions and the nature of the data in the probabilistic analysis created the discord between the probabilistic and deterministic models using a lifetime horizon. However, both models and both base cases are still well below the NICE cost effectiveness threshold.

Various sensitivity analyses were undertaken for both base cases. Alternative data about post-treatment effects was incorporated that was not included in the base cases. Sensitivity analysis also tested various resource use assumptions about bands of staff, treatment overlap (i.e. people being simultaneously treated), and resource use considered more typical in England. All sensitivity analyses did not change the conclusions.

Limitations of the analysis include that data was pooled across clinical studies that had different intensities (in terms of frequency of sessions and overall number of sessions) of acupuncture, differences in the type of acupuncture and differences in the number of acupuncture points. This is likely to affect costs and treatment effects. However, there is uncertainty around whether the pooled costs correspond with the pooled treatment effect. This is because it is unclear what it is about acupuncture that causes a benefit i.e. the frequency, or the number of sessions, type of acupuncture, number of acupuncture points or the training and experience of the individual and therefore the extent of the contextual effect. Another limitation of the model is that the linear trend lines representing treatment effect over time is a simplification of how people's quality of life would fluctuate in reality. The quality of life gain taken from the studies could also be an overestimate because it is likely that people who respond to follow up questionnaires or that have not dropped out of a trial are more engaged with the intervention. Additionally uncertainty not captured by the model included what outcomes and resource use occurred after the intervention or, for instance, whether some people received further courses of acupuncture. Some assumptions were made regarding patterns of extrapolation of the regression trend lines following discussion with the committee. No other costs have been accounted for in the analysis except for intervention costs.

Overall, this analysis has pooled data from the clinical review that reported utilities or measures that could be mapped to utilities, to estimate the potential cost effectiveness of acupuncture in general. The heterogeneity of the studies, and the number of studies used, should be taken into account when interpreting this analysis.

1.5.5 Unit costs

The unit cost of acupuncture is presented below for illustration. Acupuncture for pain management is most commonly performed as an outpatient procedure.

Table 9: Unit costs of acupuncture for pain management

Intervention	Cost (per hour)	Source
Acupuncture for pain management	£125	NHS reference costs 2017/18 AB23Z Acupuncture for Pain Management Outpatient schedule

Source: NHS Reference Costs 2017/18.[50]

Alternatively, acupuncture can be provided in a community setting. The unit cost for the bands of staff that might deliver acupuncture are provided below for consideration of cost effectiveness. The cost of acupuncture equipment has also been included for consideration.

Table 10: UK costs of healthcare professionals

Healthcare professional	Cost (per hour)
Community staff (band 5/6/7)	£51 / £64 / £78

Source: PSSRU 2018[43]

Note: These costs include the ratio of direct to indirect time with patients of 1.37 from the PSSRU. And qualification costs.

Table 11: UK costs of acupuncture equipment

Item	Description	Cost per needle
Acupuncture needles	Average of needle classic and needle with guide tube products on NHS supply chain	£0.06

Source: NHS Supply Chain catalogue (2019)[159]

1.5.6 Threshold calculations

As the economic evaluations that have been identified for inclusion in this review have limitations, such as the costs of delivering acupuncture appearing low compared to UK costs, some threshold calculations have been undertaken to crudely identify what level of acupuncture might be afforded based on UK staff costs, that would make acupuncture cost effective at the £20,000 per QALY gained threshold.

Note that for Essex 2017, this had two analyses that could be treated as base cases, and the QALYs from both have been reported here.

Table 12: Summary of QALYs from the included economic evaluations

Study	Population	Intervention length/follow up	Comparator	Incremental QALY
Willich 2006[218] (a)	Chronic neck pain	Acupuncture (12 weeks, 10-15 sessions. Follow-up at 3 months)	Wait list control	0.024
Essex 2017[60] (b)	Chronic neck pain	Acupuncture (up to 12 x 50 minute treatments once per week then once every 2 weeks) 5 month intervention, follow up at 1 year.	Usual care	0.032 (based on complete case analysis)
				0.019 (based on imputing missing data analysis)

*(a) Included economic evaluation. Used SF-6D utilities. See **Table 6**.*
*(b) Included economic evaluation. See **Table 7**.*

Assuming no difference in resource use other than acupuncture treatment between usual care and acupuncture groups, the table below illustrates some threshold calculations on the maximum cost of acupuncture that would make it cost effective, and what this cost could fund. The number of sessions afforded have been calculated based on a band 6 staff member (used as the base case cost in the original model on acupuncture undertaken for this guideline), and band 7. The threshold calculations have been undertaken for each QALY from Table 12 individually.

Table 13: Incremental cost needed to make acupuncture cost effective

Estimates of QALY gain	Maximum incremental cost	Resource use that could be funded (hours of band 6 community staff time)	Resource use that could be funded (hours of band 7 community staff time)
Willich 2006 QALY gain = 0.024	£20,000*0.024 = £480	7.5 hours	6.2 hours
Essex 2017 QALY gain (complete case analysis) = 0.032	£20,000*0.032 = £640	9.9 hours	8.3 hours
Essex 2017 QALY gain (imputed data analysis) = 0.019	£20,000*0.019 = £380	5.9 hours	4.9 hours

Note: The number of appointments or hours of physio time have been rounded down to the nearest whole number.

The results of the threshold calculations in Table 13 show the range of hours of staff time that could be afforded, depending on the magnitude of the QALY, and based on UK staff costs. The committee discussed that each session of acupuncture is not usually an hour. Sometimes it can be as little as 10 minutes, although if traditional Chinese medicine is undertaken this can take an hour. Typically, the committee opinion was that although there might be variation in how acupuncture is delivered, there was some agreement that around 6 sessions of about 30 minutes might be considered a typical course that would be offered to patients. Using the lowest QALY estimate from Table 13, shows that this could afford around 5 hours of staff time, which would mean roughly 10 sessions of 30 minutes. Therefore 6 sessions of 30 minutes could be cost effective based on the above calculations.

1.6 Evidence statements

1.6.1 Clinical evidence statements

1.6.1.1 Acupuncture versus sham acupuncture

Pain reduction

Very low quality evidence from 13 studies with 1230 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months. Low quality evidence from 2 studies with 159 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months.

Low quality evidence from 4 studies with 376 participants showed no clinically important difference between acupuncture and sham acupuncture at >3 months. Moderate quality evidence from 2 studies with 159 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at >3 months. Low quality evidence from 1 study with 61 participants showed no clinically important difference between acupuncture and sham acupuncture at >3 months

Quality of life

Low to moderate quality evidence from 2 studies with 210 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months. Moderate quality evidence from 1 study with 158 participants showed sham acupuncture to have a clinically important improvement compared to acupuncture at ≤3 months. Very low quality evidence from 3 studies with 244 participants showed no clinically important difference

between acupuncture and sham acupuncture at ≤3 months. Very low quality evidence from 2 studies with 168 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months. Very low to low quality evidence from 1 study with 178 participants showed a clinically important benefit, clinically important harm and no clinically important difference of acupuncture compared to sham acupuncture at ≤3 months (various quality of life subscales). Moderate quality evidence from 2 studies with 159 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months. Low quality evidence from 1 study with 72 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months.

Very low quality evidence from 1 study with 76 participants showed a clinically important benefit of sham acupuncture compared to verum acupuncture at >3 months. Low quality evidence from 1 study with 96 participants showed no clinically important difference between acupuncture and sham acupuncture at >3 months. Low quality evidence from 1 study with 153 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at >3 months. Moderate quality evidence from 1 study with 159 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at >3 months.

Physical function

Very low quality evidence from 1 study with 118 participants showed no clinically important difference between acupuncture and sham acupuncture at ≤3 months. Very low quality evidence from 1 study with 106 participants showed no clinically important difference between acupuncture and sham acupuncture at >3 months.

Psychological distress

Low quality evidence from 1 study with 50 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months. Low quality evidence from 2 studies with 206 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months. Low quality evidence from 1 study with 155 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at >3 months.

Pain interference

No evidence identified

Pain self-efficacy

No evidence identified

Sleep

Low quality evidence from 1 study with 52 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months. Moderate quality evidence from 1 study with 72 participants showed a clinically important benefit of acupuncture compared to sham acupuncture at ≤3 months. Moderate quality evidence from 1 study with 96 participants showed no clinically important difference between acupuncture and sham acupuncture at >3 months.

Discontinuation

Very low quality evidence from 17 studies with 1477 participants showed no clinically important difference between acupuncture and sham acupuncture at ≤3 months. Low quality evidence from 3 studies with 360 participants demonstrated that more people discontinued from acupuncture compared to sham acupuncture at >3 months.

1.6.1.2 Acupuncture versus usual care

Pain reduction

Low quality evidence from 5 studies with 234 participants showed a clinically important benefit of acupuncture compared to usual care at ≤3 months. Low quality evidence from 2 studies with 384 participants showed no clinically important difference between acupuncture and usual care at ≤3 months. Moderate quality evidence from 1 study with 3162 participants showed a clinically important benefit of acupuncture compared to usual care at ≤3 months.

Moderate quality evidence from 1 study with 344 participants showed no clinically important difference between acupuncture and usual care at >3 months.

Quality of life

Moderate quality evidence from 1 study with 3213 participants showed a clinically important benefit of acupuncture compared to usual care at ≤3 months. Very low quality evidence from 1 study with 100 participants showed both a clinically important benefit and no clinically important difference between acupuncture and usual care at ≤3 months (various quality of life subscales).

Low quality evidence from 1 study with 204 participants showed a clinically important benefit of acupuncture compared to usual care at >3 months.

Physical function

Very low quality evidence from 1 study with 45 participants showed no clinically important difference between acupuncture and usual care at ≤3 months. Very low quality evidence from 1 study with 100 participants showed a clinically important benefit of acupuncture compared to usual care at ≤3 months.

Psychological distress

Low quality evidence from 2 studies with 145 participants showed no clinically important difference between acupuncture and usual care at ≤3 months. Very low quality evidence from 1 study with 100 participants showed no clinically important difference between acupuncture and usual care at ≤3 months.

Pain self-efficacy

Very low quality evidence from 1 study with 294 participants showed a clinically important benefit of acupuncture compared to usual care at ≤3 months.

Pain interference

Very low quality evidence from 1 study with 100 participants showed a clinically important benefit of acupuncture compared to usual care at >3 months.

Sleep

Very low quality evidence from 1 study with 100 participants showed no clinically important difference between acupuncture and usual care at ≤3 months.

Discontinuation

Low quality evidence from 1 study with 66 participants showed no clinically important difference between acupuncture and usual care at ≤3 months.

1.6.1.3 Electro-acupuncture versus sham electro-acupuncture

1.6.1.4 Pain reduction

Very low quality evidence from 1 study with 61 participants showed no clinically important difference between electro-acupuncture and sham electro-acupuncture at ≤3 months. Very low quality evidence from 1 study with 61 participants showed no clinically important difference between electro-acupuncture and sham electro-acupuncture at >3 months.

Quality of life

Moderate quality evidence from 1 study with 163 participants showed no clinically important difference between electro-acupuncture and sham electro-acupuncture at ≤3 months. Low quality evidence from 1 study with 49 participants showed a clinically important benefit of electro-acupuncture compared to sham electro-acupuncture at ≤3 months. Moderate to low quality evidence from 1 study with 160 participants showed no clinically important difference between electro-acupuncture and sham electro-acupuncture at >3 months. Low quality evidence from 1 study with 49 participants showed no clinically important difference between electro-acupuncture and sham electro-acupuncture at >3 months.

Physical function

No evidence identified.

Psychological distress

No evidence identified.

Pain interference

Low quality evidence from 1 study with 49 participants showed a clinically important benefit of electro-acupuncture compared to sham electro-acupuncture at ≤3 months and >3 months.

Pain self-efficacy

No evidence identified.

Sleep

Very low quality evidence from 1 study with 55 participants showed no clinically important difference between electro-acupuncture and sham electro-acupuncture at ≤3 months.

Discontinuation

Low quality evidence from 6 studies with 444 participants showed a clinically important benefit of electro-acupuncture compared to sham electro-acupuncture at ≤3 months.

1.6.2 Health economic evidence statements

- One cost-utility analysis found that acupuncture is cost effective compared to waiting list control for the management of chronic neck pain (ICER: £11,430 per QALY gained). This analysis was assessed as partially applicable with potentially serious limitations.
- One cost-utility analysis found that acupuncture for the management of chronic neck pain:
  - is cost effective compared to usual care in the complete case analysis (ICER: £18,767 per QALY gained).
  - is not cost effective compared to usual care in the imputed data analysis (ICER: £43,838 per QALY gained).

  This analysis was assessed as directly applicable with potentially serious limitations.
- One original cost-utility analysis found that acupuncture was cost effective compared to no acupuncture for treating chronic primary pain (probabilistic ICERs: £5,710 per QALY gained (lifetime analysis), £14,552 per QALY gained (no extrapolation analysis), deterministic ICERS: £9,113 per QALY gained (lifetime analysis), £14,310 per QALY gained (no extrapolation analysis). This analysis was assessed as directly applicable with minor limitations.

1.7 The committee's discussion of the evidence

1.7.1 Interpreting the evidence

1.7.1.1 The outcomes that matter most

The committee considered pain reduction, health-related quality of life, physical function and psychological distress, pain interference and pain self-efficacy to be critical outcomes for decision-making. Use of healthcare services, sleep and discontinuation were also considered to be important outcomes. The critical and important outcomes agreed by the committee were adapted by consensus from relevant core outcome sets registered under the Core Outcome Measures in Effectiveness Trials (COMET) Initiative. This included the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations.

Evidence was identified for all critical and important outcomes.

1.7.1.2 The quality of the evidence

Evidence from 32 randomised controlled trials was identified for 3 different comparisons in this review. Comparisons with the most evidence were acupuncture versus sham acupuncture and acupuncture versus usual care, with a smaller amount of evidence available for electro-acupuncture versus sham electro-acupuncture. No evidence was identified comparing electro-acupuncture to usual care.

The majority of the evidence identified was of low to very low quality, with only a small amount of moderate quality evidence. The evidence was mainly downgraded due to risk of bias and imprecision. Risk of bias was often high due to attrition and selection bias. In the usual care comparisons there was a lack of blinding in the studies due to the nature of the intervention; this combined with the mostly subjective outcomes resulted in a high risk of performance bias. The committee took into account the low quality in their interpretation of the evidence, particularly when considering the small amount of evidence for comparisons of different types of acupuncture.

There was wide variation in the types of and intensity of interventions being applied within the evidence, which the committee noted to be a limitation of the evidence as a whole. There

were also limitations related to sham procedures within the review, due mainly to the difficulty of blinding participants to acupuncture or sham acupuncture due to the nature of the intervention. A large range of sham procedures were included within this review, which were pooled in the analysis. These included procedures such as not fully inserting needles, needles contacting the skin only or needles inserted in the wrong acupoints.

1.7.1.3 Benefits and harms

Acupuncture versus sham acupuncture

Evidence of acupuncture versus sham acupuncture was based on 19 studies and showed a benefit of treatment in terms of pain and quality of life. There was evidence for all critical and important outcomes other than pain interference and pain self-efficacy. At less than 3 months, evidence showed a benefit of acupuncture for pain, quality of life, psychological distress and sleep. Although the evidence was generally positive, the committee noted that evidence for quality of life was more uncertain, with some outcomes crossing the line of no effect or the MID threshold. The main outcome for pain showed a clinically important benefit of acupuncture, based on 13 studies and over 1000 participants. Some uncertainty again existed within this outcome, with confidence intervals crossing the MID. However, the committee agreed that this uncertainty was marginal (crossing the MID by a difference of 0.3), and agreed this outcome was therefore demonstrating a benefit of acupuncture. There was no benefit of treatment seen for physical function at less than 3 months, although this evidence was very low quality and based on one small study. The longer-term evidence (over 3 months) showed some benefit of acupuncture, although there was less evidence from which to draw a conclusion. Evidence showed a benefit for pain, quality of life and psychological distress. However, results were mixed with some evidence contrastingly showing no benefit for similar outcomes. The committee agreed that the short-term evidence for acupuncture showed a benefit for pain and was based on large sample sizes. They agreed that there was not enough evidence to determine the long-term benefits of acupuncture compared to sham acupuncture.

The committee noted that, in their experience, non-verbal communication and the belief system of the practitioner giving the acupuncture is an important aspect of the intervention, and therefore something that could have impacted the validity of the sham. The committee discussed the implications of poor blinding and noted that these could lead to overestimation of the treatment effect for acupuncture, because sham could be less effective if blinding is broken, due to loss of the placebo effect. Conversely, the committee agreed that some of the sham procedures could have a therapeutic effect, such as traditional acupuncture sham methods that involve inserting the needle a few centimetres away from the actual acupoint or meridian. In theory, these points could be deemed as an appropriate needle insertion under the definitions of western acupuncture or dry needling, and therefore underestimate the effect estimates for acupuncture treatment. Sham acupuncture could also be therapeutic by involving both validation of the person’s pain and by an empathic approach from the clinician. For these reasons, the committee agreed that the benefit of acupuncture compared to sham procedures was a promising finding.

Acupuncture versus usual care

Evidence of acupuncture versus usual care was based on 9 studies and showed a benefit of acupuncture (mainly for pain and quality of life), which was consistent to the sham comparison. There was evidence for all critical and important outcomes and the evidence quality was downgraded mainly due to risk of bias and imprecision, ranging from very low to moderate.

At less than 3 months, evidence showed a benefit of acupuncture for improving outcomes of pain with only a small amount of uncertainty around the effect size (with 95% CIs marginally crossing the MID threshold in one outcome). There was also evidence of benefit for quality of life, which was mainly based on one study with over 3000 participants. Evidence for the

physical component of the SF-36 scale had minimal uncertainty (confidence intervals did not cross the MID threshold). For the mental component of the SF-36, there was some uncertainty although the confidence intervals crossed the MID by only 0.5. Other quality of life outcomes were based on much smaller sample sizes and so the committee placed less weight on these in decision-making (with some outcomes showing a benefit for some quality of life, and others showing no difference). In addition, a small amount of evidence suggested a benefit of acupuncture for pain interference and pain self-efficacy. Evidence for physical function was mixed and based on small sample sizes, with some evidence indicating a benefit of acupuncture and other evidence indicating no benefit. There was no benefit of treatment seen for psychological distress or sleep, however this evidence was low to very low quality and based on smaller sample sizes. The evidence at over 3 months was limited, with a benefit of acupuncture for quality of life and pain self-efficacy but no difference seen for pain. The committee again agreed that the short-term evidence was promising, showing a benefit for quality of life and based on large sample sizes. They agreed that there was not enough evidence to determine the long-term benefits of acupuncture compared to sham acupuncture

Electro-acupuncture versus sham electro-acupuncture

There was less evidence for electro-acupuncture within the review. The evidence quality was downgraded mainly due to risk of bias and imprecision, and ranged from very low to low quality. For outcomes under 3 months, there was no clinically important difference seen for pain, quality of life and sleep. A clinically important benefit was seen for one quality of life outcome and discontinuation. At over 3 months follow up, there was no clinically important difference for pain or quality of life. No evidence was available for physical function, psychological distress, pain interference or pain self-efficacy.

Overall

The committee discussed the applicability of the evidence to clinical practice, and noted that there was variation among the interventions included within the review. They agreed that this was reflected in current practice, which showed a similarly wide variation in terms of type of acupuncture, length of sessions and duration of treatment programme. The committee noted that the evidence review did not demonstrate evidence of harm. They considered the potential harms related to the use of acupuncture. One of the most serious possible harms of acupuncture is organ puncture, although there were no reports of this within the evidence. The committee noted that guidance on acupuncture techniques should establish a depth of needle injection based on the target body area and other factors such as the physique or build of individuals with chronic pain. The committee also noted the importance of demonstrated competence of the person delivering acupuncture, and that single use sterile needles should be used to prevent infection.

The committee considered the overall benefit of acupuncture, particularly for reducing pain and improving quality of life, in combination with the lack of harm, other than discontinuation from the therapy. The committee agreed that although there was some uncertainty within some of the outcomes (with a small proportion of outcomes crossing the line of no effect), there was generally a benefit of acupuncture seen within the evidence when compared to both usual care and sham. The committee considered that the evidence base was large enough to justify a recommendation, and therefore agreed to recommend the use of acupuncture in clinical practice for people with chronic primary pain.

The committee noted that the majority of evidence was based on women with chronic neck pain or fibromyalgia, but that studies were also included in people with myofascial pain, vulvodynia, chronic pelvic pain and shoulder pain. The populations were pooled in the clinical review. Where there was heterogeneity in the pooled analysis, subgroup analysis was undertaken by type of chronic primary pain, but this did not explain the heterogeneity. The committee therefore agreed that there wasn’t evidence that effect differed according to type of chronic primary pain and there was no reason recommendations made based on this

evidence should not apply for all types of chronic primary pain. They also noted that the specific type of acupuncture may differ according to type of pain, which would be informed by expertise of the practitioner delivering acupuncture.

The evidence review did not compare the effectiveness of different types of acupuncture and included a wide range of acupuncture methods. There was no heterogeneity seen in the evidence that could be explained by the different types of acupuncture, and this was considered when wording the recommendation.

1.7.2 Cost effectiveness and resource use

The economic evidence review identified two relevant published economic evaluations. Original economic modelling was also undertaken.

One study was a UK-based within-trial analysis, comparing acupuncture in addition to usual care with usual care. This was in people with chronic neck pain, and had a 1 year follow up, although the intervention itself was around 5 months long (up to 12 x 50-minute treatments delivered once per week and then once every 2 weeks). Resource use included all appointments and prescriptions. Quality of life was measured using the EQ-5D. The study found that acupuncture had an ICER of £18,767 per QALY gained, suggesting acupuncture is cost effective. The 95% confidence interval was very wide (95% CI: £4,426 to £74,562). However a sensitivity analysis where missing data was imputed (and 40% of data was missing in the acupuncture arm) showed an ICER of £43,838, again with a very large confidence interval (-£216,427 to £395,047). The committee opinion was that the confidence interval led to uncertainty around cost effectiveness, although this would be the more relevant study as it is from a UK perspective. The study was directly applicable because it is a UK study and uses the EQ-5D measure of quality of life, but had potentially serious limitations because of a large amount of missing data (although it is not clear what was missing), and resource use was self-reported. Furthermore, people were asked to report resource use for both neck pain and overall resource use, and people may have been confused between the two. This could have increased the missing data or led to double counting, so pre-specified assumptions were made by the authors depending on what patients filled in. The costs of providing acupuncture (£35 per session) are likely to be lower than current staff costs that might provide acupuncture in the NHS. This might be because of the date of the costs (2012/13) or also because the costs of the sessions were based on the level of practitioner delivering the intervention in the trial, which was unclear. The study is a within trial analysis of a single study rather than incorporating clinical studies from a wider evidence-base, which may limit the generalisability of the conclusions.

The second study was a within-trial analysis conducted in Germany, comparing acupuncture to a waiting list control in people with chronic neck pain, with a three month follow-up. People in the acupuncture group received between 10 to 15 sessions of acupuncture over the three months. The study considered costs of acupuncture as well as physician visits, medication and hospital stays in both groups. This paper suggests that acupuncture is cost effective compared to waiting list control (ICER: £11,430 per QALY gained). This was assessed as partially applicable with potentially serious limitations. Limitations include: non-UK study and therefore not UK NHS setting, it used the SF-6D (mapped from the SF-36) to derive utilities as opposed to the EQ-5D, acupuncture costs were arbitrarily derived because acupuncture was not reimbursed by health insurance companies in Germany at the time and so there was no national tariff cost. Costs were also thought to be low in this study (€32/£28 per session) compared to current UK costs. The analysis was also a within-trial analysis of a single study with a short follow-up period. Sensitivity analysis conducted in this study found that results were highly sensitive to the cost of the acupuncture sessions, and hence this may be an important factor in determining whether the intervention is cost effective in the current UK NHS setting.

Overall, although both studies had outcomes favouring acupuncture, the committee noted that there still remained uncertainties about the cost effectiveness of acupuncture, as it is a limited evidence base and there are uncertainties around the cost of the intervention.

To address the uncertainty in the costs of the interventions, threshold analyses were undertaken whereby the QALYs from the published economic evaluations were used to calculate the cost of acupuncture and amount of staff time that could be afforded based on the £20,000 per QALY threshold. This showed that for acupuncture to be cost effective, the maximum incremental cost for acupuncture ranged from £380 to £640. Taking the most conservative estimate, this could fund a total of around 5 hours of sessions with a band 7 community staff member, using current NHS staffing costs (PSSRU 2018). Although this illustrates the maximum cost that would make acupuncture cost effective at the £20,000 threshold, there still remain uncertainties as to whether the same treatment effect can be gained from fewer of sessions. More specifically, the study reporting the QALY gain feeding into this calculation, provided up to 12 sessions of 50 minutes. But 5 hours of staff time would only provide five 50 minute sessions. Additionally, if sessions in UK practice are not as long, then more sessions might be afforded, however again whether more shorter sessions would provide the same QALY gain as fewer longer sessions is also uncertain. The relationship between treatment intensity and effectiveness has not been investigated in this review.

To help further explore the cost effectiveness of acupuncture, an original economic analysis was undertaken. This was a cost-utility analysis using a lifetime horizon comparing acupuncture with no acupuncture. Treatment effects were based on trials in the clinical review that reported utilities, or measures that could be mapped to utilities (SF-36, pain scales), with the model meta-analysing all available data that reported outcomes at the same time points, to derive an average treatment effect over time. Note that only studies with a usual care comparison were included in the model, as the committee view was that this is the most appropriate comparator for the economic analysis as these would give the full benefit likely to be achieved in a real world scenario. 7 out of 9 studies with a usual care comparison had outcomes that could be used in the model. Differences in quality of life between the acupuncture and no acupuncture group in each study were calculated, taking into account the change from baseline in each arm, to derive the quality of life gain from acupuncture compared to no acupuncture for each study. Note the intervention being modelled is based on a single course of acupuncture, and there was no information on repeat courses. The model estimated QALYs based on the available data by using a linear trend line fitted to the pooled quality of life gain at each time point up to 12 weeks and then applying the average change in treatment effect over time after the end of the intervention up to 18 weeks. The average treatment effect was also extrapolated beyond the available trial data, based on committee assumptions in the lifetime analysis. Costs included only the costs of the staff time involved in providing acupuncture. The total resource use from each study being used for treatment effect was identified and costed up, and a weighted average was taken based on the number of participants analysed in the intervention arm of each trial.

Two base cases were modelled, one using a lifetime horizon where treatment effects were extrapolated beyond the trial data and the other assuming no extrapolation beyond the trial data. Both base cases showed that acupuncture was cost effective compared with no acupuncture, with probabilistic ICERs of £5,710 (90% probability of acupuncture being cost effective at a threshold of £20,000 per QALY gained), and £14,552 (88% probability) respectively, and deterministic ICERs of £9,113 and £14,310 respectively. Various sensitivity analyses were undertaken, including varying resource use such as band of staff, assuming overlap of treatment, and including data omitted from the base case. The overall conclusion was robust to all sensitivity analyses tested.

The committee discussed the limitations of the analysis. These included how data was pooled across clinical studies that had different intensities of acupuncture (in terms of frequency of sessions and overall number of sessions), differences in the type of acupuncture and differences in the number of acupuncture points. They also discussed the

limitations of mapping pain scores and SF36 quality of life scores to EQ-5D quality of life scores. However, they agreed that the studies used in the economic analysis were generally representative of the populations in the review as a whole and that the mapping was appropriate as the same methodology had also been used in other cost-effectiveness studies (notably a large acupuncture meta-analysis). The committee noted the uncertainty around the relationship between resource use and treatment benefit, which needs to be taken account when interpreting the results. It was not considered appropriate to explore this relationship more formally in the model (such as by modelling each study separately), as the clinical review did not establish which characteristics of acupuncture improve outcomes.

Overall, although the committee had reservations about the two published studies, the original economic analysis used a wider pool of data, and the committee considered this to be more robust than the published evidence. Various sensitivity analyses were undertaken showing that if a higher band of staff was used for example, this would still lead to acupuncture being cost effective. Pooling the resource use from the studies using a weighted average method, led to an average of 10 sessions of around 30 minutes. A threshold analysis in the model showed that up to 15 sessions of 30 minutes could be afforded at the £20,000 per QALY threshold (based on the non-extrapolated base case). The threshold analysis on the published studies was also useful because this showed that using the most conservative published QALY, a maximum of 5 hours of band 6 staff time could be afforded, which is similar to the average resource use in the model. The model resulted in higher QALYs than some of the published estimates because it pooled many studies together and led to an overall larger treatment effect.

Based on the above, the committee were confident in the evidence to support a ‘consider’ recommendation. This was supported by clinical and cost effectiveness evidence but was not thought appropriate to have an ‘offer’ recommendation due to the uncertainty of the effects being sustained long term as well as there being some uncertainty in the cost-effectiveness and there being a high resource impact of implementing this in current practice. The recommendation was caveated with information on the number of hours of staff time, and banding of staff that would make the delivery of acupuncture cost effective. 5 hours of acupuncture was recommended as the maximum that should be considered, as this was the average resource use used in the model based on the trials included. Around 5 hours was also the most conservative estimate from the threshold calculations using the published QALYs, which increases certainty that this level of acupuncture is likely to be cost effective, as the model in fact showed that QALYs are likely to be higher than the most conservative published QALY, as it pooled many more studies. The band of staff caveated in the recommendation was a band 7. There was some debate with the committee in terms of bands of staff that would generally deliver acupuncture and so this was tested in the model. In the model a band 6 was used as the base case, however band 7 was also tested in a sensitivity analysis and the ICER remained below £20,000, and therefore a caveat of band 7 or below was felt appropriate in order to capture the variation in staff that might deliver the intervention. Stakeholder feedback highlighted that that there may be other service configurations that would allow delivery of acupuncture for a similar cost and this was also incorporated into the recommendation.

The committee noted that acupuncture used to be widely available in clinical settings but many services have been decommissioned over recent years. It was acknowledged that there is likely to be a significant resource impact even with limited uptake, given the size of the population.

1.7.3 Other factors the committee took into account

The evidence reviewed was only able to inform a recommendation for a single course of acupuncture. The committee noted that they could not assume repeated courses would have the same effectiveness, and this would have implications for cost effectiveness if repeat courses were provided within the NHS. They therefore agreed that a research

recommendation should be drafted to determine the clinical and cost-effectiveness of repeat courses of acupuncture.

The committee were aware of self-acupuncture techniques whereby a person delivers acupuncture to themselves, but no evidence was identified within this area and thus no recommendations related to this were made.

The NICE low back pain guideline (NG59) did not recommend the routine use of acupuncture. The committee discussed and compared the evidence within this guideline to the low back pain guideline and agreed there was a difference in the available evidence base between the two guidelines, with less consistent results demonstrated in NG59, and the current review demonstrating more favourable results when compared to sham acupuncture. Of most importance, they noted that the low back pain guideline included acute pain, which is not covered in this guideline; this difference in the population covered could have resulted in differences in outcomes seen across the evidence. The committee also noted that acupuncture is recommended in the NICE guideline for headaches (CG150) for prophylactic treatment of chronic tension type headache, where there was also evidence of benefit of acupuncture compared to sham.

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Appendices

Appendix A: Review protocol

Review protocol for acupuncture

ID	Field	Content
0.	PROSPERO registration number	Not registered.
1.	Review title	What is the clinical and cost effectiveness of acupuncture or dry needling for the management of chronic primary pain?
2.	Review question	What is the clinical and cost effectiveness of acupuncture or dry needling for the management of chronic primary pain?
3.	Objective	To determine the clinical and cost effectiveness of acupuncture or dry needling for the management of chronic primary pain.
4.	Searches	The following databases will be searched: • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE • CINAHL, Current Nursing and Allied Health Literature Searches will be restricted by:

		• English language • Human studies • Letters and comments are excluded. Other searches: • Inclusion lists of relevant systematic reviews will be checked by the reviewer. The searches may be re-run 6 weeks before final committee meeting and further studies retrieved for inclusion if relevant. The full search strategies will be published in the final review.
5.	Condition or domain being studied	Chronic pain in one or more anatomical regions that is characterized by significant emotional distress (anxiety, anger/frustration or depressed mood) and functional disability (interference in daily life activities and reduced participation in social roles). The diagnosis is appropriate independently of identified biological or psychological contributors unless another diagnosis would better account for the presenting symptoms.
6.	Population	Inclusion: People, aged 16 years and over, with chronic primary pain (whose pain management is not addressed by existing NICE guidance) (chronic widespread pain, complex regional pain syndrome, chronic visceral pain, chronic orofacial pain, chronic primary musculoskeletal pain other than orofacial) Exclusion: Those whose pain management is addressed by existing NICE guidance

7.	Intervention/Exposure/Test	Interventions: • acupuncture/dry needling • electro acupuncture The guideline committee agreed to pool trials of Western acupuncture, dry needling or traditional Chinese approaches, but that these should be considered separately from electro acupuncture due to the adjunctive use of electricity as a physical modality.
8.	Comparator/Reference standard/Confounding factors	Comparators: • placebo/sham • usual care
9.	Types of study to be included	Randomised controlled trials (RCTs) and systematic reviews of RCTs Cross-over RCTs will be considered if no non-cross-over RCT evidence is identified.
10.	Other exclusion criteria	Non-English language studies.
11.	Context	A clear understanding of the evidence for the effectiveness of chronic primary pain treatments: • improves the confidence of healthcare professionals in their conversations about pain, and • helps healthcare professionals and patients to have realistic expectations about outcomes of treatment.
12.	Primary outcomes (critical outcomes)	• pain reduction (any validated scale) • health related quality of life (including meaningful activity) • physical function (5 minute walk, sit to stand, Roland Morris Disability Questionnaire, Oswestry Disability Index, Canadian Occupational Performance Measure) • psychological distress (depression/anxiety) (preferably Hospital Anxiety and Depression Scale) • pain self-efficacy • pain interference

		outcomes will be extracted at the longest time point up to 3 months and at the longest time point after 3 months
13.	Secondary outcomes (important outcomes)	• use of healthcare services • sleep • discontinuation outcomes will be extracted at the longest time point up to 3 months and at the longest time point after 3 months
14.	Data extraction (selection and coding)	EndNote will be used for reference management, sifting, citations and bibliographies. All references identified by the searches and from other sources will be screened for inclusion. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. EviBASE will be used for data extraction. Study investigators may be contacted for missing data where time and resources allow.
15.	Risk of bias (quality) assessment	Risk of bias will be assessed using the Cochrane Risk of Bias (2.0) tool. Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with involvement of a third review author where necessary.
16.	Strategy for data synthesis	Pairwise meta-analyses will be performed using Cochrane Review Manager (RevMan5). GRADEpro will be used to assess the quality of evidence for each outcome, taking into account individual study quality and the meta-analysis results. The 4 main quality elements (risk of bias, indirectness, inconsistency and imprecision) will be appraised for each outcome.
17.	Analysis of sub-groups	Proposed sensitivity / subgroup analysis to be explored where there is heterogeneity: • chronic widespread pain • complex regional pain syndrome

		• chronic visceral pain • chronic orofacial pain • chronic primary musculoskeletal pain • cognitive impairment • learning difficulties • first language not English • sensory impairment • homeless • acupuncture/dry needling	
18.	Type and method of review	☒	Intervention
		☐	Diagnostic
		☐	Prognostic
		☐	Qualitative
		☐	Epidemiologic
		☐	Service Delivery
		☐	Other (please specify)
19.	Language	English	
20.	Country	England	
21.	Anticipated or actual start date	NA - not registered on PROSPERO	
22.	Anticipated completion date	19/08/2020	
23.	Named contact	5a. Named contact National Guideline Centre 5b Named contact e-mail	

		Chronicpain@nice.org.uk 5e Organisational affiliation of the review National Institute for Health and Care Excellence (NICE) and the National Guideline Centre
24.	Review team members	From the National Guideline Centre: Serena Carville, Guideline Lead Maria Smyth, Senior Systematic Reviewer Rebecca Boffa, Senior Systematic Reviewer Margaret Constanti, Senior Health Economist Joseph Runicles, Information Specialist Katie Broomfield, Project Manager
25.	Funding sources/sponsor	This systematic review is being completed by the National Guideline Centre which receives funding from NICE.
26.	Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.
27.	Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the

		manual. Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10069
28.	Other registration details	NA
39.	Reference/URL for published protocol	NA
30.	Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: notifying registered stakeholders of publication publicising the guideline through NICE's newsletter and alerts issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.
31.	Keywords	-
32.	Details of existing review of same topic by same authors	NA
33.	Additional information	-
34.	Details of final publication	www.nice.org.uk

Table 14: Health economic review protocol

Review question	All questions – health economic evidence
Objectives	To identify health economic studies relevant to any of the review questions.
Search criteria	• Populations, interventions and comparators must be as specified in the clinical review protocol above. • Studies must be of a relevant health economic study design (cost–utility analysis, cost-effectiveness analysis, cost–benefit analysis, cost–consequences analysis, comparative cost analysis). • Studies must not be a letter, editorial or commentary, or a review of health economic evaluations. (Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.) • Unpublished reports will not be considered unless submitted as part of a call for evidence. • Studies must be in English.
Search strategy	A health economic study search will be undertaken using population-specific terms and a health economic study filter – see appendix B below.
Review strategy	Studies not meeting any of the search criteria above will be excluded. Studies published before 2002. Abstract-only studies and studies from non-OECD countries or the USA will also be excluded. Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in appendix H of Developing NICE guidelines: the manual (2014).[158] **Inclusion and exclusion criteria** • If a study is rated as both 'Directly applicable' and with 'Minor limitations' then it will be included in the guideline. A health economic evidence table will be completed and it will be included in the health economic evidence profile. • If a study is rated as either 'Not applicable' or with 'Very serious limitations' then it will usually be excluded from the guideline. If it is excluded then a health economic evidence table will not be completed and it will not be included in the health economic evidence profile. • If a study is rated as 'Partially applicable', with 'Potentially serious limitations' or both then there is discretion over whether it should be included. **Where there is discretion** The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the guideline committee if required. The ultimate aim is to include health economic studies that are helpful for decision-making in the context of the guideline and the current NHS setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the committee if required, may decide to include only the most applicable studies and to selectively exclude the remaining studies. All studies excluded on the basis of applicability or methodological limitations will be listed with explanation in the excluded health economic studies appendix below. The health economist will be guided by the following hierarchies. *Setting:* • UK NHS (most applicable). • OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden).

	• OECD countries with predominantly private health insurance systems (for example, Switzerland). • Studies set in non-OECD countries or in the USA will be excluded before being assessed for applicability and methodological limitations. *Health economic study type:* • Cost–utility analysis (most applicable). • Other type of full economic evaluation (cost–benefit analysis, cost-effectiveness analysis, cost–consequences analysis). • Comparative cost analysis. • Non-comparative cost analyses including cost-of-illness studies will be excluded before being assessed for applicability and methodological limitations. *Year of analysis:* • The more recent the study, the more applicable it will be. • Studies published in 2002 or later but that depend on unit costs and resource data entirely or predominantly from before 2002 will be rated as 'Not applicable'. • Studies published before 2002 will be excluded before being assessed for applicability and methodological limitations. *Quality and relevance of effectiveness data used in the health economic analysis:* • The more closely the clinical effectiveness data used in the health economic analysis match with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.

Appendix B: Literature search strategies

The literature searches for this review are detailed below and complied with the methodology outlined in Developing NICE guidelines: the manual.[158]

For more information, please see the Methods Report published as part of the accompanying documents for this guideline.

Clinical search literature search strategy

Searches were constructed using a PICO framework where population (P) terms were combined with Intervention (I) and in some cases Comparison (C) terms. Outcomes (O) are rarely used in search strategies for interventions as these concepts may not be well described in title, abstract or indexes and therefore difficult to retrieve. Search filters were applied to the search where appropriate.

Table 15: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline (OVID)	1946 – 20 May 2020	Exclusions Randomised controlled trials Systematic review studies
Embase (OVID)	1974 – 20 May 2020	Exclusions Randomised controlled trials Systematic review studies
The Cochrane Library (Wiley)	Cochrane Reviews to 2020 Issue 5 of 12 CENTRAL to 2020 Issue 5 of 12	None

Medline search terms

1.	Chronic pain/
2.	((chronic or persist* or idiopathic or atypical or a-typical) adj4 pain).ti,ab.
3.	exp Complex Regional Pain Syndromes/
4.	(complex regional pain syndrome* or CRPS or causalgia).ti,ab.
5.	((reflex or sympathetic) adj2 dystroph*).ti,ab.
6.	fibromyalgia/
7.	(fibromyalgia* or fibrositis or myofascial pain syndrome).ti,ab.
8.	vulvodynia/
9.	(vulvodynia or vestibulodynia or dyspareunia or vulvar vestibulitis or vulvitis).ti,ab.
10.	interstitial cystitis/
11.	(interstitial adj2 cystitis).ti,ab.
12.	algodystrophy/

13.	(algodystroph* or sudek or sudeck*).ti,ab.
14.	exp myofascial pain syndromes/
15.	cystitis, interstitial/
16.	(loin pain adj (haematuria or hematuria) adj syndrome*).ti,ab.
17.	(LPHS or prostatodynia or CPPS or atypic* odontalgia or a-typic* odontalgia or burning mouth syndrome* or phantom tooth pain or neuropathic orofacial pain or "myofascial pain" or MPS).ti,ab.
18.	((pelvic or pelvis) adj pain syndrome*).ti,ab.
19.	((non-cardiac or noncardiac) adj3 chest adj3 pain).ti,ab.
20.	(temporomandibular adj3 joint adj3 pain).ti,ab.
21.	((prostate or vulv* or bladder or perineal) adj3 pain).ti,ab.
22.	(functional pain syndrome* or non-cancer pain or noncancer pain).ti,ab.
23.	((pelvic or pelvis or abdominal) adj3 pain adj3 (unknown or un-known or idiopathic or atypic* or a-typic*)).ti,ab.
24.	or/1-23
25.	letter/
26.	editorial/
27.	news/
28.	exp historical article/
29.	Anecdotes as Topic/
30.	comment/
31.	case report/
32.	(letter or comment*).ti.
33.	or/25-32
34.	randomized controlled trial/ or random*.ti,ab.
35.	33 not 34
36.	animals/ not humans/
37.	exp Animals, Laboratory/
38.	exp Animal Experimentation/
39.	exp Models, Animal/
40.	exp Rodentia/
41.	(rat or rats or mouse or mice).ti.
42.	or/35-41
43.	24 not 42
44.	limit 43 to English language

45.	exp acupuncture therapy/
46.	acupuncture points/
47.	electroacupuncture/
48.	(acupuncture or electro acupuncture or electroacupuncture or dry needl*).ti,ab.
49.	or/45-48
50.	randomized controlled trial.pt.
51.	controlled clinical trial.pt.
52.	randomi#ed.ti,ab.
53.	placebo.ab.
54.	randomly.ti,ab.
55.	Clinical Trials as topic.sh.
56.	trial.ti.
57.	or/50-56
58.	Meta-Analysis/
59.	exp Meta-Analysis as Topic/
60.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
61.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
62.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
63.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
64.	(search* adj4 literature).ab.
65.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
66.	cochrane.jw.
67.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
68.	or/58-67
69.	44 and 49 and (57 or 68)

Embase search terms

1.	Chronic pain/
2.	((chronic or persist* or idiopathic or atypical or a-typical) adj4 pain).ti,ab.
3.	exp Complex regional pain syndrome/
4.	(complex regional pain syndrome* or CRPS or causalgia).ti,ab.
5.	((reflex or sympathetic) adj2 dystroph*).ti,ab.

6.	fibromyalgia/
7.	(fibromyalgia* or fibrositis or myofascial pain syndrome).ti,ab.
8.	vulvodynia/
9.	(vulvodynia or vestibulodynia or dyspareunia or vulvar vestibulitis or vulvitis).ti,ab.
10.	interstitial cystitis/
11.	(interstitial adj2 cystitis).ti,ab.
12.	algodystrophy/
13.	(algodystroph* or sudek or sudeck*).ti,ab.
14.	myofascial pain/
15.	noncardiac chest pain/
16.	cystalgia/
17.	Pelvis pain syndrome/
18.	(loin pain adj (haematuria or hematuria) adj syndrome*).ti,ab.
19.	(LPHS or prostatodynia or CPPS or atypic* odontalgia or a-typic* odontalgia or burning mouth syndrome* or phantom tooth pain or neuropathic orofacial pain or "myofascial pain" or MPS).ti,ab.
20.	((pelvic or pelvis) adj pain syndrome*).ti,ab.
21.	((non-cardiac or noncardiac) adj3 chest adj3 pain).ti,ab.
22.	(temporomandibular adj3 joint adj3 pain).ti,ab.
23.	((prostate or vulv* or bladder or perineal) adj3 pain).ti,ab.
24.	(functional pain syndrome* or non-cancer pain or noncancer pain).ti,ab.
25.	((pelvic or pelvis or abdominal) adj3 pain adj3 (unknown or un-known or idiopathic or atypic* or a-typic*)).ti,ab.
26.	or/1-25
27.	letter.pt. or letter/
28.	note.pt.
29.	editorial.pt.
30.	case report/ or case study/
31.	(letter or comment*).ti.
32.	or/27-31
33.	randomized controlled trial/ or random*.ti,ab.
34.	32 not 33
35.	animal/ not human/
36.	nonhuman/
37.	exp Animal Experiment/

38.	exp Experimental Animal/
39.	animal model/
40.	exp Rodent/
41.	(rat or rats or mouse or mice).ti.
42.	or/34-41
43.	26 not 42
44.	limit 43 to English language
45.	exp acupuncture/
46.	electroacupuncture/
47.	(acupuncture or electro acupuncture or electroacupuncture or dry needl*).ti,ab.
48.	or/45-47
49.	randomized controlled trial.pt.
50.	controlled clinical trial.pt.
51.	randomi#ed.ti,ab.
52.	placebo.ab.
53.	randomly.ti,ab.
54.	Clinical Trials as topic.sh.
55.	trial.ti.
56.	or/49-55
57.	Meta-Analysis/
58.	exp Meta-Analysis as Topic/
59.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
60.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
61.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
62.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
63.	(search* adj4 literature).ab.
64.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
65.	cochrane.jw.
66.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
67.	or/57-66
68.	44 and 48 and (56 or 67)

Cochrane search terms

#1.	MeSH descriptor: [Chronic Pain] explode all trees
#2.	((chronic or persist* or idiopathic or atypical or a-typical) near/4 pain):ti,ab
#3.	MeSH descriptor: [Complex Regional Pain Syndromes] explode all trees
#4.	(complex regional pain syndrome* or CRPS or causalgia):ti,ab
#5.	((reflex or sympathetic) near/2 dystroph*):ti,ab
#6.	MeSH descriptor: [Fibromyalgia] explode all trees
#7.	(fibromyalgia* or fibrositis or myofascial pain syndrome):ti,ab
#8.	MeSH descriptor: [Vulvodynia] explode all trees
#9.	(vulvodynia or vestibulodynia or dyspareunia or vulvar vestibulitis or vulvitis):ti,ab
#10.	MeSH descriptor: [Cystitis, Interstitial] explode all trees
#11.	(interstitial near/2 cystitis):ti,ab
#12.	MeSH descriptor: [Reflex Sympathetic Dystrophy] explode all trees
#13.	(algodystroph* or sudek or sudeck*):ti,ab
#14.	MeSH descriptor: [Myofascial Pain Syndromes] explode all trees
#15.	(loinpain near (haematuria or hematuria) near syndrome*):ti,ab
#16.	(LPHS or prostatodynia or CPPS or atypic* odontalgia or a-typic* odontalgia or burning mouth syndrome* or phantom tooth pain or neuropathic orofacial pain or "myofascial pain" or MPS):ti,ab
#17.	((pelvic or pelvis) near pain syndrome*):ti,ab
#18.	((non-cardiac or noncardiac) near/3 chest near/3 pain):ti,ab
#19.	(temporomandibular near/3 joint near/3 pain):ti,ab
#20.	((prostate or vulv* or bladder or perineal) near/3 pain):ti,ab
#21.	(functional pain syndrome* or non-cancer pain or noncancer pain):ti,ab
#22.	((pelvic or pelvis or abdominal) near/3 pain near/3 (unknown or un-known or idiopathic or atypic* or a-typic*)):ti,ab
#23.	(or #1-#22)
#24.	MeSH descriptor: [Acupuncture Therapy] explode all trees
#25.	MeSH descriptor: [Acupuncture Points] explode all trees
#26.	MeSH descriptor: [Electroacupuncture] explode all trees
#27.	(acupuncture or electro acupuncture or electroacupuncture or dry needl*):ti,ab
#28.	(or #24-#27)
#29.	#23 and #28

Health Economics literature search strategy

Health economic evidence was identified by conducting a broad search relating to a Chronic Pain population in NHS Economic Evaluation Database (NHS EED – this ceased to be updated after March 2015) and the Health Technology Assessment database (HTA) with no date restrictions. NHS EED and HTA databases are hosted by the Centre for Research and Dissemination (CRD). Additional searches were run on Medline and Embase for health economics and economic modelling.

Table 16: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline	2014 – 20 May 2020	Exclusions Health economics studies Health economics modelling studies
Embase	2014 – 20 May 2020	Exclusions Health economics studies Health economics modelling studies
Centre for Research and Dissemination (CRD)	HTA - Inception – 20 May 2020 NHSEED - Inception to March 2015	None

Medline search terms

1.	chronic pain/ or pain, intractable/
2.	((persist* or intract* or chronic or longstanding or long standing or longterm or long term or refractory or prolong* or long last* or sustain* or linger* or syndrome*) adj3 pain*).ti,ab.
3.	((chronic or persist* or idiopathic or atypical or a-typical) adj4 pain).ti,ab.
4.	exp Complex Regional Pain Syndromes/
5.	(complex regional pain syndrome* or CRPS or causalgia).ti,ab.
6.	fibromyalgia/
7.	((reflex or sympathetic) adj2 dystroph*).ti,ab.
8.	vulvodynia/
9.	(vulvodynia or vestibulodynia or dyspareunia or vulvar vestibulitis or vulvitis).ti,ab.
10.	interstitial cystitis/
11.	(interstitial adj2 cystitis).ti,ab.
12.	algodystrophy/
13.	(algodystroph* or sudek or sudeck*).ti,ab.
14.	exp myofascial pain syndromes/
15.	cystitis, interstitial/
16.	(loin pain adj (haematuria or hematuria) adj syndrome*).ti,ab.
17.	(LPHS or prostatodynia or CPPS or atypic* odontalgia or a-typic* odontalgia or burning mouth syndrome* or phantom tooth pain or neuropathic orofacial pain or "myofascial pain" or MPS).ti,ab.
18.	((pelvic or pelvis) adj pain syndrome*).ti,ab.
19.	((non-cardiac or noncardiac) adj3 chest adj3 pain).ti,ab.
20.	(temporomandibular adj3 joint adj3 pain).ti,ab.

21.	((prostate or vulv* or bladder or perineal) adj3 pain).ti,ab.
22.	(functional pain syndrome* or non-cancer pain or noncancer pain).ti,ab.
23.	((pelvic or pelvis or abdominal) adj3 pain adj3 (unknown or un-known or idiopathic or atypic* or a-typic*)).ti,ab.
24.	(fibromyalgia* or fibrositis or myofascial pain syndrome).ti,ab.
25.	or/1-24
26.	letter/
27.	editorial/
28.	news/
29.	exp historical article/
30.	Anecdotes as Topic/
31.	comment/
32.	case report/
33.	(letter or comment*).ti.
34.	or/26-33
35.	randomized controlled trial/ or random*.ti,ab.
36.	34 not 35
37.	animals/ not humans/
38.	exp Animals, Laboratory/
39.	exp Animal Experimentation/
40.	exp Models, Animal/
41.	exp Rodentia/
42.	(rat or rats or mouse or mice).ti.
43.	or/36-42
44.	25 not 43
45.	Economics/
46.	Value of life/
47.	exp "Costs and Cost Analysis"/
48.	exp Economics, Hospital/
49.	exp Economics, Medical/
50.	Economics, Nursing/
51.	Economics, Pharmaceutical/
52.	exp "Fees and Charges"/
53.	exp Budgets/
54.	budget*.ti,ab.
55.	cost*.ti.
56.	(economic* or pharmaco?economic*).ti.
57.	(price* or pricing*).ti,ab.
58.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
59.	(financ* or fee or fees).ti,ab.
60.	(value adj2 (money or monetary)).ti,ab.
61.	or/45-60
62.	exp models, economic/

63.	*Models, Theoretical/
64.	*Models, Organizational/
65.	markov chains/
66.	monte carlo method/
67.	exp Decision Theory/
68.	(markov* or monte carlo).ti,ab.
69.	econom* model*.ti,ab.
70.	(decision* adj2 (tree* or analy* or model*)).ti,ab.
71.	or/62-70
72.	44 and (61 or 71)

Embase (Ovid) search terms

1.	chronic pain/ or pain, intractable/
2.	((persist* or intract* or chronic or longstanding or long standing or longterm or long term or refractory or prolong* or long last* or sustain* or linger* or syndrome*) adj3 pain*).ti,ab.
3.	((chronic or persist* or idiopathic or atypical or a-typical) adj4 pain).ti,ab.
4.	exp Complex regional pain syndrome/
5.	(complex regional pain syndrome* or CRPS or causalgia).ti,ab.
6.	((reflex or sympatheti) adj2 dystroph*).ti,ab.
7.	fibromyalgia/
8.	(fibromyalgia* or fibrositis or myofascial pain syndrome).ti,ab.
9.	vulvodynia/
10.	(vulvodynia or vestibulodynia or dyspareunia or vulvar vestibulitis or vulvitis).ti,ab.
11.	interstitial cystitis/
12.	(interstitial adj2 cystitis).ti,ab.
13.	algodystrophy/
14.	(algodystroph* or sudek or sudeck*).ti,ab.
15.	myofascial pain/
16.	noncardiac chest pain/
17.	cystalgia/
18.	Pelvis pain syndrome/
19.	(loin pain adj (haematuria or hematuria) adj syndrome*).ti,ab.
20.	(LPHS or prostatodynia or CPPS or atypic* odontalgia or a-typic* odontalgia or burning mouth syndrome* or phantom tooth pain or neuropathic orofacial pain or "myofascial pain" or MPS).ti,ab.
21.	((pelvic or pelvis) adj pain syndrome*).ti,ab.
22.	((non-cardiac or noncardiac) adj3 chest adj3 pain).ti,ab.
23.	(temporomandibular adj3 joint adj3 pain).ti,ab.

24.	((prostate or vulv* or bladder or perineal) adj3 pain).ti,ab.
25.	(functional pain syndrome* or non-cancer pain or noncancer pain).ti,ab.
26.	((pelvic or pelvis or abdominal) adj3 pain adj3 (unknown or un-known or idiopathic or atypic* or a-typic*)).ti,ab.
27.	or/1-26
28.	letter.pt. or letter/
29.	note.pt.
30.	editorial.pt.
31.	case report/ or case study/
32.	(letter or comment*).ti.
33.	or/28-32
34.	randomized controlled trial/ or random*.ti,ab.
35.	33 not 34
36.	animal/ not human/
37.	nonhuman/
38.	exp Animal Experiment/
39.	exp Experimental Animal/
40.	animal model/
41.	exp Rodent/
42.	(rat or rats or mouse or mice).ti.
43.	or/35-42
44.	27 not 43
45.	health economics/
46.	exp economic evaluation/
47.	exp health care cost/
48.	exp fee/
49.	budget/
50.	funding/
51.	budget*.ti,ab.
52.	cost*.ti.
53.	(economic* or pharmaco?economic*).ti.
54.	(price* or pricing*).ti,ab.
55.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.

56.	(financ* or fee or fees).ti,ab.
57.	(value adj2 (money or monetary)).ti,ab.
58.	or/45-57
59.	statistical model/
60.	exp economic aspect/
61.	59 and 60
62.	*theoretical model/
63.	*nonbiological model/
64.	stochastic model/
65.	decision theory/
66.	decision tree/
67.	monte carlo method/
68.	(markov* or monte carlo).ti,ab.
69.	econom* model*.ti,ab.
70.	(decision* adj2 (tree* or analy* or model*)).ti,ab.
71.	or/61-70
72.	44 and (58 or 71)

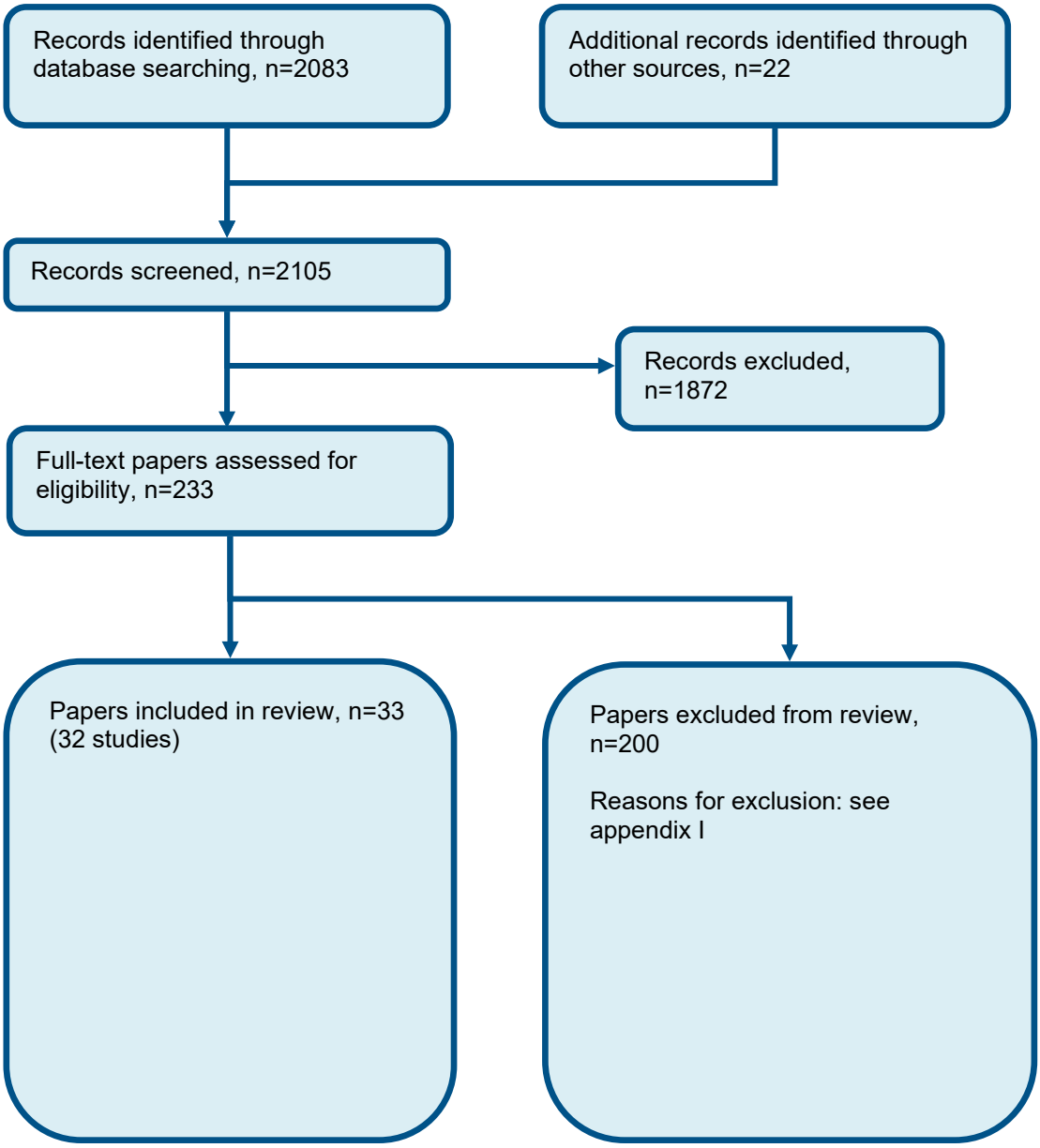
NHS EED and HTA (CRD) search terms

1.	MeSH DESCRIPTOR Chronic Pain EXPLODE ALL TREES
2.	(((persist* or intract* or chronic or longstanding or long standing or longterm or long term or refractory or prolong* or long last* or sustain* or linger* or syndrome*) adj3 pain*))
3.	(((chronic or persist* or idiopathic or atypical or a-typical) adj4 pain))
4.	MeSH DESCRIPTOR Complex Regional Pain Syndromes EXPLODE ALL TREES
5.	((complex regional pain syndrome* or CRPS or causalgia))
6.	MeSH DESCRIPTOR Fibromyalgia EXPLODE ALL TREES
7.	(((reflex or sympathetic) adj2 dystroph*))
8.	MeSH DESCRIPTOR Vulvodynia EXPLODE ALL TREES
9.	((vulvodynia or vestibulodynia or dyspareunia or vulvar vestibulitis or vulvitis))
10.	MeSH DESCRIPTOR Cystitis, Interstitial EXPLODE ALL TREES
11.	((interstitial adj2 cystitis))
12.	MeSH DESCRIPTOR Reflex Sympathetic Dystrophy EXPLODE ALL TREES
13.	((algodystroph* or sudek or sudeck*))
14.	MeSH DESCRIPTOR Myofascial Pain Syndromes EXPLODE ALL TREES
15.	((loin pain adj (haematuria or hematuria) adj syndrome*))
16.	((LPHS or prostatodynia or CPPS or atypic* odontalgia or a-typic* odontalgia or burning mouth syndrome* or phantom tooth pain or neuropathic orofacial pain or "myofascial pain" or MPS))
17.	(((pelvic or pelvis) adj pain syndrome*))
18.	(((non-cardiac or noncardiac) adj3 chest adj3 pain))

19.	((temporomandibular adj3 joint adj3 pain))
20.	(((prostate or vulv* or bladder or perineal) adj3 pain))
21.	((functional pain syndrome* or non-cancer pain or noncancer pain))
22.	(((pelvic or pelvis or abdominal) adj3 pain adj3 (unknown or un-known or idiopathic or atypic* or a-typic*)))
23.	((fibromyalgia* or fibrositis or myofascial pain syndrome))
24.	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23)

Appendix C: Clinical evidence selection

Figure 1: Flow chart of clinical study selection for the review of Acupuncture



Appendix D: Clinical evidence tables

Study	Aranha 2015[5]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=72)
Countries and setting	Conducted in Brazil; Setting: Clinical Research Laboratory, Departamento de Odontologia Infantil, Faculdade de Odontologia de Piracicaba, Universidade Estadual de Campinas
Line of therapy	Unclear
Duration of study	Intervention time and follow up: 4 weeks + 3-6 days
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Age range from 18 to 40 years; body mass index (BMI) ranging from 18 to 30 Kg/m2; regular menstrual cycle (regardless of oral contraception use); and at least one active MTrP in the upper trapezius muscle, with spontaneous local or referred persistent pain for at least six months
Exclusion criteria	Accentuated postural abnormalities (verified by physical therapist C.E.E.M.), fibromyalgia syndrome, cervical radiculopathy, systemic disease or physical therapy interventions for myofascial pain within one month before the study, pregnancy, chronic pacemaker or electronic implant use (reported by the subject). The continuous use of medications for headache and muscular pain was also an exclusion criterion. Moreover, subjects with evident cognitive impairment or communication difficulties during the first meeting were excluded
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Mean (SD): 27.33 (4.95). Gender (M:F): Women only. Ethnicity: Not reported
Extra comments	Duration of pain not reported
Indirectness of population	No indirectness

Interventions	(n=24) Intervention 1: Acupuncture - Electro acupuncture. The device used for the EAC was the EL608 NKL (ANVISA 80191680002). The needles were stainless steel, individually wrapped, sterile, and disposable, with a diameter of 0.25 mm and a length of 30 mm. The patient remained in the prone position. Needles were inserted bilaterally into points GB21 and GB20 (local analgesic acupoints) and unilaterally into LI4, LV320 (distal analgesic acupoints), and a maximum of two needles on each side directly in the region of the “Ashi Points” (painful points not predicted on meridians, not necessarily MTrP, detected before each session according to subject report at soft palpation of muscle). The equipment was programmed as follows: alternating frequency F1=2 Hz, T1=5 seconds, F2=100 Hz, T2=5 seconds; total time: 30 minutes; intensity: maximum supported by the patient without pain. There were 8 sessions, two per week. Duration 4 weeks. Concurrent medication/care: Not reported. (n=25) Intervention 2: Acupuncture. The acupuncture group received the same treatment as the electroacupuncture group but without the connection to the alternating frequency equipment. Duration 4 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness. (n=23) Intervention 3: Placebo/sham - Sham. The sham acupuncture group had the needles inserted 1 cm distally from the correct acupoints. Duration 4 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness.
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ELECTRO ACUPUNCTURE versus SHAM Protocol outcome 1: Discontinuation - Actual outcome: Discontinuation at 28 days; Group 1: 7/24, Group 2: 10/23 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus SHAM Protocol outcome 1: Discontinuation - Actual outcome: Discontinuation at 28 days; Group 1: 10/25, Group 2: 10/23 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Health related quality of life ; Physical function ; Psychological distress ; Use of healthcare services ; Sleep ; Pain reduction

Study	Assefi 2005[7]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=100)
Countries and setting	Conducted in USA; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention time and follow up: 12 weeks + 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: 1990 criteria of the American College of Rheumatology
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	English-speaking adults 18 years of age or older in whom fibromyalgia was diagnosed by a physician and who had a pre-randomisation global pain score of 4 or greater on a visual analogue scale (0 = no pain, 10 = worst pain ever). Participants agreed to undergo randomization and kept use of any fibromyalgia-related pharmacologic and non-pharmacological therapies constant throughout the study. At the baseline evaluation before randomization, a research coordinator trained in tender-point examination confirmed the diagnosis of fibromyalgia by using the 1990 criteria of the American College of Rheumatology
Exclusion criteria	Reported other pain-related medical conditions or potential contraindications to acupuncture treatment (such as bleeding disorders or severe needle phobia), were pregnant or breastfeeding, used narcotics (which could blunt the effects of acupuncture), were involved in litigation related to fibromyalgia (which might reduce their incentive for improvement), or had previously received acupuncture (to maximize blinding)
Recruitment/selection of patients	Dissemination of information on the study through newspapers, television, advertisements, signs posted at university-affiliated hospitals, and letters to local fibromyalgia support groups and health care providers with large caseloads of patients with fibromyalgia
Age, gender and ethnicity	Age - Mean (SD): acupuncture 46 (11); sham 47.65 (11.82). Gender (M:F): Women only. Ethnicity: Not reported
Extra comments	Duration of pain (years): acupuncture 12 (18); sham 9.3 (10.9)
Indirectness of population	No indirectness

Interventions	(n=25) Intervention 1: Acupuncture. Participants received directed acupuncture designed to treat fibromyalgia according to the practice of Traditional Chinese Medicine. In all groups that underwent needle insertion, needles were retained at standard depths (13) for 30 minutes at each acupoint. Disposable Chinese, Japanese, or Korean needles (34 to 40 gauge) were used, depending on the practitioner's preference. Treatments were twice a week. Duration 12 weeks. Concurrent medication/care: Participants kept use of any fibromyalgia-related pharmacologic and non-pharmacological therapies constant throughout the study. Indirectness: No indirectness. (n=71) Intervention 2: Placebo/sham - Sham. There were 3 sham treatments. One sham intervention, a control for acupoint specificity, involved acupuncture typically used to treat irregular menses or "early menses due to Blood Heat" (an unrelated condition) according to Traditional Chinese Medicine. Another sham intervention, which was also a control for acupoint specificity, used body locations not recognized as true acupoints or meridians for needling (sham needling). The third sham treatment, a control for needle insertion, consisted of non-insertive simulated acupuncture at the same acupoints used in directed acupuncture (simulated acupuncture). This technique uses a toothpick in a needle guide-tube to mimic needle insertion and withdrawal. Simulated acupuncture more closely duplicates the needle insertion experience than do techniques using placebo needles that require placing adhesive or plastic foam on the skin. In the simulated acupuncture group, participants remained on the table for 30 minutes after simulated insertion and then underwent simulated needle withdrawal. Efforts were made to imitate the sounds of opening needle packs and needle disposal. Duration 12 weeks. Concurrent medication/care: Participants kept use of any fibromyalgia-related pharmacologic and non-pharmacological therapies constant throughout the study. Indirectness: No indirectness.
Funding	Academic or government funding (By grant RO1AT00003 from the National Center for Complementary and Alternative Medicine)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus SHAM

Protocol outcome 1: Health related quality of life
- Actual outcome: SF36 physical at 6 months; Mean; least square mean difference -0.4 (95%CI -2.3 to 1.5) SF36 0-100 Top=High is good outcome, Comments: Baseline: acupuncture 28 (8); sham 31.34 (8.7);
Risk of bias: All domain - High Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2; Group 2 Number missing: 8
- Actual outcome: SF36 mental at 6 months; Mean; least square mean difference -1.5 (95%CI -4 to 1) SF36 0-100 Top=High is good outcome, Comments: Baseline: acupuncture 42 (11); sham 41.66 (9.85);
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2; Group 2 Number missing: 8

Protocol outcome 2: Pain reduction - Actual outcome: Pain at 6 months; Mean; Least square mean difference: 0.5 (95%CI -0.3 to 1.2) VAS 0-10 Top=High is poor outcome, Comments: Baseline: acupuncture 7 (2); sham 7 (2); Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2; Group 2 Number missing: 8 Protocol outcome 3: Sleep - Actual outcome: Sleep quality at 6 months; Mean; least square mean difference -0.5 (95%CI -1.3 to 0.2) VAS 0-10 Top=High is poor outcome, Comments: Baseline: acupuncture 4 (2); sham 3 (2); Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2; Group 2 Number missing: 8 Protocol outcome 4: Discontinuation - Actual outcome: Discontinuation at End of treatment; Group 1: 2/25, Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Psychological distress ; Use of healthcare services ; Physical function

Study	Birch 1998[10]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=46)
Countries and setting	Conducted in USA; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention time and follow up: 10 weeks + 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Chronic myofacial neck pain lasting for more than 6 months; an identifiable painful area with heightened sensitivity to moderate tough (most often evidence of a taut band of skeletal muscle and referred pain on compression); an unsuccessful response to physical therapy (traction, heat, ultrasound, massage), medication, and a soft collar; age between 18-65 years; and willingness to participate in the study
Exclusion criteria	Disc herniation; cervical osteoarthritis, infection, malignancy, collapsed vertebra, thoracic outlet syndrome, temporomandibular joint dysfunction, collagen-vascular disease, or brachial plexopathy. Persons with a present or past DSM-IV diagnosis of schizophrenia, delusional disorder, psychotic disorder, dissociative disorder, or bipolar disorder were also excluded as were those with ongoing litigation concerning their neck pain
Recruitment/selection of patients	Referrals to hospital based pain management centre and a neurology clinic and though publicized announcements
Age, gender and ethnicity	Age - Mean (SD): Acupuncture 40.9; sham 38; medication 38.6. Gender (M:F): 8/38. Ethnicity: Not reported
Extra comments	Duration of pain (months): acupuncture 81.9; sham 92.2; medication 91.1
Indirectness of population	No indirectness
Interventions	(n=15) Intervention 1: Acupuncture. Relevant acupuncture was conducted in 2 stages. Stage 1 consisted of the use of pre-sterilised gauge 2 (0.18 mm) Seirin needles shallowly inserted in two sequential stages at predetermined acupuncture points with set techniques. First, needles were placed bilaterally on the hands and feet at the following acupuncture points: SI-3, BL-62, GB-41, and TW-5. Needles were inserted to an approximate depth of 2-3mm at each point. The needles were connected by IP cords - thin, flexible, ensheathed copper wires 85 inches long, with small

	alligator clips on each end. A silicone diode was placed in one of the clips; one end was clipped to a needle inserted in the hand and the other to a needle in the foot. The needles and cords were left in place for a total of 10 minutes. It is believed that the diode offers minimal stimulation that enhances treatment benefit. In stage 2, needling was performed on acupuncture points in the neck, shoulder and upper back. Six of the following acupuncture points were selected: left and right GB20, left and right GB21, left and right GB12, left and right BL10, left and right BL11, and GV14. The selected points were palpated for accurate identification, and needles were inserted to a depth of 2-10mm each - deep enough to tough or just penetrate the body of the underlying muscle mass. An infrared lamp was applied over the needled area, with heat adjusted to the comfort of the patient. The needles and heat were applied for a total of 10 minutes. Each patient received a total of 14 treatments (twice a week for 4 weeks, once a week for 4 weeks and then every other week for 2 weeks). Duration 10 weeks. Concurrent medication/care: All patients were offered 500mg per day of Trilisate (and NSAID). Efforts were made to suggest that the medication would be effective in treating pain. All patients were discouraged from using other medication during the study . Indirectness: No indirectness. (n=16) Intervention 2: Placebo/sham - Sham. Irrelevant acupuncture involved pre-sterilised gauge 2 Seirin needles which were shallowly inserted in two stages. In stage 1, needles were placed bilaterally to an approximate depth of 2-3 mm in the hands and feet at the following acupuncture points: LI5, GB42, TW8 and ST41. Needles were then connected by cords that looked the same as the IP cords used in the relevant acupuncture group, but the connections were undetectably severed. The needles and cords were left in place for a total of 10 minutes. None of the selected points was cited for the treatment of neck pain in the more than 20 sources reviewed. In stage 2, the following fixed acupuncture points were needled in the shoulder and upper back: left and right BL16, left and right SI9, and left and right LI15. Six needles were inserted to a depth of 2mm at these points. A light, used to control for the heat lamp used in group 1, was shone over the area needles, but at a sufficient distance that no heat was felt. Needles and light were left in place for a total of 10 minutes. Duration 10 weeks. Concurrent medication/care: All patients were offered 500mg per day of Trilisate (and NSAID). Efforts were made to suggest that the medication would be effective in treating pain. All patients were discouraged from using other medication during the study . Indirectness: No indirectness. (n=15) Intervention 3: Usual care - Usual care. Patients received only the NSAID Trilisate but were told that they would be offered free acupuncture at the end of the study. Duration 10 weeks. Concurrent medication/care: Efforts were made to suggest that the medication would be effective in treating pain. All patients were discouraged from using other medication during the study . Indirectness: No indirectness.
Funding	Academic or government funding (Funded in part by an intramural grant of the Anesthesia Department of Brigham and Women's Hospital, Boston)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus SHAM	

Protocol outcome 1: Pain reduction - Actual outcome: Average hourly pain at Post treatment; Group 1: mean 1.87 (SD 1.9); n=11, Group 2: mean 3.37 (SD 2.14); n=13; NRS 0-10 Top=High is poor outcome; Comments: Baseline: acupuncture 4.8; sham 4.7 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 4; Group 2 Number missing: 3 Protocol outcome 2: Discontinuation - Actual outcome: Discontinuation at Post treatment; Group 1: 4/15, Group 2: 3/16 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus USUSAL CARE Protocol outcome 1: Pain reduction - Actual outcome: Average hourly pain at Post treatment; Group 1: mean 1.87 (SD 1.9); n=11, Group 2: mean 4.76 (SD 2.05); n=12; NRS 0-10 Top=High is poor outcome; Comments: Baseline: acupuncture 4.8; usual care 4.9 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 4; Group 2 Number missing: 3 Protocol outcome 2: Discontinuation - Actual outcome: Discontinuation at Post treatment; Group 1: 4/15, Group 2: 3/15 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Health related quality of life ; Psychological distress ; Use of healthcare services ; Sleep ; Physical function

Study	Casanueva 2014[16]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=120)
Countries and setting	Conducted in Spain; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 weeks + 6 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: ACR1990 criteria for FM
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients had to be 18 years or older and fulfil the ACR1990 criteria for FM, according to a diagnosis made by a rheumatologist. They should have failed to achieve improvement following other treatments including nonsteroidal anti-inflammatory drugs, major opioids, tricyclic antidepressants (amitriptyline or cyclobenzaprine), selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, anticonvulsant drugs such as pregabalin and some other multidisciplinary therapies.
Exclusion criteria	Medical or psychiatric disorders
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Mean (SD): dry needling 56.26 (12.03); control 50.82 (9.36). Gender (M:F): 10/110. Ethnicity: Not reported
Extra comments	Duration of pain not reported
Indirectness of population	No indirectness
Interventions	(n=60) Intervention 1: Dry needling. Besides maintaining their current medical treatment, patients from the experimental group received an additional weekly 1-h session of dry needling over the 18 tender points for a 6-week-period. All dry needling procedures were performed by the same investigator, and the technique used (superficial dry needling or deep dry needling) was similar to the Baldry method, using sterile Ener-Qi acupuncture needles for the punction of the tender points of fibromyalgia defined following the ACR 1990 classification criteria: Occiput bilateral, using superficial puncture, the needle (0.26 9 13) (diameter 9 length), was inserted to a depth of 5–10 mm. When muscle contraction was reached, the needle was withdrawn a few seconds. Trapezius bilateral, low-cervical bilateral,

	second rib bilateral and supraspinatus bilateral. Epicondyle bilateral (superficial puncture) and greater trochanter bilateral (in this case deep puncture). Gluteal bilateral deep puncture was performed by inserting needle (0.32 9 50) or (0.26 9 25) about 20–25 mm. Knees bilateral, superficial or deep puncture depending on the patient. Duration 6 weeks. Concurrent medication/care: Participants maintained current medical treatment. Indirectness: No indirectness. (n=60) Intervention 2: Usual care - Usual care. The control group kept on taking the same medical treatment that they received before randomization. Duration 6 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness.
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DRY NEEDLING versus USUSAL CARE

Protocol outcome 1: Health related quality of life
- Actual outcome: SF36 physical functioning at 12 weeks; Group 1: mean 31.1 (SD 18.9); n=50, Group 2: mean 28.6 (SD 17.2); n=50; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 26.8 (17.8); usual care 26.56 (15.64)
Risk of bias: All domain – Very High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly; Group 2 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly
- Actual outcome: SF36 role limitations physical at 12 weeks; Group 1: mean 18.6 (SD 35.5); n=50, Group 2: mean 4.8 (SD 18.7); n=50; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 6.5 (21.31); usual care 5.73 (18.04)
Risk of bias: All domain - Very High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly; Group 2 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly
- Actual outcome: SF36 pain at 12 weeks; Group 1: mean 28 (SD 23.42); n=50, Group 2: mean 16 (SD 14); n=50; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 20.5 (16.52); usual care 17.29 (13.54)
Risk of bias: All domain - Very High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly; Group 2 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly
- Actual outcome: SF36 general health at 12 weeks; Group 1: mean 23.6 (SD 16.7); n=50, Group 2: mean 20.7 (SD 12.1); n=50; SF36 0-100 Top=High is good outcome;

Comments: Baseline: acupuncture 22 (13.96); usual care 22.39 (11.98)
Risk of bias: All domain - Very High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly; Group 2 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly
- Actual outcome: SF36 vitality at 12 weeks; Group 1: mean 21.1 (SD 17.5); n=50, Group 2: mean 13.7 (SD 12.2); n=50; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 17.1 (14.1); usual care 12.29 (13.68)
Risk of bias: All domain - Very High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly; Group 2 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly
- Actual outcome: SF36 social functioning at 12 weeks; Group 1: mean 45.4 (SD 29.9); n=50, Group 2: mean 34.7 (SD 23.4); n=50; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 39.25 (26.36); usual care 36.45 (27.63)
Risk of bias: All domain - Very High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly; Group 2 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly
- Actual outcome: SF36 role limitation emotional at 12 weeks; Group 1: mean 38.1 (SD 46.5); n=50, Group 2: mean 17.2 (SD 34.7); n=50; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 23.32 (26.36); usual care 24.99 (38.58)
Risk of bias: All domain - Very High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly; Group 2 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly
- Actual outcome: SF36 mental health at 12 weeks; Group 1: mean 41 (SD 21.9); n=50, Group 2: mean 36.3 (SD 20.9); n=50; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 37.28 (21.23); usual care 39.21 (21.24)
Risk of bias: All domain - Very High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly; Group 2 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly

Protocol outcome 2: Pain reduction

- Actual outcome: Pain at 12 weeks; Group 1: mean 6.9 (SD 2.9); n=50, Group 2: mean 8.1 (SD 1.3); n=50; VAS 0-10 Top=High is poor outcome; Comments: Baseline: acupuncture 7.7 (2.04); usual care 7.96 (1.2)
Risk of bias: All domain - Very High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly; Group 2 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly

Protocol outcome 3: Physical function
- Actual outcome: 6 minute walk test at 12 weeks; Group 1: mean 106.7 (SD 90.2); n=50, Group 2: mean 67 (SD 74.4); n=50; Comments: Baseline: acupuncture 85.69 (72.92); usual care 76.25 (72.39)
Risk of bias: All domain - Very High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly; Group 2 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly

Protocol outcome 4: Psychological distress
- Actual outcome: Depression at 12 weeks; Group 1: mean 23.4 (SD 12.2); n=50, Group 2: mean 27.1 (SD 9.4); n=50; Beck Depression Inventory 0-63 Top=High is poor outcome; Comments: Baseline: acupuncture 25.65 (12.12); usual care 26.7 (11.04)
Risk of bias: All domain - Very High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly; Group 2 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly
- Actual outcome: Anxiety at 12 weeks; Group 1: mean 30 (SD 13.7); n=50, Group 2: mean 35.3 (SD 12.8); n=50; Beck Anxiety inventory 0-63 Top=High is poor outcome; Comments: Baseline: acupuncture 34.16 (14.24); 35.06 (11)
Risk of bias: All domain - Very High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly; Group 2 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly

Protocol outcome 5: Sleep
- Actual outcome: Sleep at 12 weeks; Group 1: mean 12.32 (SD 3.97); n=50,
Risk of bias: All domain - Very High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover -

Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly; Group 2 Number missing: 10, Reason: The most common reasons for discontinuation were mild adverse effects related to dry needling (increased pain, physical discomfort), or failure to complete the questionnaire (lack of filling it) correctly Protocol outcome 6: Discontinuation - Actual outcome: Discontinuation at 6 weeks; Group 1: 10/60, Group 2: 10/60 Risk of bias: All domain - High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Use of healthcare services

Study	Cho 2014[28]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=45)
Countries and setting	Conducted in South Korea; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3 weeks + 7 weeks
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	(1) men or women aged 25–55 years; (2) symptoms such as neck pain or stiffness in the neck and shoulders lasting for 3 months or more; (3) a score of ≥5 on the visual analogue scale (VAS) at baseline
Exclusion criteria	(1) had received acupuncture or NSAID treatment for neck pain within the past 3 months; (2) had a serious medical disease or cancer; (3) had a history of spinal trauma, had undergone surgery on the neck or had systematic neurological or other skeletal disorders; (4) were pregnant or breast feeding
Recruitment/selection of patients	advertisements in local newspapers and the hospital's home page
Age, gender and ethnicity	Age - Mean (SD): acupuncture: 39.15 (9.05); usual care: 38.2 (10.2). Gender (M:F): 29/16. Ethnicity: Not reported
Extra comments	Duration of pain not reported
Indirectness of population	No indirectness
Interventions	(n=30) Intervention 1: Acupuncture. The AC and AN groups received acupuncture treatment at the acupuncture points for chronic neck pain for 3 weeks by licensed Korean Medicine Doctors (KMDs) with at least 3 years of experience. KMDs discussed and practiced the methods of acupuncture treatment mentioned in the protocol. Based on literature reviews of acupuncture for neck pain, the widely-accepted local and distal acupuncture points were selected bilaterally.10–12 The standard points in the cervical region (local points) were SI9, SI10, SI11, SI12, SI14, BL11, BL12, TE14, TE15, TE16, TE17 and GB21 and the standard points on the extremities (distal points) were SI3, SI4 and BL65. In the acupuncture treatment groups, disposable stainless steel needles (0.25 mm×40 mm, Dongbang Acupuncture Needle Co, Korea) were inserted into the muscle to a

	depth of 20 mm. When the subject felt dull pain or the acupuncture sensation (de qi), the manipulation was stopped and the needle was left in place for 15 min. 15 participants also were instructed to take an NSAID (zaltoprofen, 80 mg) three times a day and were asked to record daily in a patient diary any doses and dates of missed medication. There were 3 acupuncture sessions per week. Duration 3 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness. (n=15) Intervention 2: Usual care - Usual care. Patients were instructed to take an NSAID (zaltoprofen, 80 mg) three times a day and record daily in a patient diary any doses and dates of missed medication. Duration 3 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness.
Funding	Academic or government funding (funded by the program of the Kyung Hee University for young medical researcher in 2009)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus USUSAL CARE

Protocol outcome 1: Pain reduction
- Actual outcome: Pain at 7 weeks; Group 1: mean 4.05 (SD 1.828); n=30, Group 2: mean 4.5 (SD 2.2); n=15; VAS 0-10 Top=High is poor outcome; Comments: Baseline: acupuncture 6.9 (1.06); usual care 6.07 (0.5)
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness

Protocol outcome 2: Physical function
- Actual outcome: Neck disability at 7 weeks; Group 1: mean 17.6 (SD 5.157); n=30, Group 2: mean 17.3 (SD 5.7); n=15; Neck disability index 0-100 Top=High is poor outcome; Comments: Baseline: acupuncture 24.75 (5.684); usual care 22.3 (4)
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness

Protocol outcome 3: Psychological distress
- Actual outcome: Depression at 7 weeks; Group 1: mean 26.45 (SD 5.485); n=30, Group 2: mean 28.5 (SD 7.3); n=15; BDI 0-63 Top=High is poor outcome; Comments: Baseline: acupuncture 30.9 (6.84); usual care 30.7 (5.6)
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness

Protocol outcome 4: Discontinuation
- Actual outcome: Discontinuation at 7 weeks; Group 1: 5/30, Group 2: 2/15

Risk of bias: All domain - ; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Health related quality of life ; Sleep ; Use of healthcare services

Study	Chou 2011[32]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=45)
Countries and setting	Conducted in China; Setting: Not reported
Line of therapy	Unclear
Duration of study	Follow up (post intervention): 1 month
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	(1) patients experienced chronic pain at subjective pain levels greater than 5/10 (where 0/10 is no pain) on one side of the shoulder because of active myofascial trigger points in the ipsilateral upper trapezius muscle; (2) patients had no previous acupuncture; (3) patients demonstrated poor response to previous conservative treatment and non-invasive treatments such as medicine or physical therapy
Exclusion criteria	(1) patients with conditions of contraindication for needling such as intake of anticoagulant medicine, local infection, malignancy, or pregnancy with threatened abortion; (2) patients with conditions that might interfere with assessments of pain intensity or pain threshold, such as use of analgesics or sedatives, substance abuse or cognitive deficiency; (3) those with previous trauma or surgery to the neck, upper back or upper limb regions; and (4) patients with a history of significant neurologic disease involving the neck or upper limb
Recruitment/selection of patients	Recruited from a rehabilitation department
Age, gender and ethnicity	Age - Mean (SD): acupuncture 34.15 (9.32); placebo 33.9 (8.3). Gender (M:F): 22/23. Ethnicity: Not reported
Extra comments	Duration of pain (months): acupuncture 6.1 (2.25); placebo 6.2 (2.2)
Indirectness of population	No indirectness
Interventions	(n=30) Intervention 1: Acupuncture. Modified acupuncture or simple needling. Participants in the modified acupuncture group had acupuncture needles inserted into the regular depth in the subcutaneous layer. The needle was moved in and out into different directions at a speed of about 2cm/sec to elicit LTRs. Simultaneous rotation of the needle was also performed to facilitate the in and out movement (screwing in and out technique). With this rapid

	needle movement (high pressure) the LTRs were much easier to elicit. This technique continued for 15 secs to further elicit as many LTRs as possible, then the needle insertion was maintained without any movement for 3 minutes or longer for the temporary relief of pain accompanied with LTRs. The TE-5 acupoint was treated first. Five minutes after completion of needle manipulation at TE5, the LI11 point was treated with the same procedure whereas the acupuncture needle remained motionless in the TE5 point. Five minutes after the completion of needle manipulation at LI11, both needles were manipulated simultaneously for 15 seconds, then maintained in a steady position for 3 minutes. The acupuncturist simultaneously used two hands for the manipulation of the two needles. For the simple needling, acupuncture needles were inserted into the regular depth at both acupuncture points. After, the needle was maintained without movement throughout the course of treatment. Duration Unclear. Concurrent medication/care: Not reported. (n=15) Intervention 2: Placebo/sham - Placebo. Each patient was treated with an acupuncture needle inserted into a rubber connector that was firmly taped onto the marked point for acupuncture. There was needle to skin contact, and the patient would be able to feel the sharp needle tip; the needle however did not penetrate the skin. The needle was maintained in the previously mentioned position throughout the course of the treatment. Duration Unclear. Concurrent medication/care: Not reported. Indirectness: No indirectness
Funding	Academic or government funding (National Science Council of Taiwan and Taiwan Department of Health Clinical Trial and Research Center of Excellence)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus PLACEBO Protocol outcome 1: Pain reduction - Actual outcome: Pain at 1 month; Group 1: mean 4.6 (SD 1.585); n=30, Group 2: mean 7.07 (SD 0.88); n=15; NRS 0-10 Top=High is poor outcome; Comments: Baseline: acupuncture 7.53 (1.125); placebo 7.60 (1.12) Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness Protocol outcome 2: Discontinuation - Actual outcome: Discontinuation at 1 month; Group 1: 0/30, Group 2: 0/15 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Health related quality of life ; Psychological distress ; Use of healthcare services ; Sleep ; Physical function

Study	Coan 1981[33]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=30)
Countries and setting	Conducted in USA; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 12 weeks
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Neck pain and/or radicular arm and hand pain present for at least 6 months; no history of previous acupuncture treatments, diabetes, infection or cancer; and not more than two previous neck surgeries
Exclusion criteria	Not reported
Recruitment/selection of patients	Public service announcements in newspapers
Age, gender and ethnicity	Age - Mean (range): acupuncture 51.6 (27-74); control 47 (34-63). Gender (M:F): 8/22. Ethnicity: Not reported
Extra comments	Duration of pain (years): acupuncture 7.8; sham 8.3
Indirectness of population	No indirectness
Interventions	(n=15) Intervention 1: Acupuncture. Acupuncture was performed according to the classical Oriental meridian theory of promoting healing by stimulating the energy flow in the body. Acupuncture point selection varied from patient to patient, and even from day to day in the same patient, according to the findings at the time of each treatment. Treatments were given from 3-4 times per week. Electroacupuncture and moxibustion were used on some patients. Duration 2-3 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness. (n=15) Intervention 2: Usual care - Usual care. Waiting list. No further details. Duration 2-3 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness.
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus USUSAL CARE Protocol outcome 1: Pain reduction - Actual outcome: Pain at 12 weeks; Group 1: mean 3.63 (SD 2.22); n=15, Group 2: mean 5.37 (SD 2.23); n=15; NRS 0-10 Top=High is poor outcome; Comments: Baseline: acupuncture 5.97 (1.78); control 5.3 (2.31) Risk of bias: All domain - High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0	
Protocol outcomes not reported by the study	Health related quality of life ; Psychological distress ; Use of healthcare services ; Sleep ; Discontinuation ; Physical function

Study	Couto 2014[42]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=78)
Countries and setting	Conducted in Brazil; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention time: 4 weeks
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Women aged 19-50 who experienced limitations in their routine activities due to MPS several times a week during the last 3 months and who visited a primary care unit. One of more positive answers to the following questions: during the last 3 months, did the pain interfere several times a weeks with your 1) work, 2) enjoyable activities, 3) responsibilities at home 4), relationships, 5) personal goals, 6) thinking clearly, problem solving, concentration, or memory
Exclusion criteria	Rheumatoid arthritis, fibromyalgia, pervious surgery on the affected areas, prior experience with acupuncture, primary radiculopathy, current use of psychotropic drugs, or habitual use of anti-inflammatory steroids
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Mean (SD): acupuncture group 35.84 (5.02); placebo 33.52 (5.07). Gender (M:F): Women only. Ethnicity: Not reported
Extra comments	Duration of pain not reported
Indirectness of population	No indirectness
Interventions	(n=26) Intervention 1: Dry needling. Acupuncture needles with guide tubes that were 40mm in length and 0.25 mm in diameter were used. The needling for the paraspinal multiple deep intramuscular stimulation therapy (MDIMST) was applied to the dermatomes, myotome, or sclerotome where the trigger points were found. For trigger point deep dry needling, the needle was inserted directly into the trigger point or the palpable taut band. A local twitch response confirmed that the needle was placed in a taut band or trigger point. A maximum of stimulation time was of 1 minute per trigger point and 3 minutes per MDIMST was permitted. There were two sessions a week. Duration 4 weeks.

	Concurrent medication/care: Not reported. Indirectness: No indirectness. (n=26) Intervention 2: Placebo/sham - Placebo. An electroacupuncture device was used which was adjusted beforehand to prevent the current from passing through the electrodes. The electrical connection between the stimulator and the patient was broken at the output jack plug of the stimulator so that no current could pass to the patient. The patients were informed that this was a high frequency low intensity stimulation and that they would most likely feel no sensation from it. The paraspinal electrodes were placed over the dermatomes, myotome, or sclerotome where the trigger point were found and also over the main painful trigger points or tender spots at the muscle taut band, and the nerve stimulation until was left in front of the patient for 30 minutes. The positioning ensured that the flashing diode that simulated the electrical stimulus was visible and audible. Duration 4 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness.
Funding	Academic or government funding (Grants from: The Committee for the Development of Higher education Personnel, the National Council for Scientific and Technological Development, and the Foundation of Support of Research at Rio Grande do Sul)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DRY NEEDLING versus PLACEBO

Protocol outcome 1: Health related quality of life
- Actual outcome: Quality of life - physical health at End of treatment; Group 1: mean 55.04 (SD 10.99); n=26, Group 2: mean 45.11 (SD 10.2); n=26; SF12 0-100 Top=High is good outcome; Comments: Baseline: dry needling 40.12 (10.47); placebo 43.73 (10.28)
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness
- Actual outcome: Quality of life - mental health at End of treatment; Group 1: mean 50.79 (SD 12.14); n=26, Group 2: mean 65.96 (SD 10.93); n=26; SF12 0-100 Top=High is good outcome; Comments: Baseline: dry needling 50.38 (11.82); placebo 51.78 (10.63)
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness

Protocol outcome 2: Pain reduction
- Actual outcome: Pain at End of treatment; Group 1: mean 2.48 (SD 1.48); n=26, Group 2: mean 4.494 (SD 1.54); n=26; VAS 0-10 Top=High is poor outcome; Comments: Baseline: dry needling 6.61 (1.25); placebo 6.66 (0.78)
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness

Protocol outcome 3: Sleep
- Actual outcome: Sleep quality of the previous night compared with habitual sleep at End of treatment; Group 1: mean 6.27 (SD 1.04); n=26, Group 2: mean 4.79 (SD

1.48); n=26; VAS 0-10 Top=High is good outcome; Comments: Baseline not reported Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness Protocol outcome 4: Discontinuation - Actual outcome: Discontinuation at End of treatment; Group 1: 1/25, Group 2: 1/25 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Psychological distress ; Use of healthcare services ; Physical function

Study	Deluze 1992[49]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=70)
Countries and setting	Conducted in Switzerland; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention time: 3 weeks
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients with fibromyalgia defined by the American College of Rheumatology (widespread pain, mild or greater tenderness in 11 or more of 18 tender point sites) were admitted to the study
Exclusion criteria	Severe concomitant disease, treatment with morphine-like drugs or anticoagulants, peripheral neuropathy, bleeding disorders, language difficulties, and past treatment with acupuncture
Recruitment/selection of patients	Patients referred to divisions for fibromyalgia
Age, gender and ethnicity	Age - Mean (SD): acupuncture 46.8 (2.3); control 49 (2). Gender (M:F): 16/54. Ethnicity: Not reported
Extra comments	Duration of pain (years): acupuncture 14.4 (3.7); control 6.9 (1.3)
Indirectness of population	No indirectness
Interventions	(n=36) Intervention 1: Acupuncture - Electro acupuncture. Treatment consisted of six sessions of electroacupuncture spread over three weeks. An electrostimulator (Unipuls, Seirin AG, Neu-Isenburg, Germany) with five pairs of electrodes was used. The current was rectangular with a biphasic top out voltage of 10 volts at 1000 ohm and frequency 1-99 Hz with continuous scanning of the frequency spectrum; every 250 ms an interval of 250 ms was programmed. Intensity of the current was maximally 10 mA, which is above the perception threshold but just below the pain threshold and induces a visible muscular contraction. Four to 10 stainless steel needles (0 3 mm by 25 mm, excluding the handle), autoclaved before use, were implanted to a depth of 10-25 mm and fixed with tape. Depth of insertion was determined according to the sensitivity of the site ("needling sensation") as indicated by the patient. In patients having electroacupuncture four common acupuncture points were used-the first dorsal interosseous muscle of

	the hand and the anterior tibial muscle (5 cm beneath the inferior margin of the patella and 1 cm below the anterior crest of the tibia) on both sides. At most six other sites were chosen depending on the patient's symptoms and pain pattern and according to the empirical efficacy of the sites in the treatment of pain. Duration 3 weeks. Concurrent medication/care: The patients continued with their other usual treatments (physiotherapy, analgesics, anti-inflammatory agents, tricyclic anti-depressants). Indirectness: No indirectness. (n=34) Intervention 2: Placebo/sham - Sham. In the controls a similar number of needles were used but they were put about 20 mm away from the point which would have been chosen for real electro-acupuncture, including the four points common to all patients. The needles were inserted to a depth of 3-4 mm and fixed with tape. The current used was similar to but weaker than that used in the real procedure. No increase was made after the threshold of perception had been reached. There was no muscular contraction. Duration 3 weeks. Concurrent medication/care: The patients continued with their other usual treatments (physiotherapy, analgesics, anti-inflammatory agents, tricyclic anti-depressants). Indirectness: No indirectness.
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ELECTRO ACUPUNCTURE versus SHAM

Protocol outcome 1: Pain reduction
- Actual outcome: Pain at End of treatment; Group 1: mean 39.89 (SD 26.3); n=28, Group 2: mean 53.78 (SD 22.71); n=27; VAS 0-100 Top=High is poor outcome;
Comments: Baseline: acupuncture 56.61 (16.88); sham 60.89 (21.15)
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Baseline details: Number of men/women; duration of disease; Group 1 Number missing: 8; Group 2 Number missing: 7

Protocol outcome 2: Sleep
- Actual outcome: Sleep at End of treatment; Group 1: mean 5.96 (SD 2.49); n=28, Group 2: mean 4.85 (SD 2.23); n=27; VAS 0-10 Top=High is good outcome;
Comments: baseline: acupuncture 4.11 (1.69); sham 4.7 (1.97)
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Baseline details: Number of men/women; duration of disease; Group 1 Number missing: 8; Group 2 Number missing: 7

Protocol outcome 3: Discontinuation
- Actual outcome: Discontinuation at End of treatment; Group 1: 8/36, Group 2: 7/34
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Baseline details: Number of men/women; duration of disease

Health related quality of life ; Psychological distress ; Use of healthcare services ; Physical function	
Protocol outcomes not reported by the study	

Study	Edwards 2003[55]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=40)
Countries and setting	Conducted in United Kingdom; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3 weeks + 3 weeks
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged 18 and over; presence of active TrP identifiable by a) spot tenderness in a taut muscular band, b) subject recognition of pain on palpation, c) painful limitation of affected muscle's full range of movement, d) LTR, e) pain in expected distribution (a, b, c essential to inclusion; d and e not essential but used to confirm diagnosis); patient agrees not to receive additional treatment for their painful condition during the trial (apart from NSAIDs and pain killers); patient is capable of complying with the trial
Exclusion criteria	Acute condition requiring treatment before six weeks; skin lesion, infection or inflammatory oedema at TrP site; needle phobia; previous adverse reaction to acupuncture or anaesthetic; serious neurological or systemic disorder
Recruitment/selection of patients	Patients that were referred for physiotherapy by five GPs at an inner city Lancaster practice
Age, gender and ethnicity	Age - Mean (SD): acupuncture 57 (12); usual care 56 (18). Gender (M:F): 12/28. Ethnicity: Not reported
Extra comments	Duration of pain (months): acupuncture 16 (23); usual care 13 (14.46)
Indirectness of population	No indirectness
Interventions	(n=14) Intervention 1: Acupuncture. Patients received a course of superficial dry needling to affected TrPs, followed by appropriate stretching exercises to be continued at home. Exercises used were those recommended by Simons et al. TrPs implicated in the condition were palpated and marked with a small dot on the skin at each treatment session, then needled in turn, usually working from proximal to distal. Sterile stainless steel acupuncture needles (25 x 0.30mm) with

	coiled copper handles and plastic guide tubes were used (Helio Medical Supplies, Inc.). The needle was inserted to the depth allowed by the guide tube (4mm). If not secured into the skin, further gentle pressure was applied, fractionally increasing penetration. The needle was not manipulated or stimulated and was left in situ until any sensations experienced by the patient, following needle insertion, had subsided. The duration of needle retention was recorded. The number of attendances over the three week treatment depended on the severity of condition and patient / therapist convenience, as is normal physiotherapy practice. Patients were advised on correction of daytime or sleeping postures if contributing to TrP activation. Following the three weeks' intervention, patients had no treatment for three weeks, but continued with home regimes. Duration 3 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness. (n=26) Intervention 2: Usual care - Usual care. 13 patients received instruction in appropriate stretching exercises, as recommended by Simons et al, for involved muscle(s) containing TrPs. As with acupuncture patients they were asked to carry out home exercises, repeating three stretches three times daily. The importance of relaxing muscles between stretches was stressed. Follow up appointments were made to check / alter exercises according to the condition. Patients were advised on correction of daytime or sleeping postures if contributing to TrP activation. Following the three weeks' intervention, patients had no treatment for three weeks, but continued with home regimes. 13 patients received no treatment. Duration 3 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness.
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus USUSAL CARE Protocol outcome 1: Pain reduction - Actual outcome: Pain at 6 weeks; Group 1: mean 9.1 (SD 11.6); n=14, Group 2: mean 15.05 (SD 9.96); n=26; SF McGill Pain Questionnaire Unclear Top=High is poor outcome; Comments: Baseline: acupuncture 24.3 (6.3); usual care 21.65 (7.66) Risk of bias: All domain - High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness Protocol outcome 2: Discontinuation - Actual outcome: Discontinuation at 6 weeks; Group 1: 0/14, Group 2: 0/26 Risk of bias: All domain - High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Health related quality of life ; Psychological distress ; Use of healthcare services ; Sleep ; Physical function

Study	Harris 2005[83]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=114)
Countries and setting	Conducted in USA; Setting: Not specified
Line of therapy	Unclear
Duration of study	Intervention time: 9 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: ACR criteria for fibromyalgia
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	(1) widespread pain for more than 50% of the time (2) met ACR criteria for FM
Exclusion criteria	Previous acupuncture treatments including sufficient knowledge that would prevent blinding, bleeding diathesis, autoimmune or inflammatory disease, daily narcotic analgesic use or a history of substance abuse, contraindication to use of acetaminophen or ibuprofen, in other clinical studies, pregnancy or lactation, receiving disability payment or litigation related to fibromyalgia
Recruitment/selection of patients	Washington DC metropolitan area
Age, gender and ethnicity	Age - Mean (SD): 46 (10.1) years. Gender (M:F): Define. Ethnicity: 90% White, 5% African American, 5% other
Extra comments	Mean pain duration 5.5(3.71) years. Acupuncture naive patients
Indirectness of population	No indirectness
Interventions	(n=29) Intervention 1: Acupuncture. Traditional acupuncture sites with manual needle stimulation. The active point formula (Du 20, LI 11, LI 4, GB 34, bi- lateral St 36, Sp 6, Liv 3, and Ear-Shenmen) was chosen based on the points' ability to relieve FM symptoms in Traditional Chinese Medicine. Total of 18 treatments over 9 weeks (3 weeks of 1 treatment per week, 2 treatments per week and 3 treatments per week). Duration 9 weeks. Concurrent medication/care: Co-interventions: participants were allowed to continue normal treatments including antidepressants. They were not allowed to make any changes during the trial and not to seek acupuncture outside of the trial. Indirectness: No indirectness Further details: 1. Acupuncture or dry needling: Acupuncture

	(n=85) Intervention 2: Placebo/sham - Sham. 3 different interventions (pooled in the analysis): Non-traditional points with stimulation (n=28) Traditional points without stimulation (n=30) Non-traditional points without stimulation (n= 27). Duration 9 weeks. Concurrent medication/care: participants were allowed to continue normal treatments including antidepressants. They were not allowed to make any changes during the trial and not to seek acupuncture outside of the trial. Indirectness: No indirectness Further details: 1. Acupuncture or dry needling: Acupuncture
Funding	Academic or government funding (NIH grant)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus SHAM

Protocol outcome 1: Health related quality of life
- Actual outcome: SF-36 physical component summary at 9 weeks; Group 1: mean 35.91 (SD 7.96); n=22, Group 2: mean 39.55 (SD 9.52); n=54; SF-36 summary score 0-100 Top=High is good outcome; Comments: Baseline: 31.8(7.35); 37.1(8.7)
Risk of bias: All domain - Very high, Selection - Low, Blinding - Low, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 7; Group 2 Number missing: 31
- Actual outcome: SF-36 physical component summary at 15 weeks; Group 1: mean 34.73 (SD 8.64); n=22, Group 2: mean 39.79 (SD 10.02); n=54; SF-36 summary score 0-100 Top=High is good outcome; Comments: Baseline: 31.8(7.35); 37.1(8.7)
Risk of bias: All domain - Very high, Selection - Low, Blinding - Low, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 7; Group 2 Number missing: 31

Protocol outcome 2: Pain reduction
- Actual outcome: NRS at 9 weeks; Group 1: mean 48.26 (SD 28.59); n=22, Group 2: mean 52.51 (SD 27.84); n=54; NRS 0-100 Top=High is poor outcome; Comments: Baseline: 56.46(20.46); 54.6 (22.59)
Risk of bias: All domain - Very high, Selection - Low, Blinding - Low, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 7; Group 2 Number missing: 31
- Actual outcome: NRS at 15 weeks; Group 1: mean 54.17 (SD 32.09); n=22, Group 2: mean 51.68 (SD 25.24); n=54; NRS 0-100 Top=High is poor outcome; Comments: Baseline: 56.46(20.46); 54.6 (22.59)
Risk of bias: All domain - Very high, Selection - Low, Blinding - Low, Incomplete outcome data - Very high, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 7; Group 2 Number missing: 31

Protocol outcome 3: Discontinuation
- Actual outcome: Discontinuation at 9 weeks; Group 1: 7/29, Group 2: 31/85
Risk of bias: All domain - Low, Selection - Low, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;

Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Psychological distress; Use of healthcare services; Sleep; Physical function

Study	He 2004[86], He 2005 [85]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=24)
Countries and setting	Conducted in Norway; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3-4 weeks + 3 years
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Women aged between 20-50 years old, having worked in sedentary occupations or being engaged in light repetitive activities. Their perceived pain in the neck and shoulder regions was so severe that the subjects' work and spare time activities were affected, but none of the subjects were on a sick leave at the start of the study. The chronic pain was taken as being experienced for at least 3 months during the last year.
Exclusion criteria	Persons with diabetes, neurological, rheumatologic, or other diseases were excluded, as were pregnant and breast feeding women
Recruitment/selection of patients	Recruited from 5 large companies in Oslo by the company's occupational physician
Age, gender and ethnicity	Age - Mean (SD): acupuncture 48 (8); sham 45 (10). Gender (M:F): Female only. Ethnicity: Not reported
Extra comments	Duration of pain (years): acupuncture 12 (8); placebo 12 (10)
Indirectness of population	No indirectness
Interventions	(n=14) Intervention 1: Acupuncture - Electro acupuncture. Acupuncture treatment was a combination of body acupuncture, body electroacupuncture and ear acupressure. Altogether 16 body acupoints and 6 ear acupoints were used. Each participant received 3 treatments per week (total of 10 treatments), each treatment lasted 45 minutes. Real acupuncture was on acupoints assumed to have a positive effect on chronic pain in the neck and shoulder regions. Electrodes of the electroacupuncture instrument were first placed on the body acupoints of the neck and shoulder areas. The stimulation for each pulse was approximately half of a sinus wave lasting 100µs and with amplitude of 170-

	200 V followed by ringing with an amplitude ≤40 V decaying exponentially to a non-detectable level within 10 ms. The stimulation frequency was 5Hz, and each electroacupuncture treatment lasted 30 minutes. After the electro-stimulation was started sterile acupuncture needles 25-40mm long and with a diameter of 0.25-0.35 mm were inserted bilaterally in three body points, and the depth of insertion was 10-30 mm. The needles were kept on the points for 30 minutes and rotated every 5 minutes. After the electrodes and needles were removed, plant seeds were placed of 6 ear acupoints for acupressure. Each seed was kept in place by a piece of 6 x 6 mm tape until the next treatment. The subjects were instructed to press on each of the ear acupoints a series of 100 repeats 4 times a day. Duration 3-4 weeks. Concurrent medication/care: Not reported. Indirectness: Serious indirectness; Indirectness comment: Included acupressure and body acupuncture. (n=10) Intervention 2: Placebo/sham - Placebo. Electroacupuncture was carried out without applying any voltage. However the instrument did send a short beep at each pulse given, thus giving an auditive signal that a pulse has been sent. During the sham electroacupuncture the instrument still sent beeps but no voltage. The body acupuncture was applied to points 10-40 mm distal to presumed real acupoints, and ear acupressure was applied on points 4-6mm below presumed real acupoints. Apart from the different sites of points and electroacupuncture voltage used there were no differences in the treatment procedures between the groups. Duration 3-4 weeks. Concurrent medication/care: Not reported. Indirectness: Serious indirectness.
Funding	Academic or government funding (Main author has PhD scholarship from the Norwegian Research Council)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ELECTRO ACUPUNCTURE versus PLACEBO Protocol outcome 1: Pain reduction - Actual outcome: Pain at Post treatment; Group 1: mean 15 (SD 5); n=14, Group 2: mean 36 (SD 8); n=10; VAS 0-100 Top=High is poor outcome; Comments: Baseline: electroacupuncture 57 (7); placebo 48 (9) Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness - Actual outcome: Pain at 3 years; Group 1: mean 19 (SD 6); n=14, Group 2: mean 44 (SD 11); n=10; VAS 0-100 Top=High is poor outcome; Comments: Baseline: electroacupuncture 57 (7); placebo 48 (9) Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Health related quality of life ; Psychological distress ; Use of healthcare services ; Sleep ; Discontinuation ; Physical function

Study	Ilbuldu 2004[93]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=40)
Countries and setting	Conducted in Turkey; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 4 weeks + 6 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	People with trigger points in the upper trapezius muscle. The major criteria for myofascial pain syndrome are as follows: local pain; pain and sensory difference that refers from the TP; palpable taut band in the muscles that can be reached; extreme sensitivity in one point along the taut band; limitation of measurable range of motion. Minor criteria are the following: appearance of clinical pain complaint and/or sensitivity difference with forceful palpation of TP; local twitch response with palpation or needling of the sensitive point in the taut band; decrease of pain with injection into the sensitive point or stretching of the muscle
Exclusion criteria	Patients who had a tumour, infectious disease, stage 3 and 4 osteoarthritis, pregnancy, scoliosis, bleeding diathesis, and chronic obstructive lung disease
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Mean (SD): Dry needling 35.29 (9.18); placebo 32.35 (6.88). Gender (M:F): Female only. Ethnicity: Not reported
Extra comments	Duration of pain (months): dry needling 38.48 (31.94); placebo 36.95 (33.65)
Indirectness of population	No indirectness
Interventions	(n=20) Intervention 1: Dry needling. Dry needling was applied to the upper trapezius trigger points with a 0.25 x 25 size acupuncture needle once a week for 4 weeks. Duration 4 weeks. Concurrent medication/care: Paracetamol as analgesic was prescribed to the patients when they had pain. Upper and middle trapezius and pectoral muscle stretching exercises were shown to all of the participants. They were required to exercise regularly during the treatment period.

	Indirectness: No indirectness. (n=20) Intervention 2: Placebo/sham - Placebo. Placebo laser was applied to the upper trapezius trigger points three times a week by applying the probe on the trigger point only. The machine was turned on and set but no beam was applied. Duration 4 weeks. Concurrent medication/care: Paracetamol as analgesic was prescribed to the patients when they had pain. Upper and middle trapezius and pectoral muscle stretching exercises were shown to all of the participants. They were required to exercise regularly during the treatment period. Indirectness: No indirectness.
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DRY NEEDLING versus PLACEBO

Protocol outcome 1: Health related quality of life
- Actual outcome: Nottingham Health Profile - pain at End of treatment; Group 1: mean 33.86 (SD 28.37); n=20, Group 2: mean 32.16 (SD 28.4); n=20; Nottingham Health Profile 0-100 Top=High is poor outcome; Comments: Baseline: dry needling 70.01 (30.71); placebo 60.42 (31.39)
Risk of bias: All domain - Very High, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: dry needling 70.01 (30.71); placebo 60.42 (31.39);
- Actual outcome: Nottingham Health Profile - pain at 6 months; Group 1: mean 32.66 (SD 35.15); n=20, Group 2: mean 27.89 (SD 23.65); n=20; Nottingham Health Profile 0-100 Top=High is poor outcome; Comments: Baseline: dry needling 70.01 (30.71); placebo 60.42 (31.39)
Risk of bias: All domain - Very High, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: dry needling 70.01 (30.71); placebo 60.42 (31.39);
- Actual outcome: Nottingham Health Profile - physical activity at End of treatment; Group 1: mean 23.07 (SD 19.09); n=20, Group 2: mean 19.35 (SD 14.14); n=20; Nottingham Health Profile 0-100 Top=High is poor outcome; Comments: Baseline: dry needling 32.8 (15.71); placebo 25.59 (17.73)
Risk of bias: All domain - Very High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ;
- Actual outcome: Nottingham Health Profile - physical activity at 6 months; Group 1: mean 13.68 (SD 16.62); n=20, Group 2: mean 16.08 (SD 17.43); n=20; Nottingham Health Profile 0-100 Top=High is poor outcome; Comments: Baseline: dry needling 32.8 (15.71); placebo 25.59 (17.73)
Risk of bias: All domain - Very High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ;
- Actual outcome: Nottingham Health Profile - fatigue at End of treatment; Group 1: mean 57.1 (SD 38.78); n=20, Group 2: mean 47.16 (SD 42.07); n=20; Nottingham health profile 0-100 Top=High is poor outcome; Comments: Baseline: dry needling 75.24 (34.81); placebo 59.44 (45.51)
Risk of bias: All domain - Very High, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: dry needling 75.24 (34.81); placebo 59.44 (45.51);
- Actual outcome: Nottingham Health Profile - fatigue at 6 months; Group 1: mean 44.85 (SD 40.91); n=20, Group 2: mean 43.2 (SD 41.54); n=20; Nottingham Health Profile 0-100 Top=High is poor outcome; Comments: Baseline: dry needling 75.24 (34.81); placebo 59.44 (45.51)
Risk of bias: All domain - Very High, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover -

Low; Indirectness of outcome: No indirectness ; Baseline details: dry needling 75.24 (34.81); placebo 59.44 (45.51);
- Actual outcome: Nottingham Health Profile - sleep at End of treatment; Group 1: mean 29.6 (SD 31.11); n=20, Group 2: mean 16.08 (SD 21.06); n=20; Nottingham Health Profile 0-100 Top=High is poor outcome; Comments: Baseline: dry needling 38.86 (35.35); placebo 37.3 (29.58)
Risk of bias: All domain - Very High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ;
- Actual outcome: Nottingham Health Profile - sleep at 6 months; Group 1: mean 22.74 (SD 32.02); n=20, Group 2: mean 20.55 (SD 23.61); n=20; Nottingham Health Profile 0-100 Top=High is poor outcome; Comments: Baseline: dry needling 38.86 (35.35); placebo 37.30 (29.58)
Risk of bias: All domain - Very High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ;
- Actual outcome: Nottingham Health Profile - social isolation at End of treatment; Group 1: mean 11.22 (SD 21.66); n=20, Group 2: mean 11.81 (SD 25.6); n=20; Nottingham Health Profile 0-100 Top=High is poor outcome; Comments: Baseline: dry needling 29.43 (32.03); placebo 22.13 (35.48)
Risk of bias: All domain - Very High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ;
- Actual outcome: Nottingham Health Profile - social isolation at 6 months; Group 1: mean 13.8 (SD 15.68); n=20, Group 2: mean 13.22 (SD 32.17); n=20; Nottingham Health Profile 0-100 Top=High is poor outcome; Comments: Baseline: dry needling 29.43 (32.03); placebo 22.13 (35.48)
Risk of bias: All domain - Very High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ;
- Actual outcome: Nottingham Health Profile - emotional reaction at End of treatment; Group 1: mean 21.72 (SD 23.67); n=20, Group 2: mean 23.09 (SD 27.5); n=20; Nottingham Health Profile 0-100 Top=High is poor outcome; Comments: Baseline: dry needling 45.96 (35.74); placebo 31.13 (33.56)
Risk of bias: All domain - Very High, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: dry needling 45.96 (35.74); placebo 31.13 (33.56);
- Actual outcome: Nottingham Health Profile - emotional reaction at 6 months; Group 1: mean 16.98 (SD 27.47); n=20, Group 2: mean 17.13 (SD 31.17); n=20; Nottingham health profile 0-100 Top=High is poor outcome; Comments: Baseline: dry needling 45.96 (35.74); placebo 31.13 (33.56)
Risk of bias: All domain - Very High, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: dry needling 45.96 (35.74); placebo 31.13 (33.56)

Protocol outcome 2: Pain reduction
- Actual outcome: Pain at End of treatment; Group 1: mean 3.71 (SD 2.33); n=20, Group 2: mean 3.65 (SD 2.03); n=20; VAS 0-10 Top=High is poor outcome; Comments: Baseline: dry needling 5.10 (1.97); placebo 5.70 (1.81)
Risk of bias: All domain - Very High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ;
- Actual outcome: Pain at 6 months; Group 1: mean 2.59 (SD 2.18); n=20, Group 2: mean 2.89 (SD 2.63); n=20; VAS 0-10 Top=High is poor outcome; Comments: Baseline: dry needling 5.10 (1.97); placebo 5.70 (1.81)
Risk of bias: All domain - Very High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness

Psychological distress ; Use of healthcare services ; Sleep ; Discontinuation ; Physical function	
Protocol outcomes not reported by the study	

Study	Itoh 2014[101]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=16)
Countries and setting	Conducted in Japan; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 5 weeks + 20 weeks
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	(1) shoulder pain lasting for >6 months; (2) no neurological disorders causing shoulder pain; (3) an average pain score of 50 mm or on a 100-mm visual analogue scale (VAS) in the pre month; (4) age between 40 years and 70 years; (5) no referred pain from the cervical spine; (6) no osteoarthritis of the glenohumeral joint or systemic bone and joint disorder (e.g., rheumatoid arthritis); (7) no history of shoulder surgery; (8) no other current therapy involving analgesics; (9) had not received acupuncture in the last 6 months; and (10) insufficient response to the medications prescribed by their orthopaedic specialist
Exclusion criteria	Major trauma or systemic disease, and other conflicting or ongoing treatments
Recruitment/selection of patients	Recruited from the Meiji University of Integrative Medicine Hospital
Age, gender and ethnicity	Age - Mean (SD): Acupuncture 55 (12.6); sham 59.3 (15.6). Gender (M:F): 3/15. Ethnicity: Not reported
Extra comments	Duration of pain (years): acupuncture 2.1 (1.6); sham 2.2 (1.6)
Indirectness of population	No indirectness
Interventions	(n=8) Intervention 1: Acupuncture. The trigger point acupuncture group received acupuncture treatment at trigger points. The correct application of the technique required experience in palpation and localisation of taut muscle bands and myofascial trigger points. Precise needling of active myofascial trigger points provokes a brief contraction of muscle fibres. This local twitch response should be elicited for successful therapy but it may be painful. The most important muscles of the neck and superior limb were examined for myofacial trigger points. Disposable stainless steel needles (0.2x50mm) were inserted into the skin over the trigger point to a depth of 5-15mm, appropriate to the muscle

	targeted, attempting to elicit a local muscle twitch response using the so called sparrow pecking technique. After the local twitch response was elicited, or a reasonable attempt made, the needle was retained for a further 10 minutes. The mean number of needle insertions was 4.1. Patients had 5 treatments, once a week for 30 minutes. Duration 5 weeks. Concurrent medication/care: The patients could continue to use their medications as they had before enrolment. Indirectness: No indirectness. (n=8) Intervention 2: Placebo/sham - Sham. The sham (SH) group received SH treatment at trigger points. The methods of choosing trigger points were the same. For the SH group, similar stainless steel needles (0.2 mm □ 50 mm) were used, but the tips had been cut off to prevent the needle from penetrating the skin. The cut ends were smoothed with sandpaper manually under clean conditions. The acupuncturist pretended to insert and manipulate the needle: place the needle with a guide tube over the designated point and tap the top of the needle handle and then remove the tube while holding the needle tip with the thumb and the forefinger of the left hand and thrust and withdraw the needle with the right hand, which holds the needle handle (sparrow pecking technique). A simulation of needle extraction was performed after 10 minutes, by touching the patient and noisily dropping needles into a metal case. The mean number of insertions was 4.4. Patients had 5 treatments, once per week for 30 minutes. Duration 5 weeks. Concurrent medication/care: Patients could continue to use their medications as they had before enrolment. Indirectness: No indirectness.
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus SHAM Protocol outcome 1: Discontinuation - Actual outcome: Discontinuation at 1 month; Group 1: 0/8, Group 2: 1/8 Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Health related quality of life ; Physical function ; Psychological distress ; Use of healthcare services ; Sleep ; Pain reduction

Study	Karatay 2018[111]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=75)
Countries and setting	Conducted in Turkey; Setting: Physical Medicine and Rehabilitation Department
Line of therapy	Not applicable
Duration of study	Intervention + follow up: 4 weeks + 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: 1990 American College of Rheumatology (ACR) FM criteria
Stratum	Overall: NA
Subgroup analysis within study	Not applicable: NA
Inclusion criteria	Female patients with fibromyalgia (20-50 years)
Exclusion criteria	People who had taken nonsteroidal anti-inflammatory drugs, selective serotonin reuptake inhibitors, tricyclic antidepressant or any antidepressant drugs in the previous 15 days, and who smoked, who had a bleeding diathesis or painful medical conditions other than FM, patients who had prior experience with any acupuncture therapy
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Range: 20-50 years . Gender (M:F): 0/75. Ethnicity: not reported
Indirectness of population	No indirectness: NA
Interventions	(n=25) Intervention 1: Acupuncture. Acupuncture treatment was performed on 18 acupoints designed to treat FM with 0.25 mm stainless steel needles. These standardized acupoints were Du-14 (Da Zhui), Si-15 (Jian Zhong Shu), Li-4 (He Gu), Li-11 (Qu Chi), H-7 (Shen Men), P-6 (Nei Guan), Ren-6 (Qihai), Liv-3 (Tai Chong), St-36 (Zu San Li), and Sp-6 (San Yin Jiao). They were used bilaterally, except Du-14 and Ren-6 points. Duration 8 x 30 minute sessions over 4 weeks. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA Further details: 1. Acupuncture or dry needling: Acupuncture. (n=25) Intervention 2: Placebo/sham - Sham. 18 needles, the same size as the AcG's needles, were inserted into 18 sham points that are not recognized as acupoints or in meridians. These sham points were defined by using an acupuncture point search dedector approximately 1–2cm from AcG's acupoints. The points, which have lower signals than acupoints according to the dedector, were used as sham points. Duration 8 x 30 minute sessions over 4 weeks.

	Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA Further details: 1. Acupuncture or dry needling: Acupuncture. (n=25) Intervention 3: Placebo/sham - Placebo. 18 identical real acupoints with the AcG were used. Non-insertive simulated acupuncture was performed. First, a small circular adhesive bandage was applied on an acupoint. Then, a short needle (0.25□15 mm) was inserted into the bandage but not into the skin. In this group, short needles were preferred, so that patients assumed that the needles had been inserted into the skin. While the needles were inserted into acupoints and sham points, they were not inserted into the points of the SiG. Also, small circular adhesive bandages were used in all groups to ensure the same appearance among patients. Duration 8 x 30 minute sessions over 4 weeks. Concurrent medication/care: not reported. Indirectness: No indirectness; Indirectness comment: NA Further details: 1. Acupuncture or dry needling : Acupuncture.
Funding	No funding

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus SHAM

Protocol outcome 1: Health related quality of life
- Actual outcome: FIQ final values at Post-intervention; Group 1: mean 43.64 (SD 18.2); n=24, Group 2: mean 57.05 (SD 21.19); n=48; FIQ 0-100 Top=High is poor outcome
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ;

Protocol outcome 2: Pain reduction
- Actual outcome: VAS pain reduction at Post-intervention; Group 1: mean 4.47 (SD 2.62); n=24, Group 2: mean 7.58 (SD 2.41); n=48; VAS 0-10 Top=High is poor outcome
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ;

Protocol outcome 3: Psychological distress
- Actual outcome: Beck depression inventory at Post-intervention; Group 1: mean 10.13 (SD 8.18); n=24, Group 2: mean 33.27 (SD 17.12); n=23; BDI 0-61 Top=High is poor outcome
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ;

Protocol outcome 4: Sleep
- Actual outcome: Nottingham hill profile sleep subscale at Post-intervention; Group 1: mean 9.7 (SD 19.95); n=24, Group 2: mean 55.29 (SD 39.19); n=48

Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Protocol outcome 5: Discontinuation - Actual outcome: Discontinuation at Post-intervention; Group 1: 1/25, Group 2: 2/50 Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ;	
Protocol outcomes not reported by the study	Use of healthcare services; Physical function

Study	Lee 2011[126]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=90)
Countries and setting	Conducted in Malaysia; Setting: Urology clinic
Line of therapy	Unclear
Duration of study	Intervention time: 10 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: National Institutes of Health Chronic Prostatitis Symptom Index
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Men aged ≥20 years with a National Institutes of Health Chronic Prostatitis Symptom Index total score ≥15 and symptoms for 3 or more months within the preceding 6 months
Exclusion criteria	Bacterial prostatitis, urinary tract infection within 1 year, any traditional or complimentary alternative medicine treatment within 6 weeks, or any consensus CP/CPPS exclusion criterion
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Mean (SD): acupuncture 40.9 (11); sham 42.8 (9.4). Gender (M:F): Men only. Ethnicity: Not reported
Extra comments	Duration of pain (months): acupuncture 22.4 (28.4); sham 27.5 (26.9)
Indirectness of population	No indirectness
Interventions	(n=45) Intervention 1: Acupuncture. Treatment points were prepared with 70% alcohol prep pads. Sterile stainless steel disposable 0.3 x 25 mm, 0.3 x 40 mm, 0.3 x 50 mm or 0.3 x 60 mm needles were used. Acupuncture points for CP/CPPS that were most cited as efficacious included: CV1, CV4, SP6, and SP9. Needle stimulation, herbal medicines or other acupuncture approaches were not employed. Each needle placement lasted for 30 minutes with participants in the supine position. There were two treatments per week. Duration 10 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness. (n=45) Intervention 2: Placebo/sham - Sham. Shallow needling at sites corresponding to the selected acupoints but off

	the site of each meridian point was employed. All other variables were kept similar to the acupuncture treatment. Duration 10 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness.
Funding	Academic or government funding (NIH grants, National Institutes of Health)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus SHAM Protocol outcome 1: Pain reduction - Actual outcome: Pain at End of treatment; Group 1: mean 2.5 (SD 1.4); n=44, Group 2: mean 1.8 (SD 1.5); n=45; VAS 0-10 Top=High is poor outcome; Comments: Baseline: acupuncture 3.8 (2.3); sham 2.1 (2) Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Baseline: acupuncture 3.8 (2.3); sham 2.1 (2); Group 1 Number missing: 1; Group 2 Number missing: 0 Protocol outcome 2: Discontinuation - Actual outcome: Discontinuation at End of treatment; Group 1: 1/45, Group 2: 0/45 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Baseline: acupuncture 3.8 (2.3); sham 2.1 (2)	
Protocol outcomes not reported by the study	Health related quality of life ; Psychological distress ; Use of healthcare services ; Sleep ; Physical function

Study	Liang 2011[131]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=190)
Countries and setting	Conducted in China; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3 weeks + 3 months
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Male or female adult aged 18-60 years; neck pain or stiffness in neck and shoulder, frequent attack with more than one monthly recurrence, the symptoms continued for 6 months or more; the score of baseline assessment by visual analogue scale was between 3-7; not receiving acupuncture for neck pain within the latest 6 months; willing to join the study and sign an informed consent document
Exclusion criteria	Had received acupuncture due to neck pain in the past 6 months; were unwilling to follow the study protocol for treatment or provide informed consent; had a history of cervical or thoracic vertebra trauma, or had received surgery on the neck or had systematic neurological, skeletal disorders; were afraid of acupuncture treatment; were pregnant or breast feeding; had severe medical disease or cancer
Recruitment/selection of patients	Leaflets given to patients of an outpatient clinic
Age, gender and ethnicity	Age - Mean (SD): acupuncture 36.72 (10.21); control 37.25 (9.56). Gender (M:F): 49/129. Ethnicity: Not reported
Extra comments	Duration of pain (unit not reported): acupuncture 50.43 (49.61); control 44.89 (36.78)
Indirectness of population	No indirectness
Interventions	(n=93) Intervention 1: Acupuncture. Participants received traditional acupuncture on classic acupuncture points. Acupuncture point selection was based on the consensus of senior Chinese medicine doctors, and acupuncturists in the hospital, and included DU14, SI15, and Ex-HN15 (all selected bilaterally) in the cervical region. Disposable stainless steel needles (0.3mm x 40 mm) were inserted into the muscle to a depth of 20mm by well-trained acupuncture doctors with the tube guide method. The doctor would manipulate the inserted needles till the patient felt numbness or other

	acupuncture sensation, and the needles left in place for 20 minutes. During the treatment, the patients received infrared irradiation on the cervical region. The intervention lasted for 3 weeks with 9 sessions. Duration 3 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness. (n=97) Intervention 2: Placebo/sham - Placebo. Participants received placebo acupuncture on the sham points which were 1cm lateral to the standard acupuncture points selected in the study group. Disposable stainless steel needles (0.18mm x 40mm) which were identical in appearance to those used in the study group were applied. The needles were inserted into the skin to a depth of approximately 3mm, and remained in the subcutaneous tissues for 20 minutes. The doctor used tube guided method, and any manipulation for acupuncture sensation or de qi was forbidden. Patients also received infrared irradiation on the cervical region, and the intervention lasted for 3 weeks with 9 sessions. Duration 3 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness.
Funding	Academic or government funding (Funded by the research project the Eleventh Five-year Scientific Project and supported by the State Ministry of Science and Technology and the Scientific project supported by Guangdon Provincial Administration of Science and Technology)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus PLACEBO

Protocol outcome 1: Health related quality of life
- Actual outcome: Quality of life - physical function at 3 months; Group 1: mean 84.26 (SD 15.24); n=88, Group 2: mean 85.88 (SD 14.01); n=90; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 80.79 (14.83); placebo 79.22 (19.13)
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 7
- Actual outcome: Quality of life - role physical at 3 months; Group 1: mean 76.13 (SD 31.69); n=88, Group 2: mean 82.22 (SD 29.8); n=90; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 57.10 (40.10); placebo 62.77 (34.80)
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 7
- Actual outcome: Quality of life - bodily pain at 3 months; Group 1: mean 70.09 (SD 13.03); n=88, Group 2: mean 66.93 (SD 13.98); n=90; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 51.73 (15.05); 51.03 (15.94)
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 7
- Actual outcome: Quality of life - general health at 3 months; Group 1: mean 60.76 (SD 16.51); n=88, Group 2: mean 59.9 (SD 17.4); n=90; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 49.14 (17.96); control 53.48 (15.93)
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 7
- Actual outcome: Quality of life - vitality at 3 months; Group 1: mean 64.26 (SD 9.75); n=88, Group 2: mean 60.33 (SD 12.49); n=90; SF36 0-100 Top=High is good

outcome; Comments: Baseline: acupuncture 55.34 (12.92); placebo 54.77 (13.89) Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 7 - Actual outcome: Quality of life - social functioning at 3 months; Group 1: mean 83.38 (SD 12.09); n=88, Group 2: mean 80.13 (SD 14.13); n=90; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 74.28 (16.23); placebo 73.61 (19.78) Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 7 - Actual outcome: Quality of life - role emotional at 3 months; Group 1: mean 73.48 (SD 32.42); n=88, Group 2: mean 71.11 (SD 34.69); n=90; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 47.72 (40.04); placebo 60.37 (37.69) Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 7 - Actual outcome: Quality of life - mental health at 3 months; Group 1: mean 67.13 (SD 10.04); n=88, Group 2: mean 61.64 (SD 10.69); n=90; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 63.50 (15.43); placebo 59.51 (14.41) Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 7 Protocol outcome 2: Pain reduction - Actual outcome: Pain at 3 months; Group 1: mean 2.88 (SD 1.72); n=88, Group 2: mean 3.19 (SD 1.31); n=90; VAS 0-10 Top=High is poor outcome; Comments: Baseline: acupuncture 5.3 (1.91); placebo 5.49 (1.56) Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 7 Protocol outcome 3: Discontinuation - Actual outcome: Discontinuation at 3 months; Group 1: 5/93, Group 2: 7/97 Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Psychological distress ; Use of healthcare services ; Sleep ; Physical function

Study	Lopez-martos 2018[136]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=40)
Countries and setting	Conducted in Spain; Setting: Outpatient clinic
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3 weeks + 70 days
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: MRI
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Age between 18 and 65 years; myogenic pain in the temperomandibular area of at least 6 months duration; moderately limited mandiubular movement (interincisal opening limited to 40 mm and requiring passive stretching to increase opening by >5mm), according to group I criteria of the RDC/TMD Consortium; criteria satisfied for active trigger points in the LMP (pain upon intraoral palpation, limited range of movement, painful chin protrusion against resistance, lateralisation of the contralateral side with mouth opening, and pain in the ipsilateral TMJ) according to the protocol used previously, following confirmation according to magnetic resonance study and panoramic radiography to rule out other conditions
Exclusion criteria	The presence of trigger points in any other masticatory or cervical muscle; intra-articular pathology according to diagnostic criteria for temporomandibular disorders; dentofacial deformities; facial paralysis; vascular diseases; tension headache or migraine; previous infectious inflammatory diseases of dental origin; belonephobia; fibromyalgia; depression; or other medical comorbidities
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Median (range): dry needling 36 (19-58); sham 42 (25-62). Gender (M:F): 3/37. Ethnicity: Not reported
Extra comments	Duration of pain not reported
Indirectness of population	No indirectness
Interventions	(n=20) Intervention 1: Dry needling. The technique used for deep dry needling has been previously described. A deep intramuscular puncture of the trigger points was carried out without the introduction of any substance (dry puncture).

	The objective was to provoke a jump reaction or local twitch response when the needle was inserted in a trigger point. During the procedure, the operator used the volume of the electrotherapy equipment as a guide, simulating the EPI technique. The sessions were once a week. Duration 3 weeks. Concurrent medication/care: Two weeks after each procedure, all subjects were instructed to perform concentric exercises with the masticatory muscles. Indirectness: No indirectness. (n=20) Intervention 2: Placebo/sham - Sham. The needle was pressed against the skin with its plastic protective tube, simulating a puncture with the same noise reproduced with the EPI equipment. Duration 3 weeks. Concurrent medication/care: Two weeks after each procedure, all subjects were instructed to perform concentric exercises with the masticatory muscles. Indirectness: No indirectness. (n=20) Intervention 3: Acupuncture - Electro acupuncture. The PNE group received a transcutaneous puncture in the LPM, according to the technique described by Koole et al. (18). Sterile stainless-steel needles (length 40 mm/ caliber 0.25 mm, with a cylindrical plastic guide, Agu-punt ®, Barcelona, Spain) were used for the muscle puncture. The puncture needles were connected to an electrosurgical device, and the electrotherapy equipment (EPI® Advanced Medicine, Barcelona, Spain) produced a continuous galvanic current of 2 mA for 3 seconds, three times through the cathode (electro- surgical scalpel), while the patient held the anode (hand electrode). Duration 3 weeks. Concurrent medication/care: Two weeks after each procedure, all subjects were instructed to perform concentric exercises with the masticatory muscles. Indirectness: No indirectness.
Funding	Academic or government funding (Supported by the Instituto de Salud Carlos III-Fondo de Investigacion Sanitaria)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DRY NEEDLING versus SHAM

Protocol outcome 1: Discontinuation
- Actual outcome: Discontinuation at End of treatment; Group 1: 2/20, Group 2: 1/20
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ELECTRO ACUPUNCTURE versus SHAM

Protocol outcome 1: Discontinuation
- Actual outcome: Discontinuation at End of treatment; Group 1: 0/20, Group 2: 2/20
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;

Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Health related quality of life ; Physical function ; Psychological distress ; Use of healthcare services ; Sleep ; Pain reduction

Study	Macpherson 2015[139] (Essex et al 2017 [60]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=517)
Countries and setting	Conducted in United Kingdom; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 12 sessions + 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Neck pain lasting at least 3 months and a score of at least 28% on the Northwick Park Questionnaire for neck pain and associated disability
Exclusion criteria	Serious underlying pathology; prior cervical spine surgery; history of psychosis; rheumatoid arthritis; ankylosing spondylitis; osteoporosis; hemophilia; cancer; HIV or hepatitis; current or recent alcohol or drug dependency; actively pursuing compensation or with litigation pending; unable to communicate in English; participation in another clinical trial that might interfere with the current study; currently receiving acupuncture for neck pain' attendance at 1 to 1 Alexander Technique lessons in the past 2 years
Recruitment/selection of patients	Primary care patients were sent invitation letters
Age, gender and ethnicity	Age - Mean (SD): acupuncture 52 (13.8); usual care 53.9 (13). Gender (M:F): 108/237. Ethnicity: white 89%; Indian 2.5%; Bangladeshi 0.2%; Pakistani 1%; Chinese 0.5%; Afro-Caribbean 0.4%; other 5%
Extra comments	Duration of neck pain (median), months: acupuncture 60 (5-600); usual care 96 (5-600)
Indirectness of population	No indirectness
Interventions	(n=173) Intervention 1: Acupuncture. Participants were offered up to 12 fifty minute sessions plus usual care. Sessions were delivered once per week initially and then once every 2 weeks later. Acupuncture practice was based on traditional Chinese medical theory, encompassing acupuncture specific diagnostic explanations and related lifestyle advice. Duration 12 sessions. Concurrent medication/care: Not reported. Indirectness: No indirectness.

	(n=172) Intervention 2: Usual care - Usual care. General neck pain specific treatments such as prescribed medications and visits to physical therapists. Duration Unclear. Concurrent medication/care: Not reported. Indirectness: No indirectness.
Funding	Academic or government funding (Sponsored by the University of York. Funded by clinical studies grant from Arthritis Research UK)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus USUSAL CARE

Protocol outcome 1: Health related quality of life
- Actual outcome: EQ-5D at 12 months; Group 1: mean 0.766 (SD 0.188); n=104, Group 2: mean 0.727 (SD 0.197); n=100 , EQ-5D, -0.594-1, Top=High is good outcome
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Baseline details: Duration of neck pain

Protocol outcome 2: Pain reduction
- Actual outcome: Northwick Park Questionnaire at 3 months; Mean; acupuncture: 37.23 (CI 30.35-44.11); usual care 43.46 (35.4-51.52) Northwick Park Questionnaire 0-100 Top=High is poor outcome, Comments: baseline: acupuncture 39.64 (9.71); usual care 40.46 (11.60);
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Baseline details: Duration of neck pain;
- Actual outcome: Northwick Park Questionnaire at 12 months; Mean; acupuncture: 37.07 (CI 30.35-43.79); usual care 40.99 (33.01-48.96) Northwick Pain Questionnaire 0-100 Top=High is poor outcome, Comments: baseline: acupuncture 39.64 (9.71); usual care 40.46 (11.60);
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Baseline details: Duration of neck pain
- Actual outcome: Pain self-efficacy scale at 12 months; Mean; -2.29 (SE 1.53); 0-8 Top=High is poor outcome
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Baseline details: Duration of neck pain

Protocol outcome 3: Discontinuation
- Actual outcome: Discontinuation at 3 months; Group 1: 16/173, Group 2: 12/172
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Baseline details: Duration of neck pain

Protocol outcomes not reported by the study	Psychological distress ; Use of healthcare services ; Sleep ; Physical function

Study	Martin 2006[143]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=50)
Countries and setting	Conducted in USA; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 2-3 weeks + 7 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	People with a diagnosis of fibromyalgia, with sufficient cognitive ability to read the consent form and to complete the survey instruments and within a geographic range to allow for participation
Exclusion criteria	Prior experience with acupuncture or a bleeding diathesis
Recruitment/selection of patients	Patients referred to the Mayo Fibromyalgia Treatment Program in Rochester, Minn
Age, gender and ethnicity	Age - Mean (SD): acupuncture 47.9 (11.2); control 51.7 (14.1). Gender (M:F): 1/49. Ethnicity: Not reported
Extra comments	Duration of pain not reported
Indirectness of population	No indirectness
Interventions	(n=25) Intervention 1: Acupuncture. Patients in the acupuncture group were positioned in the sitting position with a screen placed so that they could not observe placement of the treatments yet were allowed eye contact with the acupuncturist. Acupuncture points were standardised for all patients and not modified for the specific symptoms of the patient. Strong regulatory points that commonly recur in acupuncture literature were picked. Specifically, bilateral points at large intestine 4 , stomach 36, liver 2, spleen 6, pericardium 6, and heart 7 were used, as well as axial paramedian points along the ladder meridian at the cervical spine during the first 3 sessions and at the lumbar spine during the last 3 sessions. At each point, the skin was wiped with alcohol, and an adhesive bandage was placed over the point. The needle was inserted through the bandage to the acupuncture point. The sensation of de Qi was not specifically elicited. Electrical stimulation was applied at 2 Hz between large intestine 4 and stomach 36, bilaterally, and at 10 Hz over the axial circuits. All stimulator wires were taped to the skin to avoid moving needles. The pulse generator

	produced short, bipolar current spikes at an amplitude typically tolerable to most patients. After placement of all the needles and initiation of electrical stimulation, patients were allowed to rest quietly in a darkened room for 20 minutes. There were 6 sessions in total. Duration 2-3 weeks. Concurrent medication/care: Before acupuncture, all patients had 1.5 days of education, counselling, and group discussion about symptom management. Indirectness: No indirectness. (n=25) Intervention 2: Placebo/sham - Sham. Participants in the control group were positioned identically to patients in the acupuncture group so that they could not observe the treatments. Identical points were used. Each point was wiped with alcohol, the skin was indented with a dull surgical instrument, and a small circular adhesive bandage was supplied that had previously been rigged with an acupuncture needle such that the needle handle stuck out of the bandage but did not pierce the skin. Instead, the needle was bent to form a tripod so that it was supported on the skin surface and appeared as if it were anchored within the skin. Patients in the control group felt the wipe with alcohol, a mild pricking sensation, and placement of an adhesive bandage. Electrical stimulation was applied to the same points as the acupuncture group. Even though the lights flashed on the pulse generator, the resistance of the skin prevented any perceptible current flow. After treatment, patients relaxed in a darkened room for 20 minutes. Duration 2-3 weeks. Concurrent medication/care: Before acupuncture, all patients had 1.5 days of education, counselling, and group discussion about symptom management. Indirectness: No indirectness.
Funding	Academic or government funding (Supported by the Mayo Foundation and the Mayo Anesthesia Clinical Research Unit. Lead author supported in part by a Research Starter Grant from the Foundation for Anesthesia Education and Research)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus SHAM

Protocol outcome 1: Health related quality of life
- Actual outcome: Quality of life at 1 month; Group 1: mean 38.4 (SD 12.1); n=25, Group 2: mean 42.2 (SD 10.2); n=24; Fibromyalgia impact questionnaire 0-100 Top=High is poor outcome; Comments: Baseline: acupuncture 42.4 (11); sham 44 (9.8)
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 1
- Actual outcome: Quality of life at 7 months; Group 1: mean 38.1 (SD 12.1); n=25, Group 2: mean 42.7 (SD 9.6); n=24; FIQ 0-100 Top=High is poor outcome; Comments: Baseline: acupuncture 42.4 (11); sham 44 (9.8)
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 1

Protocol outcome 2: Pain reduction
- Actual outcome: Pain severity at 1 month; Group 1: mean 34.2 (SD 11.4); n=25,
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 1

- Actual outcome: Pain severity at 7 months; Group 1: mean 37.3 (SD 13.1); n=25, Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 1 Protocol outcome 3: Discontinuation - Actual outcome: Discontinuation at 7 months; Group 1: 0/25, Group 2: 1/25 Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness - Actual outcome: Discontinuation at 1 month; Group 1: 0/25, Group 2: 1/25 Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Psychological distress ; Use of healthcare services ; Sleep ; Physical function

Study	Mist 2018[150]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	30 (n=1)
Countries and setting	Conducted in USA; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 10 weeks + 4 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Women aged 18-75, with confirmed diagnosis of fibromyalgia using the 1990 American College of Radiology definition. All participants reported an average pain of 5 or higher on a VAS over the last week and agreed not to change any medication or treatment during the study. The population was limited to those with a score of less than 29 on the Beck Depression Inventory and those who has not used acupuncture in the previous 6 months. Participants had to have a Traditional Chinese Medicine diagnosis that included either Liver Qi Stagnation, Qi and Blood Stagnation or Qi and Blood deficiency
Exclusion criteria	Those with a routine daily use of narcotics or a history of substance abuse, pregnant or nursing mothers, those with a known coagulation abnormality that might have precluded the safe use of acupuncture such as thrombocytopenia, those with a concurrent autoimmune disease such as rheumatoid arthritis that could potentially confound the analysis, and those undergoing disability determination or who were involved in litigation related to fibromyalgia
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Mean (SD): acupuncture 52.3 (12.9); usual care 56 (12). Gender (M:F): Define. Ethnicity: Not reported
Extra comments	Duration of pain not reported
Indirectness of population	No indirectness
Interventions	(n=16) Intervention 1: Acupuncture. Group acupuncture was twice weekly using the Traditional Chinese Medicine style of diagnosis, each session lasted 40 minutes. Traditional Chinese Medicine diagnosis included traditional pulse and tongue examination and in depth patient interviews. The practitioners had prior experience diagnosing this population

	and had participated in a calibration exercise prior to starting the treatment. The treatments took place in a room where 8 acupuncture tables were set up. Patients were allowed to talk to each other but tended to rest quietly once the needles were in place. Each treatment was limited to a total of 25 single use needles with standard depth and no requirement of de qi response. Needles were manipulated manually if required and were retained for a maximum of 20 minutes. Duration 10 weeks. Concurrent medication/care: Not reported. Indirectness: Serious indirectness; Indirectness comment: group acupuncture. (n=14) Intervention 2: Usual care - Usual care. Group education involved a facilitated education process. Participants had group discussion on chapters from a fibromyalgia book focusing on current understanding of fibromyalgia aetiology, demographics, and pharmacologic and non-pharmacological treatment options. The discussions were facilitated but led primarily by the participants. Group education was selected as it is a commonly offered treatment. Duration 10 weeks. Concurrent medication/care: Not reported. Indirectness: Serious indirectness.
Funding	Academic or government funding (National Center for Complementary and Integrative Health and by the National Centre for Advancing Translational Sciences of the National Institutes of Health)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus USUSAL CARE Protocol outcome 1: Discontinuation - Actual outcome: Discontinuation at 4 weeks; Group 1: 1/16, Group 2: 2/14 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Health related quality of life ; Physical function ; Psychological distress ; Use of healthcare services ; Sleep ; Pain reduction

Study	Molsberger 2010[152]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=424)
Countries and setting	Conducted in Germany; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 weeks + 3 months
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	One sided shoulder pain for at least 6 weeks and up to two years; an average pain score of 50 mm or more on a 100mm VAS in the past week; age between 25-65 years; the ability to communicate in German; no neurological disorders causing shoulder pain; no referred pain from the cervical spine; no osteoarthritis of the gleno-humeral joint or systemic bone and joint disorder; no history of shoulder surgery; no other current therapy involving analgesics; no overt psychiatric illness; no pregnancy; no incapacity for work longer than 3 months preceding the trial; and no pending compensation procedure
Exclusion criteria	Not reported
Recruitment/selection of patients	Recruited by orthopaedists
Age, gender and ethnicity	Age - Mean (SD): Verum acupuncture 50.3 (9.6); sham 51.3 (9.4). Gender (M:F): 101/197. Ethnicity: Not reported
Extra comments	Duration of pain (months): verum acupuncture 10.7 (9.7); sham 11.6 (11.4)
Indirectness of population	No indirectness
Interventions	(n=154) Intervention 1: Acupuncture. Verum acupuncture patients received 15 treatments of Chinese acupuncture, one to three per week each lasting 20 minutes. The following points were selected: one to three locus dolendi points; local and distal points according to the channel and the individual location of the pain: ventral - Lung 1, 2: ventrolateral - Large intestine 4, 11, 14, 15; lateral Sanjiao 5, 13, 14: dorsal - small intestine 3, 9. Additionally distal points on the homolateral leg could be selected from stomach 38, gallbladder 34, bladder 58; while needling these distal points a brief movement of the shoulder was allowed. Depending on the site and quality of the reported pain, 5-10 needles

	were inserted unilaterally to a depth of 1-2cm. Needle manipulation was mild to strong, to achieve a feeling of heat and numbness around the acupuncture point. Duration 6 weeks. Concurrent medication/care: not reported. Indirectness: No indirectness. (n=135) Intervention 2: Placebo/sham - Sham. Patients received 15 treatments, one to three per week, each lasting 20 minutes. Sham acupuncture was carried out by the same physicians as verum acupuncture and was standardised to 8 needles d non-acupuncture points, 4 needles above the medial part of the tibia bilaterally, with the depth of the needle insertion less than 5mm. Other than that, management of these patients and information provided to them was identical to the treatment group. Duration 6 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness.
Funding	Academic or government funding (Grant from the German Ministry of Education, Science and Research)
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus SHAM Protocol outcome 1: Pain reduction - Actual outcome: Pain at 3 months; Group 1: mean 19 (SD 23.3); n=154, Group 2: mean 33 (SD 29.6); n=135; VAS 0-100 Top=High is poor outcome; Comments: Baseline: acupuncture 66.3 (13.6); sham 66 (13.8) Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness Group 1 Number missing: 26, Reason: Lost to follow up; Group 2 Number missing: 61, Reason: Lost to follow up Protocol outcome 2: Discontinuation - Actual outcome: Discontinuation at 3 months; Group 1: 26/154, Group 2: 61/135 Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Health related quality of life ; Psychological distress ; Use of healthcare services ; Sleep ; Physical function

Study	Qin 2018[168]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=68)
Countries and setting	Conducted in China; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 8 weeks + 32 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: detailed history, physical examination and laboratory workup
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Men with chronic prostatitis/chronic pelvic pain syndrome, defined as discomfort in the perineum and the suprapubic region with lower urinary tract symptoms without infection. The diagnosis was based on a detailed history, physical examination and laboratory workup. Men were aged 18-50 years old with a history of pain or discomfort perceived in the prostate region with no other lower urinary tract pathology for a minimum of 3 of the last 6 months, a CP/CPPS history greater than 1 year and a NIH-CPSI total score greater than 15
Exclusion criteria	Participants with any of certain conditions were excluded, including specific disease associated pelvic pain or discomfort caused by non CP/CPPS diseases (e.g. acute prostatitis, bacterial prostatitis, benign prostatic hyperplasia, prostate cancer, urinary tuberculosis, or urinary tract infection), the presence of a serious or an acute disease of the heart, liver, kidney or blood and receipt of acupuncture or medication treatment in the week before baseline assessment
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Mean (SD): acupuncture 33.8 (6.8); sham 35.1 (9.6). Gender (M:F): Males only. Ethnicity: Not reported
Extra comments	Duration of pain (years): acupuncture 2 (0.7); sham 2.2 (1)
Indirectness of population	No indirectness
Interventions	(n=34) Intervention 1: Acupuncture. Disposable acupuncture needles (0.30 x 40 mm/0.30 x 75 mm) were used. Participants received acupuncture at bilateral Zhongliao (BL33), Shenshu (BL23), Huiyang (BL35) and Sanyinjiao (SP6). After skin disinfection sterile adhesive pads were placed on the acupoints. For bilateral BL33 acupuncture needles were

	inserted through the adhesive pads for approximately 50-60 mm at a 45 degree angle. For BL35 the needles were inserted to a depth of 50-60mm in a slight superolateral direction. For BL23 and SP6 the needles were inserted vertically to a depth of 25-30 mm. Following needle insertion the acupuncturists twirled the needle handles back and forth to achieve the sensation of heaviness, acheyness and numbness known as de qi, at all acupoints except BL33. Participants received 3 treatment sessions per week, each session lasted for 30 minutes and acupuncture needle manipulation was performed every 10 minutes. Duration 8 weeks. Concurrent medication/care: In the event of intolerable pelvic pain participants were allowed celecoxib (200mg) as a rescue medication. Indirectness: No indirectness. (n=34) Intervention 2: Placebo/sham - Sham. Pragmatic placebo needles (0.30 x 25 mm) were used. Participants received sham acupuncture at the same acupoints as the acupuncture group. Pragmatic placebo needles with a blunt tip were used, similar to the Streitberger needle design, but they could not penetrate the skin. Procedures and other treatment parameters were the same as in the acupuncture group but there was no acupuncture needle manipulation. Duration 8 weeks. Concurrent medication/care: In the event of intolerable pelvic pain participants were allowed celecoxib (200mg) as a rescue medication. Indirectness: No indirectness.
Funding	Academic or government funding (Supported by China Academy of Chinese Medical Sciences Grant)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus SHAM

Protocol outcome 1: Health related quality of life
- Actual outcome: Quality of life at 40 weeks; Mean; Mean (CI): acupuncture 6.2 (5.6-6.8); sham 8 (7.5-8.6), Comments: Baseline: acupuncture 9.5 (1.5); sham 8.9 (1.1);
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness
- Actual outcome: Quality of life at 8 weeks; Mean; Mean (CI): acupuncture 6.5 (8.1-7); sham 7.6 (7.1-8) NIH-CPSI quality of life subscore 0-12 Top=High is poor outcome, Comments: Baseline: acupuncture 9.5 (1.5); sham 8.9 (1.1);
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness

Protocol outcome 2: Pain reduction
- Actual outcome: Pain at 8 weeks; Mean; mean (CI): acupuncture: 6.9 (6-7.8); sham 8.6 (7.7-9.5) NIH-CPSI pain subscale 0-21 Top=High is poor outcome, Comments: Baseline: acupuncture 12.4 (2.8); sham 11.4 (2.1);
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness
- Actual outcome: Pain at 40 weeks; Mean; Mean (CI): acupuncture 6.8 (5.9-7.7); sham 9.3 (8.4-10.2), Comments: Baseline: acupuncture 12.4 (2.8); sham 11.4 (2.1);
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;

Indirectness of outcome: No indirectness Protocol outcome 3: Discontinuation - Actual outcome: Discontinuation at 8 weeks; Group 1: 2/34, Group 2: 2/34 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness - Actual outcome: Discontinuation at 40 weeks; Group 1: 2/34, Group 2: 2/34 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Psychological distress ; Use of healthcare services ; Sleep ; Physical function

Study	Sahin 2010[175]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=31)
Countries and setting	Conducted in Turkey; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3-4 weeks + 3 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: history, physical examination, laboratory and radiological imagings
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged between 18-65; with chronic soft tissue neck pain lasting for more than 3 months; who scored above 3 in visual analogue scale for pain; who did not respond to physical therapy (electrotherapy, traction, massage, warming), medical therapy (analgesic drugs, NSAIDs, topical gels, muscle relaxants) or collar continued for one month; and who had not previously received acupuncture therapy
Exclusion criteria	Having complaints of radicular pain, neurological deficits, and disk herniation; lumbar pain for the last 3 months with a VAS score about 5; radiological evidence of narrowing of cervical neural formen and facet osteoarthritis; fracture; congenital neck deformities such as lordosis and scoliosis except mild cases; spondylolysis or spondylolithesis; history of trauma, vertebral collapse, infection, malignancy, systemic disease, thoracic outlet syndrome, temporomandibular joint dysfunction; history of spinal cord surgery, diagnosed psychotic disorder, pregnancy, previous use of antineoplastic and immunosuppressive medications, bleeding diathesis as well as receiving physical therapy, medical therapy or manual interventions performed within a week before the initiation of the study
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Mean (SD): acupuncture 38.5 (10.47); control 35.2 (9.18). Gender (M:F): 3/26. Ethnicity: Not reported
Extra comments	Duration of pain not reported
Indirectness of population	No indirectness
Interventions	(n=15) Intervention 1: Acupuncture - Electro acupuncture. Conventional body acupuncture, 3 sessions per week, each lasting 30 minutes with 10 sessions in total. The local and distant acupuncture point in relevant meridians were

	selected as recommended by previous studies: bilateral bladder 10, bladder 60, large intestine 4, triple energiser 5, gall bladder 20, gall bladder 21, governor 14. Patients were treated sitting down. After sterilisation of the above mentioned acupuncture points with alcohol, disposable, stainless steel acupuncture needles (25 x 0.25 mm) were introduced perpendicular to the skin, advanced to a depth of around 20mm using sparrow pecking technique and stimulated until de qi perception was obtained with numbness pain and heaviness. a low resistance detector that was a part of electoacupuncture device was used to identify the points. Electric stimulation was given for 30 minutes at low frequency (1-4 Hz), pulse width of 200μs, interrupted currents with high intensity (sufficient to generate phasic muscle contractions, tolerated by participants, to produce an uncomfortable reaction, to produce sufficient contraction without creating pain. Duration 3-4 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness. (n=16) Intervention 2: Placebo/sham - Sham. The sham acupuncture was similar to the method used on the patients in the electroacupuncture group, but acupuncture needles were inserted into points 1-2cm away from the meridian points above, to a depth of about 20mm but without sparrow necking. Electrical stimulation was administered as in the treatment group until the patient perceived the current, after which it was switched off. Duration 3-4 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness.
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ELECTRO ACUPUNCTURE versus SHAM Protocol outcome 1: Pain reduction - Actual outcome: Pain at rest at 3 months; Group 1: mean 4 (SD 2.97); n=13, Group 2: mean 3.54 (SD 3.13); n=16; VAS 0-10 Top=High is poor outcome; Comments: Baseline: acupuncture 4 (3.03); sham 5.25 (1.95) Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 2; Group 2 Number missing: 0 Protocol outcome 2: Discontinuation - Actual outcome: Discontinuation at 3 months; Group 1: 2/15, Group 2: 0/16 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Health related quality of life ; Psychological distress ; Use of healthcare services ; Sleep ; Physical function

Study	Sahin 2015[176]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=100)
Countries and setting	Conducted in Turkey; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 6 weeks + 24 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients with lower urinary tract symptoms suggestive of prostatitis who were evaluated for bacterial infection by Meares-Steamey criteria who were found to be negative for leucocyte and culture. Patients with CP/CPPS had a history of disease refractory to standard conventional therapy including antibiotics, alpha-blockers, and anti-inflammatory agents, and had symptoms of pain or discomfort in the pelvic region for at least 3 of the 6 previous months
Exclusion criteria	Acute prostatitis or bacterial prostatitis, BPH, prostate cancer, urinary tract infection within 1 year, pathology at urinary system ultrasonography including bladder and urethral stones, and any traditional or alternative medical therapy within the past 6 weeks. Localised skin infections concerning the acupoints, bleeding diathesis and use of anticoagulation, as well as severe chronic or uncontrolled co-morbid disease were also criteria for exclusion. Patients over 50 were also excluded to minimise the confounding role of BHP-related symptoms
Recruitment/selection of patients	Outpatient clinic
Age, gender and ethnicity	Age - Mean (SD): acupuncture 32.1 (7.2); sham 32.8 (7). Gender (M:F): Males only. Ethnicity: Not reported
Extra comments	Duration of pain (months): acupuncture 9.6 (3.5); sham 9.5 (2.3)
Indirectness of population	No indirectness
Interventions	(n=50) Intervention 1: Acupuncture. A total of 7 acupoints (bilaterally), selected according to the theory of neuoanatomy and myofascial pain syndrome. Acupuncture was performed using two disposable stainless steel needles (0.3 x 60mm) that were inserted to a depth of maximum 2.5-3cm or 0.5-1cm deep for spots in the perineum. The sensation of ache or heaviness in the area surrounding the inserted needle was always achieved. The treatment lasted

	for 20 minutes and half of this period covered by needle stimulation through rotation. Sessions were every week. Duration 6 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness. (n=50) Intervention 2: Placebo/sham - Sham. Punctures in the sham group were performed 1cm left of each selected acupoint with the same type of needles, of the same duration and frequency. Duration 6 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness.
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus SHAM

Protocol outcome 1: Health related quality of life
- Actual outcome: Quality of life at 8 weeks; Group 1: mean 2.51 (SD 0.79); n=45, Group 2: mean 4.8 (SD 2.72); n=46; NIH-CPSI quality of life subscore 0-12 Top=High is poor outcome; Comments: Baseline: acupuncture 9.1 (1.5); sham 8.9 (1.4)
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 4
- Actual outcome: Quality of life at 24 weeks; Group 1: mean 3.47 (SD 1.29); n=45, Group 2: mean 6.54 (SD 3.46); n=46; NIH-CPSI quality of life subscore 0-12 Top=High is poor outcome; Comments: Baseline: acupuncture 9.1 (1.5); sham 8.9 (1.4)
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 4

Protocol outcome 2: Pain reduction
- Actual outcome: Pain at 8 weeks; Group 1: mean 6.31 (SD 1.42); n=45, Group 2: mean 8.59 (SD 3.23); n=46; National Institutes of Health Chronic Prostatitis Symptom Index - pain subscore 0-21 Top=High is poor outcome; Comments: Baseline: acupuncture 13.2 (2.3); sham 13 (2.2)
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 4
- Actual outcome: Pain at 24 weeks; Group 1: mean 7.16 (SD 1.81); n=45, Group 2: mean 6.54 (SD 3.46); n=46; NIH-CPSI - pain subscore 0-21 Top=High is poor outcome; Comments: Baseline: acupuncture 13.2 (2.3); sham 13 (2.2)
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 5; Group 2 Number missing: 4

Protocol outcome 3: Discontinuation
- Actual outcome: Discontinuation at 24 weeks; Group 1: 5/50, Group 2: 4/50
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness

Psychological distress ; Use of healthcare services ; Sleep ; Physical function	
Protocol outcomes not reported by the study	

Study	Schlaeger 2015[183]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=36)
Countries and setting	Conducted in USA; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention time: 5 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: Diagnosed by obstetrician/gynecologists, urogynecologists or minimally invasive gynecologic surgeons
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Women at least 18 years of age previously diagnosed with either generalised vulvodynia or localised vestibulodynia. The vulvodynia could be provoked or unprovoked in nature
Exclusion criteria	Pregnancy, menopause, interstitial cystitis, irritable bowel syndrome, untreated vaginitis, cervicitis, pelvic inflammatory disease, any other pelvic pathology causing pain, and concomitant physical therapy, biofeedback, massage, or additional acupuncture
Recruitment/selection of patients	Participants were recruited from referral from local health care practitioners or by advertisement
Age, gender and ethnicity	Age - Mean (SD): acupuncture group 35 (8.6); control group 35 (6.8). Gender (M:F): Females only. Ethnicity: Not reported
Extra comments	Duration of pain: acupuncture group 5.4 (5.3); control group 4.63 (3.2)
Indirectness of population	No indirectness
Interventions	(n=18) Intervention 1: Acupuncture. All points were needled for 30 minutes each treatment. A lifting and thrusting technique was used to stimulate the needles and therefore the qi in the meridian. It was performed at 3 separate times: at 10 and 20 minutes after insertion, and just prior to removal at 30 minutes after insertion. Needles were inserted using the standards of clean needle technique established by the Council of Colleges of Acupuncture and Oriental Medicine. Once size of acupuncture needles, 0.25 diameter x 40mm length was used. All acupuncture needles were made of surgical stainless steel with stainless steel wound heads. There were two session a week. Duration 5

	weeks. Concurrent medication/care: Participants were allowed to continue medications prescribed to treat vulvodynia as well as other health conditions. Indirectness: No indirectness. (n=18) Intervention 2: Usual care - Usual care. Participants continued their usual care. Duration 5 weeks. Concurrent medication/care: Participants were allowed to continue medications prescribed to treat vulvodynia as well as other health conditions. Indirectness: No indirectness.
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus USUSAL CARE Protocol outcome 1: Pain reduction - Actual outcome: Pain at Post intervention; Group 1: mean 2.7 (SD 1.7); n=18, Group 2: mean 5.1 (SD 2.9); n=18; Short form McGill Pain Questionnaire - VAS 0-100 Top=High is poor outcome; Comments: Baseline: acupuncture 5.6 (1.9); control group 5.7 (2.31) Risk of bias: All domain - High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness Protocol outcome 2: Discontinuation - Actual outcome: Discontinuation at Post intervention; Group 1: 0/18, Group 2: 0/18 Risk of bias: All domain - High, Selection - High, Blinding - Very high, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Health related quality of life ; Psychological distress ; Use of healthcare services ; Sleep ; Physical function

Study	Tekin 2013[201]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=46)
Countries and setting	Conducted in Turkey; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention time: 4 weeks
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: MPS diagnosis was made according to Travell and Simons' criteria
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Not specified
Exclusion criteria	Not specified
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Mean (SD): Dry needling 42.9 (10.9); placebo 42 (12). Gender (M:F): Define. Ethnicity: Not reported
Further population details	1. Chronic orofascial pain: Yes 2. Chronic primary musculoskeletal pain: No 3. Chronic visceral pain: No 4. Chronic widespread pain: No 5. Cognitive impairment: Not stated / Unclear 6. Complex regional pain syndrome: No 7. First language not English: Not stated / Unclear 8. Homeless: Not stated / Unclear 9. Learning difficulties: Not stated / Unclear 10. Sensory impairment: Not stated / Unclear
Extra comments	Duration of pain (months): 63.5 (50.7); sham 57.9 (48.3)
Indirectness of population	No indirectness
Interventions	(n=23) Intervention 1: Dry needling. While the patient was in a sitting position, the trigger point area was determined, and the skin was cleaned with an appropriate antiseptic solution. The trigger point was ensured to be immobilized between the thumb and index finger. Then, the needle was inserted perpendicularly through the skin and moved forward until the trigger point was reached. The needle was withdrawn immediately after pricking. With the aid of insertion tubes, the standard single-use sterile acupuncture needles (0.25 mm×25 mm) were employed to provide a noxious stimulus. In order to minimize the pain of insertion and thus to improve the patients' tolerance of the needling,

	a certain pressure was applied to the skin with the insertion tube, and then each needle was inserted swiftly to the skin over the trigger points. The treatment protocol was composed of six sessions performed in a period of 4 weeks. The first four sessions were performed twice a week for 2 weeks, and the last two were performed once a week for the last 2 weeks. Duration 4 weeks. Concurrent medication/care: No exercise program and physical therapy modalities were given during the treatment process. Subjects were asked not to take any nonsteroidal anti-inflammatory or muscle relaxant drugs as well. They were only allowed to take paracetamol, and the number of tablets used was recorded. (n=23) Intervention 2: Placebo/sham - Sham. After the trigger points were determined and the skin was cleaned with the same procedures, the blunted needle for sham dry needling which causes a pricking sensation was applied to the trigger points without penetrating the skin after application of a certain pressure to the skin with the insertion tube. The treatment protocol was composed of six sessions performed in a period of 4 weeks. The first four sessions were performed twice a week for 2 weeks, and the last two were performed once a week for the last 2 weeks. Duration 4 weeks. Concurrent medication/care: No exercise program and physical therapy modalities were given during the treatment process. Subjects were asked not to take any nonsteroidal anti-inflammatory or muscle relaxant drugs as well. They were only allowed to take paracetamol, and the number of tablets used was recorded.
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: DRY NEEDLING versus SHAM Protocol outcome 1: Pain reduction - Actual outcome: Pain at End of treatment; Group 1: mean 2.2 (SD 2); n=22, Group 2: mean 5.3 (SD 1.8); n=17; VAS 0-10 Top=High is poor outcome; Comments: Baseline: dry needling 6.6 (1.3); sham 6.4 (1.6) Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 1; Group 2 Number missing: 6 Protocol outcome 2: Discontinuation - Actual outcome: Discontinuation at End of treatment; Group 1: 1/23, Group 2: 6/23 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Health related quality of life ; Psychological distress ; Use of healthcare services ; Sleep ; Physical function

Study	Ugurlu 2017[208]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=50)
Countries and setting	Conducted in Turkey; Setting: Outpatient clinic
Line of therapy	Unclear
Duration of study	Intervention time: 8 week
Method of assessment of guideline condition	Adequate method of assessment/diagnosis: 1990 ACR classification criteria
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	(1) widespread pain for six months or more and to be diagnosed with FM according to the 1990 ACR classification criteria; (2) normal neurological examination findings, including deep tendon reflexes, voluntary muscle action and sensory function; 3) having failed to achieve improvement following other treatments including nonsteroidal anti-inflammatory drugs, major opioids, tricyclic antidepressants (amitriptyline or cyclobenzaprine), selective serotonin re-uptake inhibitors, serotonin-norepinephrine re-uptake inhibitors, anticonvulsant drugs such as gabapentin, pregabalin and some other multidisciplinary therapies
Exclusion criteria	(1) sufficient knowledge of acupuncture which may prevent blinding (e.g. having received acupuncture previously); (2) known bleeding diathesis; (3) autoimmune or inflammatory diseases; (4) participation in other clinical trials; (5) pregnancy or lactation; or (6) diabetes mellitus, multiple sclerosis, alcoholism, polyneuropathy, kidney failure, asthma, emphysema, bronchitis, epilepsy, schizophrenia, or psychosis
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Mean (SD): acupuncture 47.28 (7.86); sham 43.6 (8.18). Gender (M:F): Females only. Ethnicity: Not reported
Extra comments	Duration of pain (years): acupuncture 6.28 (4.97); sham 6.32 (2.21)
Indirectness of population	No indirectness
Interventions	(n=25) Intervention 1: Acupuncture. In acupuncture group; needle penetration was 10–30 millimeter without extra rotational or manual stimulation after needle insertion and the depth of needle penetration was determined by the patient's sensitivity until "chi" sensation was obtained. Needles were placed on the acu-points while the patients were

	supine or prone position. The inclination of the needle was 90° in all points. The acupuncturist used disposable, sterilized, flexible stainless steel 0.25 × 40 millimeter needles. The acupuncture points employed were LI 4, ST 36, LV 3, GB 41, GB 34, GB 20, SI 3, SI 4, UB 62, UB 10, SP 6, HT 7, DU 20, DU 14, Kd 27, Ren 6, PC 6. Patients in both groups received 3 sessions in the first week, 2 sessions/week in the following 2 weeks and 1 session/week in the following 5 weeks (totally 12 sessions) lasting for 30 minutes each session. Duration 8 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness. (n=25) Intervention 2: Placebo/sham - Sham. In the sham acupuncture intervention, Park sham devices were used. It is a non-penetrating needle device with a blunt and retractable needle and a guide tube. A pre-cut guide tube which is fixed by a self-adhesive pad was slightly depressed down onto the selected point. And then, the blunt sham needle is carefully placed into the guide tube. When pressed, it telescopes into the handle and induces a pricking sensation rather than penetrates the skin. During this process, no twirling lifting and thrusting manipulation is conducted. Duration 8 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness.
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus SHAM

Protocol outcome 1: Health related quality of life
- Actual outcome: Quality of life - physical at End of treatment; Group 1: mean 42.93 (SD 6.77); n=25, Group 2: mean 38.84 (SD 7.75); n=25; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 30.17 (5.27); sham 28.65 (7.28)
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness
- Actual outcome: Quality of life - mental at End of treatment; Group 1: mean 48.67 (SD 8.29); n=25, Group 2: mean 41.1 (SD 5.88); n=25; SF36 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 33.77 (8.03); sham 30.31 (7.24)
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness

Protocol outcome 2: Pain reduction
- Actual outcome: Pain at rest at End of treatment; Group 1: mean 2.58 (SD 1.32); n=25, Group 2: mean 5.6 (SD 2.04); n=25; VAS 0-10 Top=High is poor outcome; Comments: Baseline: acupuncture 8.12 (1.42); sham 8.76 (0.96)
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness

Protocol outcome 3: Psychological distress
- Actual outcome: Depression at End of treatment; Group 1: mean 9.48 (SD 7.68); n=25, Group 2: mean 18.76 (SD 8.31); n=25; Becks depression inventory 0-40

Top=High is poor outcome; Comments: Baseline: acupuncture 28.24 (8.87); sham 28.44 (9.30) Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness Protocol outcome 4: Discontinuation - Actual outcome: Discontinuation at End of treatment; Group 1: 0/25, Group 2: 0/25 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Use of healthcare services ; Sleep ; Physical function

Study	Vas 2016[211]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=164)
Countries and setting	Conducted in Spain; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 9 weeks + 12 months
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged over 17 years and had been diagnosed with fibromyalgia according to ACR criteria
Exclusion criteria	Chronic pain in relation to any process other than fibromyalgia, using anticoagulants or opiates, pregnant or a nursing mother, or involved in occupational litigation for reasons involving fibromyalgia
Recruitment/selection of patients	Referred by their general practitioner
Age, gender and ethnicity	Age - Mean (SD): 52.8 (9.6). Gender (M:F): Define. Ethnicity: Not reported
Extra comments	Duration of pain (months): acupuncture 70.7 (44.5); sham 69.2 (43.7)
Indirectness of population	No indirectness
Interventions	(n=82) Intervention 1: Acupuncture. The true acupuncture group received individualised acupuncture based on their TCM diagnosis and according to a previously established algorithm. Each session was 20 minutes. Duration 9 weeks. Concurrent medication/care: Participants in both groups also received pharmacological treatment prescribed by their GP. Indirectness: No indirectness. (n=82) Intervention 2: Placebo/sham - Sham. The SA group received an acupuncture simulation on the dorsal and lumbar regions, in which guide tubes for the same type of needle as used in the real acupuncture group were applied to the body surface, but after removal of the needles. Each session lasted 20 minutes. Duration 9 weeks.

	Concurrent medication/care: Participants in both groups also received pharmacological treatment prescribed by their GP. Indirectness: No indirectness.
Funding	Academic or government funding (Funded by the Spanish Ministry of Health and Consumer Affairs (Carlos III Health Institute, project number PI10/00675) and by the Andalusian Public Health System (project number PI0436/09))

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus SHAM

Protocol outcome 1: Health related quality of life
- Actual outcome: Quality of life - physical at 10 weeks ; Mean; mean (CI): acupuncture 39 (28.7, 49.3); sham 18.1 (10, 26.3) SF12 0-100 Top=High is good outcome, Comments: Baseline: acupuncture 28.5 (8.3); sham 31 (8.4);
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Group 1 Number missing: 4; Group 2 Number missing: 1
- Actual outcome: Quality of life - physical at 12 months; Mean; mean (CI): acupuncture 37.2 (26.8, 47.5); sham 11.4 (2.7, 20.2) SF12 0-100 Top=High is good outcome, Comments: Baseline: acupuncture 28.5 (8.3); sham 31 (8.4);
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Group 1 Number missing: 9; Group 2 Number missing: 2
- Actual outcome: Quality of life - mental at 12 months; Mean; mean (CI): acupuncture 22.9 (13, 32.7); sham 9.3 (1.6, 17) SF12 0-100 Top=High is good outcome, Comments: Baseline: acupuncture 32.8 (11.1); sham 34.1 (10.4);
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Group 1 Number missing: 9; Group 2 Number missing: 2
- Actual outcome: Quality of life - mental at 10 weeks; Mean; mean (CI): acupuncture 45.5 (33.3, 57.8); sham 29.4 (17.7, 41.1) SF12 0-100 Top=High is good outcome, Comments: Baseline: acupuncture 32.8 (11.1); sham 34.1 (10.4);
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Group 1 Number missing: 4; Group 2 Number missing: 1

Protocol outcome 2: Pain reduction
- Actual outcome: Percentage reduction in pain at 10 weeks; Mean; mean (CI): acupuncture -41.2 (-47.6, -34.9); sham -27 (-33.2, -20.8) VAS 0-100 Top=High is poor outcome, Comments: Baseline: acupuncture 79.3 (11); sham 75.8 (13.3);
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Group 1 Number missing: 4; Group 2 Number missing: 1
- Actual outcome: Percentage reduction in pain at 12 months; Mean; mean (CI): acupuncture -20.3 (-25.5, -15.1); sham -6 (-11.2, -0.9) VAS 0-100 Top=High is poor outcome, Comments: Baseline: acupuncture 79.3 (11); sham 75.8 (13.3);
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Group 1 Number missing: 9; Group 2 Number missing: 2

Protocol outcome 3: Psychological distress - Actual outcome: Depression at 10 weeks; Mean; mean (CI): acupuncture -23.6 (-35.6, -11.6); sham -15.7 (-26.2, -5.2) Hamilton Depression Rating hetero-evaluation Scale 0-52 Top=High is poor outcome, Comments: Baseline: acupuncture 16.3 (7); sham 16.6 (6.7); Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 4; Group 2 Number missing: 1 - Actual outcome: Depression at 6 months; Mean; mean (CI): acupuncture -20.6 (-36.7, -4.6); sham -5.6 (-16.5, 5.4) Hamilton Depression Ration hetero-evaluation Scale 0-52 Top=High is poor outcome, Comments: Baseline: acupuncture 16.3 (7); sham 16.6 (6.7); Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 7; Group 2 Number missing: 2 Protocol outcome 4: Discontinuation - Actual outcome: Discontinuation at 10 weeks; Group 1: 4/82, Group 2: 1/82 Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; - Actual outcome: Discontinuation at 12 months; Group 1: 9/82, Group 2: 2/82 Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Use of healthcare services ; Sleep ; Physical function

Study	White 2004[216]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=135)
Countries and setting	Conducted in United Kingdom; Setting: Outpatient hospital department
Line of therapy	Unclear
Duration of study	Intervention + follow up: 4 weeks + 12 months
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	18 to 80 years of age, had chronic (>2 months) mechanical neck pain, and had a pain score of more than 30 mm on a visual analogue scale (VAS) for 5 of 7 pre-treatment days (possible score on this VAS ranges from 0 to 100 mm)
Exclusion criteria	Pregnant patients; those with a history of fracture or surgery to the neck, cervical congenital abnormality, uncontrolled low back pain, contraindication to acetaminophen, systemic illness (for example, rheumatoid arthritis), or ongoing neck-related litigation or disability claims; and those with current or recent manual neck treatment or steroid use (oral or local injection)
Recruitment/selection of patients	Referred by rheumatologists or family physicians or from physiotherapy waiting lists
Age, gender and ethnicity	Age - Mean (SD): Acupuncture group 53.9 (15.71); placebo group 52.8 (15.6). Gender (M:F): 48/87. Ethnicity: Not reported
Extra comments	Duration of pain (years): acupuncture group 4.81 (7.03); placebo group 7.71 (11.39)
Indirectness of population	No indirectness
Interventions	(n=70) Intervention 1: Acupuncture. We used single-use, sterile, silver-handle, prepacked needles without guide tubes. Sizes used were 13 mm x 0.25 mm, 25 mm x 0.25 mm, and 40 mm x 0.25 mm. We based point selection on individualized western acupuncture techniques by using a list of points previously reported as being effective in neck pain (18, 19) and by reaching a consensus according to our own clinical and teaching practice. The specific points for each individual were defined at each treatment session, depending on the patient's pain distribution and palpation of

	the neck and thorax to determine ah-shi points, or local tender points, for acupuncture. At least 1 distal point was used. Point location and depth of insertion were as described in traditional texts. Six points on average, per side if pain was bilateral, were used on each patient, and deqi (a term used to describe acupuncture needle sensation) was obtained on each needle. Twenty-minute treatment sessions were given. The patient was checked every 6 or 7 minutes to ascertain whether deqi was still present, and needles were manipulated again if required. Patients were treated twice per week for 4 weeks. Duration 4 weeks. Concurrent medication/care: Patients in both groups were instructed to use acetaminophen alone for pain relief and were not given or permitted any other form of treatment, including exercises or stretches, during the study and for 2 months after treatment ended. Indirectness: No indirectness. (n=65) Intervention 2: Placebo/sham - Placebo. The Noma FM-4 electroacupuncture stimulator (Noma Ltd., Southampton, United Kingdom) was used. It has 4 channels, allowing pseudostimulation of up to 8 acupuncture points simultaneously, and emits visual and audio signals. Reusable electrodes (Body Clock Health Care Ltd., London, United Kingdom) were fixed to the surface of the patient's skin and were connected to the stimulator through decommissioned cables. The cables were severed inside the output plug, so that no current could reach the patient. Examination and point selection were the same as with real acupuncture for each treatment. Point location and treatment variables were changed during subsequent treatment sessions if patients felt they were not progressing. Patients were told that the machine could stimulate acupuncture points through high-frequency, low-intensity stimulation and therefore would not produce any sensation. If patients reported sensation, the therapist adjusted the unit for comfort (although since this was a sham procedure, such adjustment made no real difference). Patients were treated twice per week for 4 weeks. Duration 4 weeks. Concurrent medication/care: Patients in both groups were instructed to use acetaminophen alone for pain relief and were not given or permitted any other form of treatment, including exercises or stretches, during the study and for 2 months after treatment ended. Indirectness: No indirectness.
Funding	Other (Funded by the Henry Smiths Charity and the Hospital Savings Association)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus PLACEBO

Protocol outcome 1: Health related quality of life
- Actual outcome: Quality of life - physical component at 8 weeks; Group 1: mean 41.19 (SD 7.89); n=59, Group 2: mean 43.75 (SD 10.04); n=59; SF36 - physical component summary 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 36.83 (7.91); placebo 36.33 (9.3)
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in duration of pain; Group 1 Number missing: 11; Group 2 Number missing: 6
- Actual outcome: Quality of life - mental component at 8 weeks; Group 1: mean 52.49 (SD 8.59); n=59, Group 2: mean 50.33 (SD 10.13); n=59; SF36 mental component 0-100 Top=High is good outcome; Comments: Baseline: acupuncture 46.89 (10.38); placebo 48.30 (9.87)

Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in duration of pain; Group 1 Number missing: 11; Group 2 Number missing: 6 Protocol outcome 2: Pain reduction - Actual outcome: Pain at 12 weeks; Group 1: mean 17.29 (SD 18.96); n=59, Group 2: mean 23.19 (SD 20.88); n=58; VAS 0-100 Top=High is poor outcome; Comments: Baseline: acupuncture 49.60 (12.35); 54.11 (14.62) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in duration of pain; Group 1 Number missing: 11; Group 2 Number missing: 6 - Actual outcome: Pain at 12 months; Group 1: mean 20.91 (SD 25.69); n=54, Group 2: mean 24.36 (SD 26.68); n=53; VAS 0-100 Top=High is poor outcome; Comments: Baseline: acupuncture 49.60 (12.35); placebo 54.11 (14.62) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in duration of pain; Group 1 Number missing: 16; Group 2 Number missing: 12 Protocol outcome 3: Physical function - Actual outcome: Neck disability at 8 weeks; Group 1: mean 10.98 (SD 6.27); n=59, Group 2: mean 12.68 (SD 7.79); n=59; Neck disability index 0-100 Top=High is poor outcome; Comments: Baseline: acupuncture 16.84 (6.34); placebo 17.18 (6.13) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in duration of pain; Group 1 Number missing: 11; Group 2 Number missing: 6 - Actual outcome: Neck disability at 12 months; Group 1: mean 8.89 (SD 6.57); n=53, Group 2: mean 10.72 (SD 9.11); n=53; Neck disability index 0-100 Top=High is poor outcome; Comments: Baseline: acupuncture 16.84 (6.34); placebo 17.18 (6.13) Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in duration of pain; Group 1 Number missing: 16; Group 2 Number missing: 12 Protocol outcome 4: Discontinuation - Actual outcome: Discontinuation at 8 weeks; Group 1: 11/70, Group 2: 7/65 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Baseline details: Difference in duration of pain	
Protocol outcomes not reported by the study	Use of healthcare services ; Sleep ; Psychological distress

Study	Witt 2006[220]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=3766)
Countries and setting	Conducted in Germany; Setting: Not specified
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3 month intervention and 3 month follow up
Method of assessment of guideline condition	Unclear method of assessment/diagnosis: clinical diagnosis of chronic neck pain
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	(1) clinical diagnosis of chronic neck pain with a disease duration of more than 6 months (2) >18 years
Exclusion criteria	(1) protusio or prolapse of one or more intervertebral discs with concurrent neurological symptoms (2) prior veterbral column surgery (3) infectious spondylopathy (4) neck pain caused by other conditions (inflammatory, malignant or autoimmune (5) congenital deformation of spine or other spinal conditions
Recruitment/selection of patients	People insured by one of the participating social health insurance funds were recruited after contacting participating physician due to neck pain.
Age, gender and ethnicity	Age - Mean (SD): 50(12.9) years. Gender (M:F): Define. Ethnicity: Not specified
Extra comments	Mean pain duration 6 (7.1) years
Indirectness of population	No indirectness
Interventions	(n=1880) Intervention 1: Acupuncture. Physicians giving acupuncture were required to hold at least an A-diploma based on 140 hours of certified acupuncture education Each participant received up to 15 acupuncture sessions during the first 3 months. Each participant was treated individually and the number of needles and points used were chosen at the physicians' discretion. Only needle acupuncture were allowed. 77.3% received 5-10 sessions, 17.7% received more than 10 and 5% received less than 5. Duration 3 months. Concurrent medication/care: not specified. Indirectness: No indirectness.

	(n=1886) Intervention 2: Usual care - Usual care. No treatment - no acupuncture allowed, no further details. Duration 3 months. Concurrent medication/care: Not stated. Indirectness: No indirectness.
Funding	Academic or government funding (German social health insurance funds)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ACUPUNCTURE versus USUSAL CARE

Protocol outcome 1: Health related quality of life
- Actual outcome: SF-36 physical component score at 3 months; Mean; Change scores 0-100 SF-36 summary score Top=High is poor outcome, Comments: Acupuncture: 5.8 (CIs 5.5 to 6.2)
Control: 1.2 (CIs 0.8 to 1.5)
Baseline: 37.6(8.4);38.1(9.1);
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Group 1 Number missing: 127/1880; Group 2 Number missing: 188/1886
- Actual outcome: SF-36 mental component score at 3 months; Mean; change scores, Comments: Acupuncture: 4.2 CIs 3.7 to 4.7)
Control: 1 (CIs 0.5 to 1.5)

Baseline: 43.1(12.1); 43.8(12.1);
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Group 1 Number missing: 127/1880; Group 2 Number missing: 188/1886

Protocol outcome 2: Pain reduction
- Actual outcome: Neck pain and disability scale at 3 months; Mean; change scores, Comments: A: -16.2(SE 0.4)
C: -3.9(SE 0.4)
Baseline: 55(15.8); 53.9(16);
Risk of bias: All domain - High, Selection - Low, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Group 1 Number missing: 127/1880; Group 2 Number missing: 188/1886

Protocol outcome 3: Discontinuation
- Actual outcome: Discontinuation at 3 months; Group 1: 106/1880, Group 2: 132/1886
Risk of bias: All domain - ; Indirectness of outcome: No indirectness

Protocol outcomes not reported by the study	Psychological distress ; Use of healthcare services ; Sleep ; Physical function

Study	Zhang 2013[232]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=206)
Countries and setting	Conducted in Hong Kong (China); Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention time: 3 weeks
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Overall
Subgroup analysis within study	Not applicable
Inclusion criteria	Adults with chronic mechanical neck pain for more than 3 months
Exclusion criteria	Patients with surgery to the neck, neurological deficits, a history of malignancy, congenital abnormality of the spine, systemic diseases, and those treated by acupuncture in the last 6 months
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Mean (SD): 45.8 years. Gender (M:F): Not reported. Ethnicity: Not reported
Extra comments	Duration of pain: 75.4 months
Indirectness of population	No indirectness
Interventions	(n=103) Intervention 1: Acupuncture - Electro acupuncture. Sterile acupuncture needles 25-40mm long with a diameter of 0.25 to 0.3mm were inserted into Hegu, Houxi, Feng Chi, Jiangjing, and Bailao and stimulated with an electroacupuncture machine for 45 minutes. Two additional points could be chosen from tender points or acupuncture points immediately near the tender points. Treatments were 3 times a week. Duration 3 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness. (n=103) Intervention 2: Placebo/sham - Sham. Sham laser acupuncture was delivered via a mock laser pen that only emitted a red light. Neither the patients nor the practitioners were informed that the laser pen was inactivated. Each point was treated for 2 minutes with the pen at a distance of 0.5 to 1 cm from the skin. Duration 3 weeks. Concurrent medication/care: Not reported. Indirectness: No indirectness.

Funding	Academic or government funding (Supported by the Health and Health Service Research Fund, Food and Health Bureau, Hong Kong SAR Government. The School of Chinese Medicine of Hong Kong Baptist University provided additional funding)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ELECTRO ACUPUNCTURE versus SHAM

Protocol outcome 1: Health related quality of life
- Actual outcome: Quality of life - physical at 3 months; Mean; Acupuncture: 52.8; sham 53.3 SF36 physical component 0-100 Top=High is good outcome, Comments: CI: acupuncture 53-53.7; sham 52.4-54.2
Baseline: acupuncture 52.5 (51.5-53.4); sham 52.7 (51.9-53.6);
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Group 1 Number missing: 16; Group 2 Number missing: 26
- Actual outcome: Quality of life - mental at 3 months; Mean; Acupuncture 45.9; sham 45.3 SF36 - mental component 0-100 Top=High is good outcome, Comments: CI: acupuncture 46-46.8; sham 44.2-46.4
Baseline: acupuncture 43.8 (42.9-44.8); sham 43.7 (42.6-44.8);
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Group 1 Number missing: 16; Group 2 Number missing: 26
- Actual outcome: Quality of life - mental at 6 months; Mean; Acupuncture 45.4; sham 44.4 SF36 - mental component 0-100 Top=High is good outcome, Comments: CI: acupuncture 44.5-46.3; sham 43.4-45.4
Baseline: acupuncture 43.8 (42.9-44.8); sham 43.7 (42.6-44.8)
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Group 1 Number missing: 19; Group 2 Number missing: 28
- Actual outcome: Quality of life - physical at 6 months; Mean; Acupuncture: 53; sham 53.2 SF36 - physical 0-100 Top=High is good outcome, Comments: CI: Acupuncture 52-53.9; sham 52.3-54
Baseline: acupuncture 52.5 (51.5-53.4); sham 52.7 (51.9-53.6);
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Group 1 Number missing: 19; Group 2 Number missing: 28

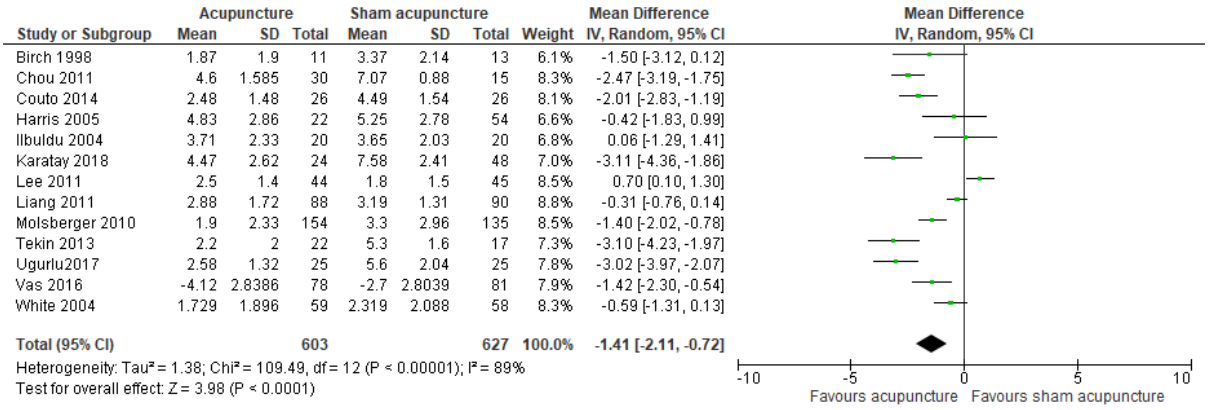
Protocol outcome 2: Pain reduction
- Actual outcome: Pain at 6 months; Mean; Acupuncture 46.8; sham 43.6 Numeric pain intensity scale 0-100 Top=High is poor outcome, Comments: CI: acupuncture 42-51.5; sham 38.8-48.4
Baseline: acupuncture 54.7 (50.9-58.4); sham 51.6 (47.6-55.7);
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low;
Indirectness of outcome: No indirectness ; Group 1 Number missing: 19; Group 2 Number missing: 28
- Actual outcome: Pain at 3 months; Mean; Acupuncture 46.6; sham 45.1 Numeric pain intensity scale 0-100 Top=High is poor outcome, Comments: CI: acupuncture

42.2-51; sham 40.5-49.6 Baseline: acupuncture 54.7 (50.9-58.4); sham 51.6 (47.6-55.7); Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 16; Group 2 Number missing: 26 Protocol outcome 3: Discontinuation - Actual outcome: Discontinuation at 3 months; Group 1: 16/103, Group 2: 25/103 Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness	
Protocol outcomes not reported by the study	Psychological distress ; Use of healthcare services ; Sleep ; Physical function

Appendix E: Forest plots

E.1 Acupuncture versus sham acupuncture

Figure 2: Pain (VAS/NRS; 0-10; final & change scores; high is poor outcome) at ≤3 months



NB: Heterogeneity not explained by subgroup analysis

Figure 3: Pain (NIH-CPSI; 0-21, high is poor outcome, final values) at ≤3 months

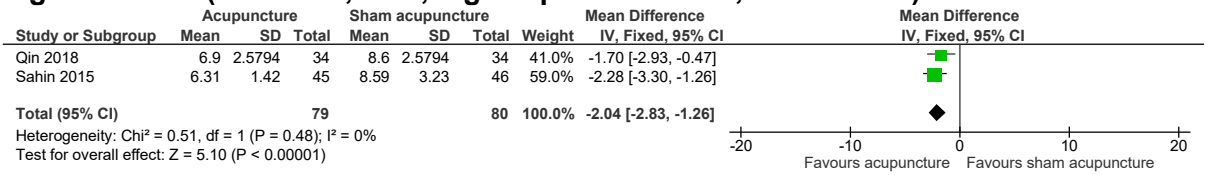


Figure 4: Pain (VAS; 0-10; final & change scores; high is poor outcome) at >3 months

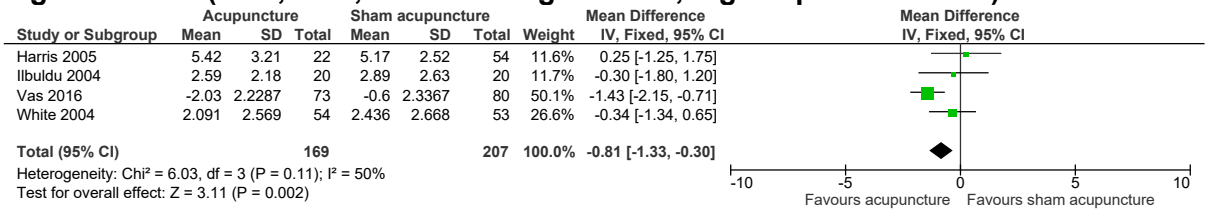


Figure 5: Pain (NIH-CPSI; 0-20; high is poor outcome, final values) at >3 months

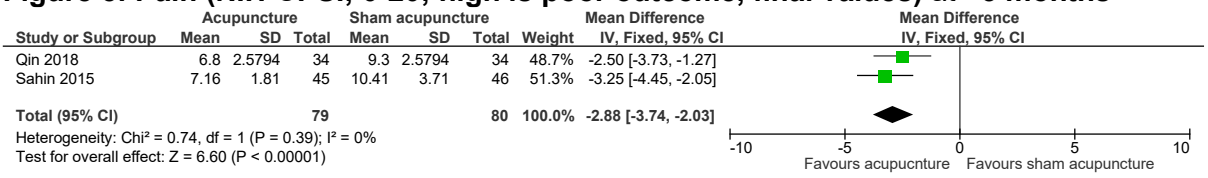


Figure 6: Pain (least square mean difference; VAS; 0-10, final values, high is poor outcome) at >3 months

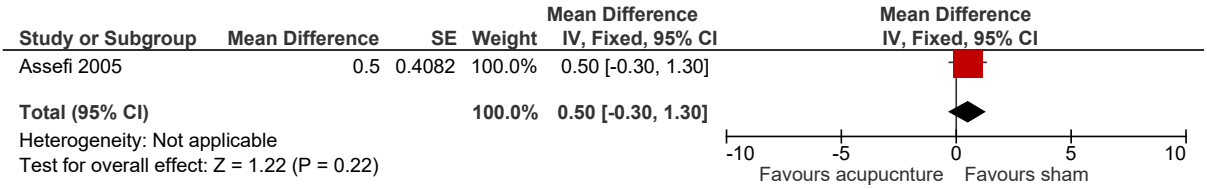


Figure 7: Health related quality of life (SF12 physical composite; 0-100, final values; high is good outcome) at ≤3 months

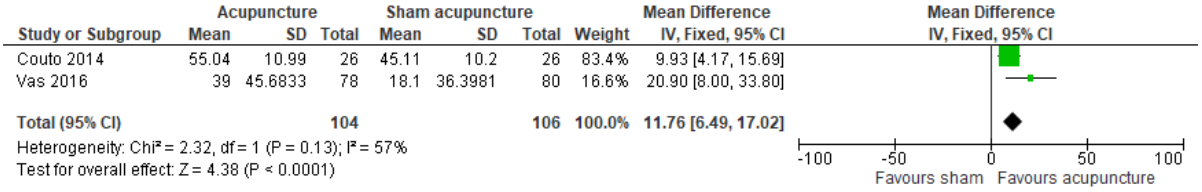


Figure 8: Health related quality of life (SF12 mental composite; 0-100, final values; high is good outcome) at ≤3 months

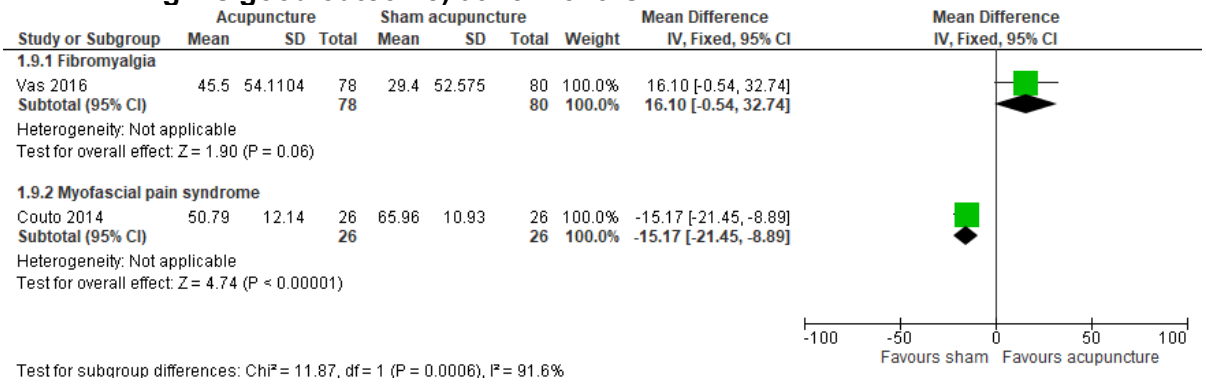


Figure 9: Health related quality of life (SF36 physical component summary; 0-100, high is good outcome, final values) at ≤3 months

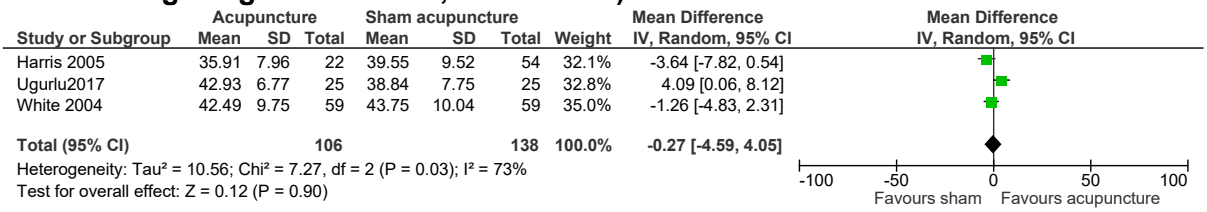
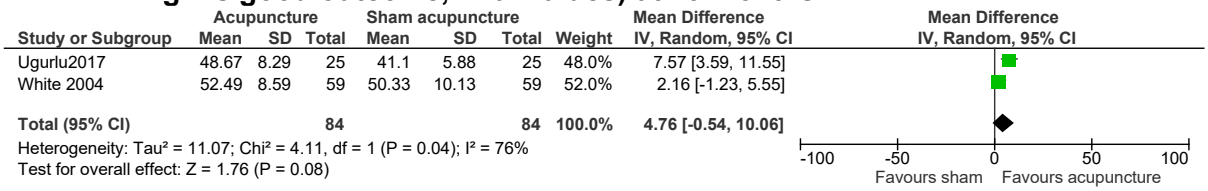


Figure 10: Health related quality of life (SF36 mental component summary; 0-100, high is good outcome, final values) at ≤3 months



NB: Heterogeneity not explained by subgroup analysis

Figure 11: Health related quality of life (SF36 physical functioning subscale; final values, 0-100, high is good outcome, final values) at ≤3 months

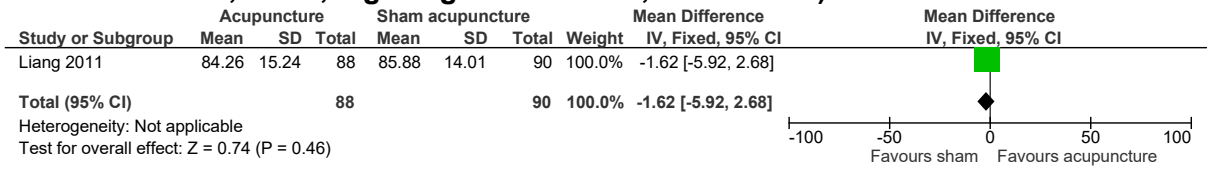


Figure 12: Health related quality of life (SF36 physical role subscale, final values and change scores; 0-100, high is good outcome, final values) at ≤3 months

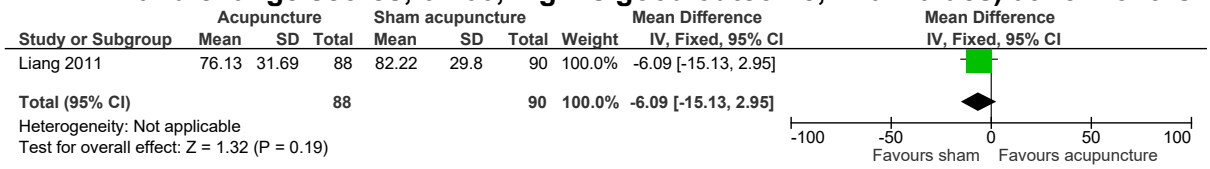


Figure 13: Health related quality of life (SF36 bodily pain subscale, final values; 0-100, high is good outcome, final values) at ≤3 months

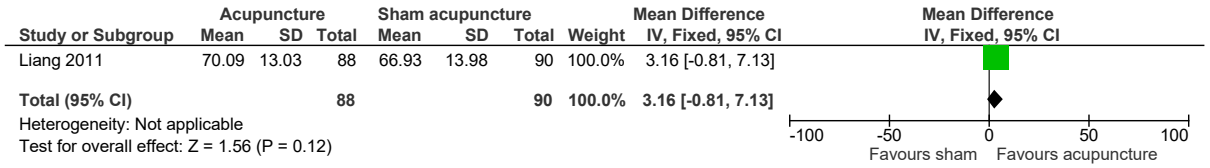


Figure 14: Health related quality of life (SF36 general health subscale, final values; 0-100, high is good outcome, final values) at ≤3 months

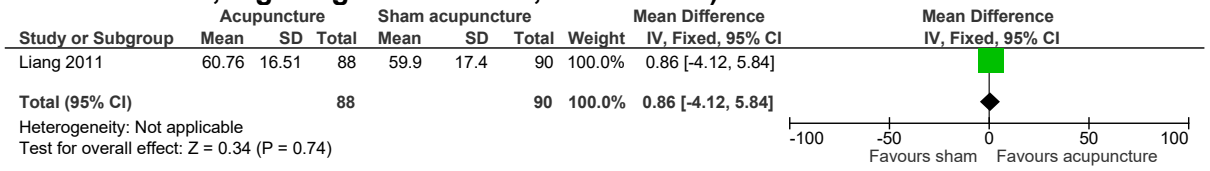


Figure 15: Health related quality of life (SF36 emotional role subscale, final values; 0-100, high is good outcome, final values) at ≤3 months

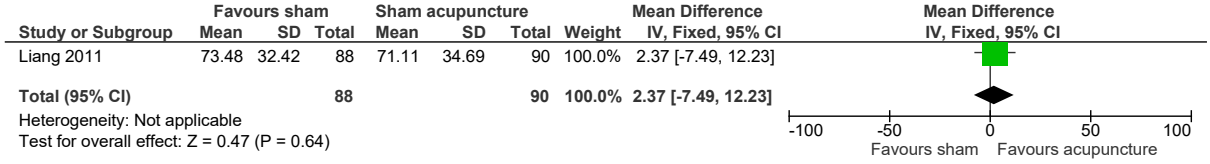


Figure 16: Health related quality of life (SF36 vitality subscale, final values; 0-100, high is good outcome, final values) at ≤3 months

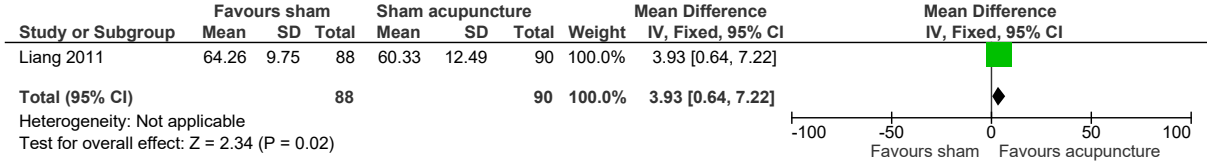


Figure 17: Health related quality of life (SF36 social functioning subscale, final values; 0-100, high is good outcome, final values) at ≤3 months

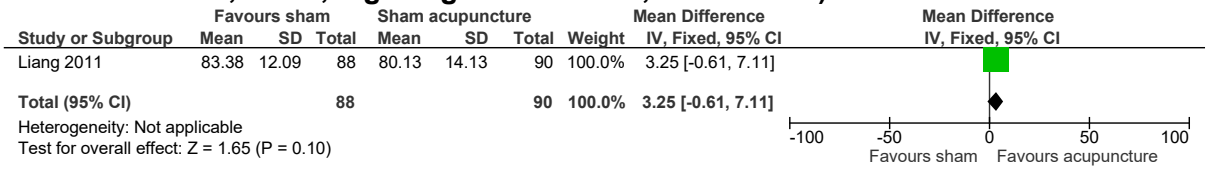


Figure 18: Health related quality of life (SF36 mental health subscale, final values; 0-100, high is good outcome, final values) at ≤3 months

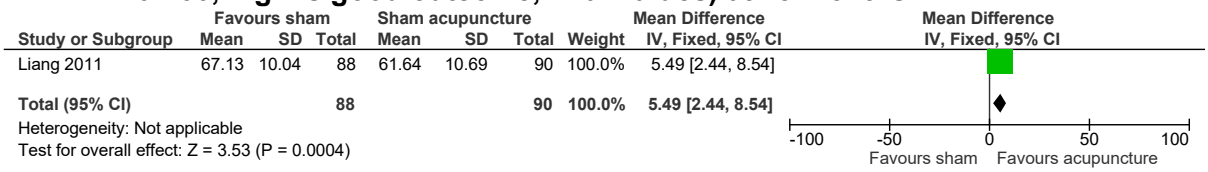


Figure 19: Health related quality of life (NIH-CPSI; 0-12; high is poor outcome, final values) at ≤3 months

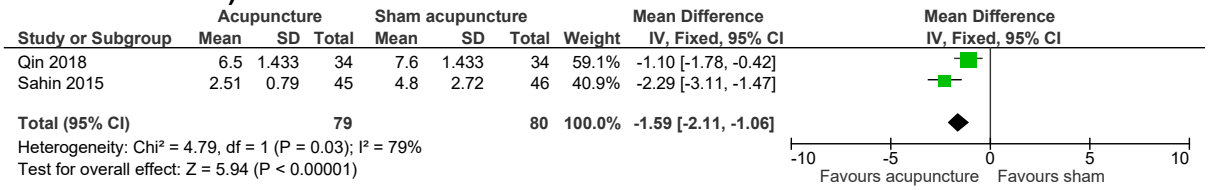


Figure 20: Health related quality of life (FIQ; 0-100; high is poor outcome final values) at ≤3 months

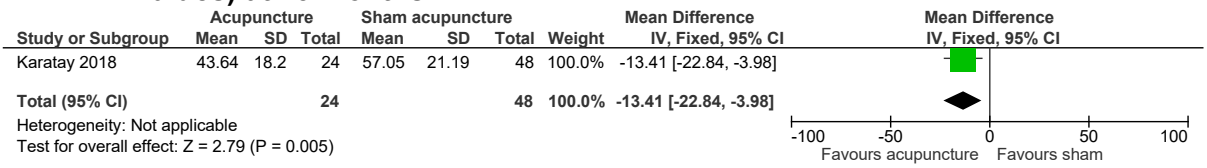


Figure 21: Health related quality of life (SF36 physical component summary; 0-100, high is good outcome, change scores) at >3 months

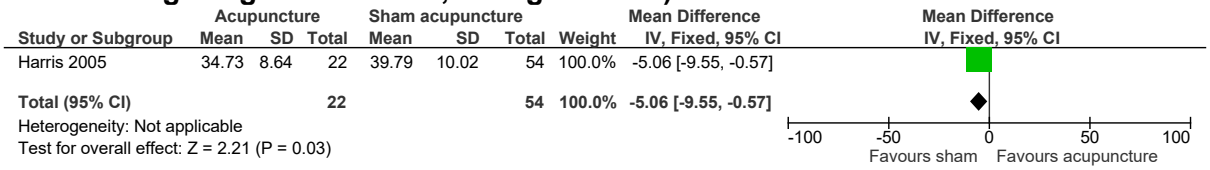


Figure 22: Health related quality of life (SF36 physical component summary; change scores; 0-100, high is good outcome) at >3 months

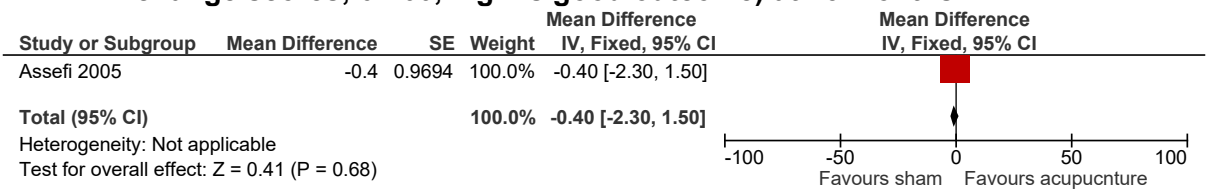


Figure 23: Health related quality of life (SF36 mental component summary; change scores; 0-100, high is good outcome) at >3 months

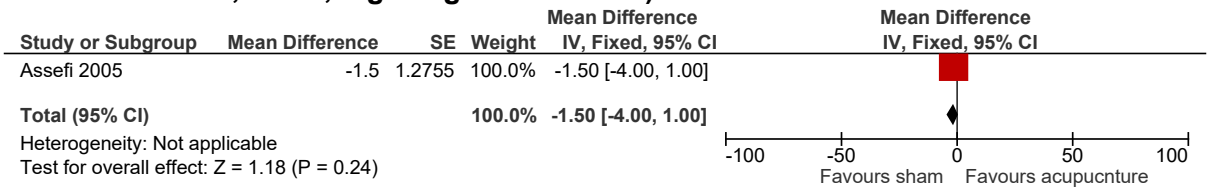


Figure 24: Health related quality of life (SF12 physical component summary; change scores; 0-100, high is good outcome) at >3 months

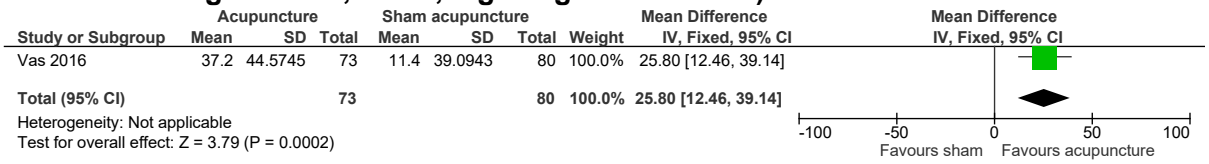


Figure 25: Health related quality of life (SF12 mental component summary; change scores; 0-100, high is good outcome) at >3 months

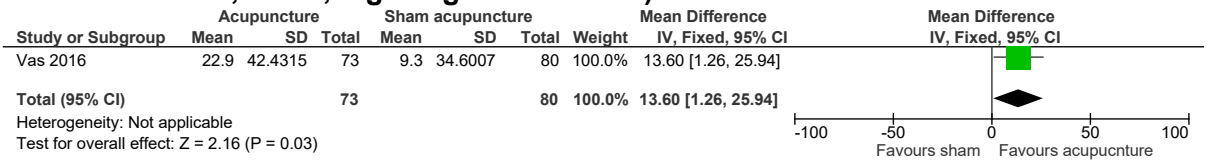


Figure 26: Health related quality of life (NIH-CPSI; 0-12; final values, high is poor outcome) at >3 months

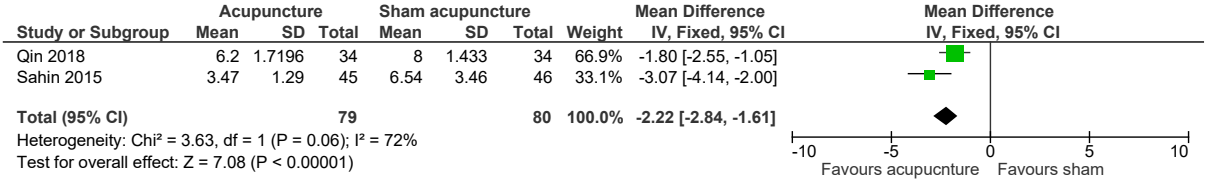


Figure 27: Physical function (Neck Pain Questionnaire/Neck Disability Index; 0-100; high is poor outcome, final values) at ≤3 months

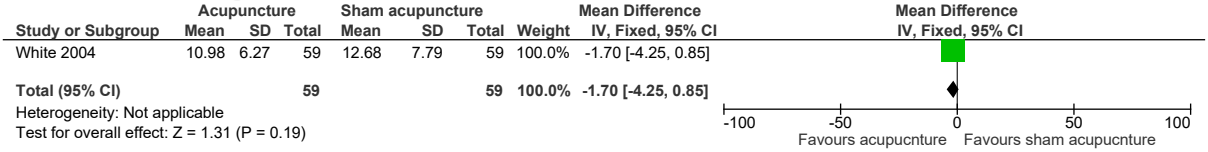


Figure 28: Physical function (Neck Disability Index; 0-100;high is poor outcome, final values) at >3 months

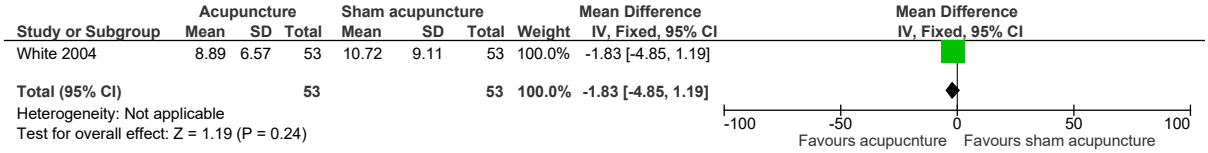


Figure 29: Psychological distress (BDI; 0-63) high is poor outcome final values) at ≤3 months

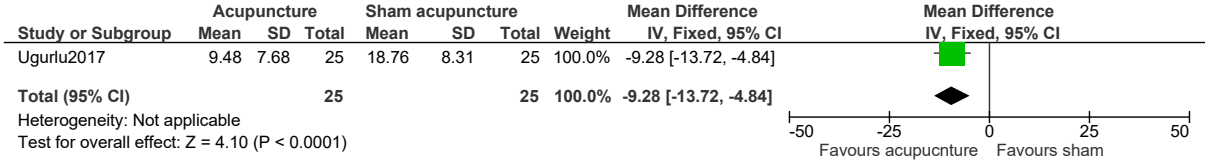


Figure 30: Psychological distress HDRS; 0-52; high is poor outcome; change scores and final values at ≤3 months

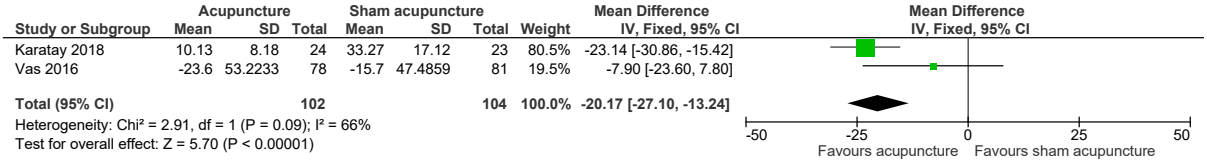


Figure 31: Psychological distress (HDRS; change score; 0-52; high is poor outcome) at >3 months

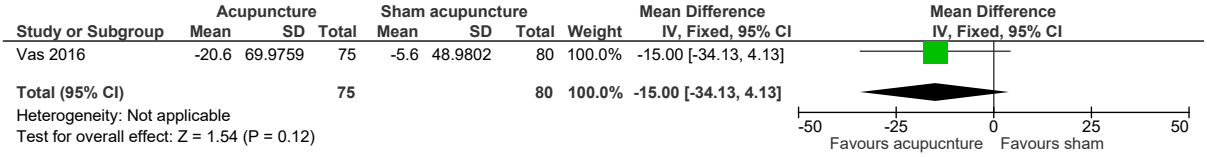


Figure 32: Sleep (Visual analogue sleep quality scale; 0-10, final values, high is good outcome) at ≤3 months

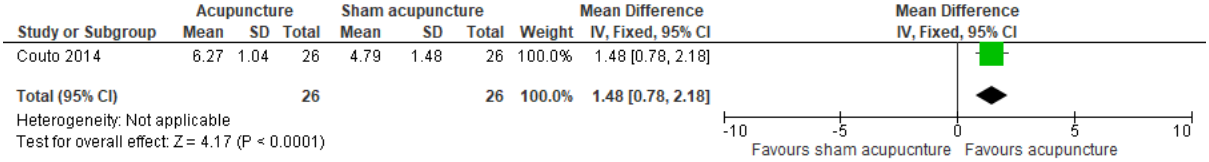


Figure 33: Sleep (Nottingham Health Profile sleep subscale; 0-100; final values, high is poor outcome) at ≤3 months

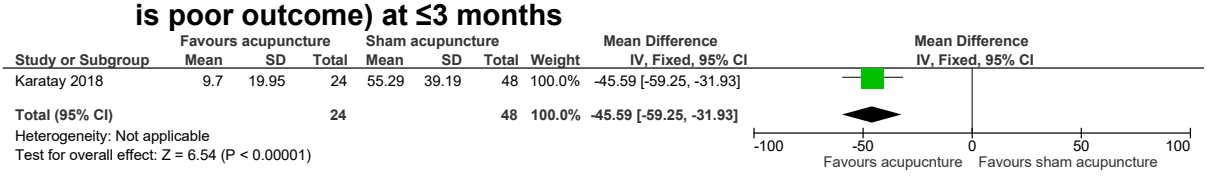


Figure 34: Sleep (VAS; 0-10, change scores, high is poor outcome) at >3 months

Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Fixed, 95% CI
Assefi 2005	-0.5	0.3571	100.0%	-0.50 [-1.20, 0.20]
Total (95% CI)			**100.0%**	**-0.50 [-1.20, 0.20]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.40 (P = 0.16)

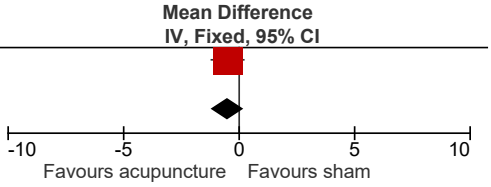
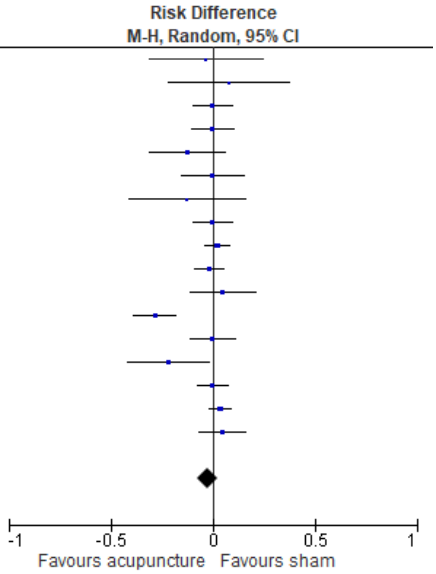


Figure 35: Discontinuation at ≤3 months

Study or Subgroup	Acupuncture Events	Acupuncture Total	Sham acupuncture Events	Sham acupuncture Total	Weight	Risk Difference M-H, Random, 95% CI
Aranha 2015	10	25	10	23	2.5%	-0.03 [-0.31, 0.24]
Birch 1998	4	15	3	16	2.3%	0.08 [-0.22, 0.37]
Chou 2011	0	30	0	15	7.2%	0.00 [-0.10, 0.10]
Couto 2014	1	26	1	26	6.8%	0.00 [-0.10, 0.10]
Harris 2005	7	29	31	85	4.2%	-0.12 [-0.31, 0.06]
He 2005	0	14	0	10	5.2%	0.00 [-0.15, 0.15]
Itoh 2014	0	8	1	8	2.4%	-0.13 [-0.41, 0.16]
Karatay 2018	1	25	2	50	7.2%	0.00 [-0.09, 0.09]
Lee 2011	1	45	0	45	8.5%	0.02 [-0.04, 0.08]
Liang 2011	5	93	7	97	8.1%	-0.02 [-0.09, 0.05]
Lopez-Martos 2018	2	20	1	20	4.9%	0.05 [-0.11, 0.21]
Molsberger 2010	26	154	61	135	6.9%	-0.28 [-0.39, -0.18]
Qin 2018	2	34	2	34	6.6%	0.00 [-0.11, 0.11]
Tekin 2013	1	23	6	23	4.0%	-0.22 [-0.42, -0.02]
Ugurlu2017	0	25	0	25	7.9%	0.00 [-0.07, 0.07]
Vas 2016	4	82	1	82	8.7%	0.04 [-0.02, 0.09]
White 2004	11	70	7	65	6.5%	0.05 [-0.06, 0.16]
Total (95% CI)		**718**		**759**	**100.0%**	**-0.03 [-0.08, 0.03]**
Total events	75		133			

Heterogeneity: Tau² = 0.01; Chi² = 59.80, df = 16 (P < 0.00001); I² = 73%
Test for overall effect: Z = 1.00 (P = 0.32)

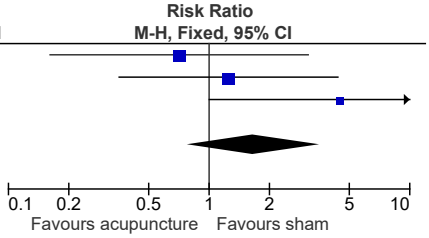


NB: Heterogeneity not explained by subgroup analysis

Figure 36: Discontinuation at >3 months

Study or Subgroup	Acupuncture Events	Acupuncture Total	Sham acupuncture Events	Sham acupuncture Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Assefi 2005	2	25	8	71	41.0%	0.71 [0.16, 3.12]
Sahin 2015	5	50	4	50	39.3%	1.25 [0.36, 4.38]
Vas 2016	9	82	2	82	19.7%	4.50 [1.00, 20.19]
Total (95% CI)		**157**		**203**	**100.0%**	**1.67 [0.78, 3.56]**
Total events	16		14			

Heterogeneity: Chi² = 3.16, df = 2 (P = 0.21); I² = 37%
Test for overall effect: Z = 1.32 (P = 0.19)



E.2 Acupuncture versus usual care

Figure 37: Pain (VAS; 0-10; final & change scores; high is poor outcome) at ≤3 months

Study or Subgroup	Acupuncture Mean	Acupuncture SD	Acupuncture Total	Usual care Mean	Usual care SD	Usual care Total	Weight	Mean Difference IV, Fixed, 95% CI
Birch 1998	1.87	1.9	11	4.76	2.05	12	10.4%	-2.89 [-4.50, -1.28]
Casanueva 2014	6.9	2.3	50	8.1	1.3	50	50.4%	-1.20 [-1.93, -0.47]
Cho 2014	4.05	1.828	30	4.5	2.2	15	16.2%	-0.45 [-1.74, 0.84]
Coan 1981	3.63	2.22	15	5.37	2.23	15	10.6%	-1.74 [-3.33, -0.15]
Schlaeger 2015	-2.9	2.1	18	-0.54	2.4	18	12.4%	-2.36 [-3.83, -0.89]
Total (95% CI)			**124**			**110**	**100.0%**	**-1.46 [-1.98, -0.94]**

Heterogeneity: Chi² = 7.40, df = 4 (P = 0.12); I² = 46%
Test for overall effect: Z = 5.49 (P < 0.00001)

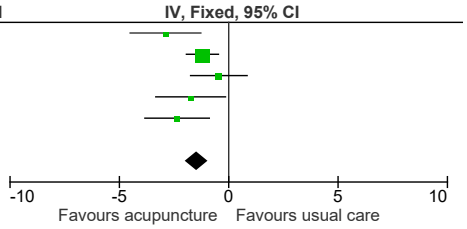


Figure 38: Pain (SF McGill Pain Questionnaire and Northwick pain questionnaire; final values, high is poor outcome) at ≤3 months

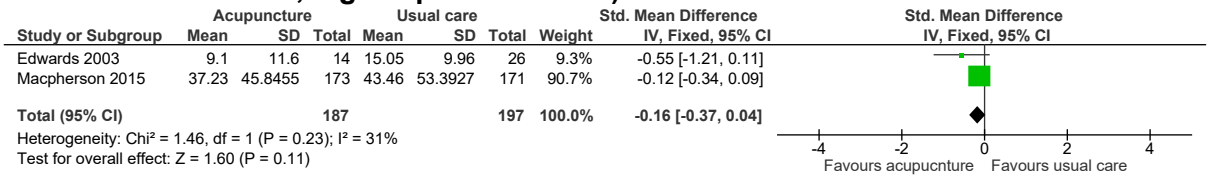


Figure 39: Pain (Neck pain and disability scale; 0-100, change scores, high is poor outcome) at ≤3 months

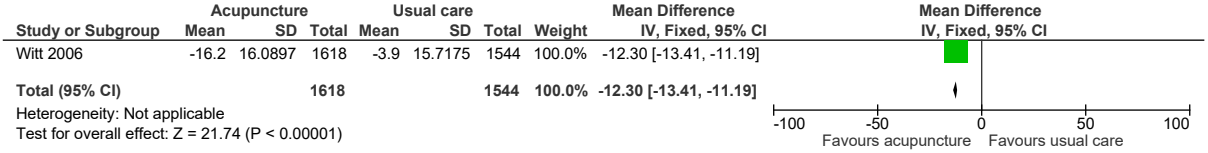


Figure 40: Pain (Northwick park questionnaire; 0-100, final values, high is poor outcome) at >3 months

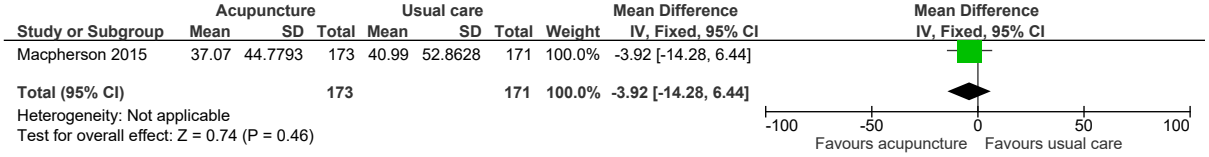


Figure 41: Quality of life (SF36 physical component; 0-100; change scores; high is good outcome) at ≤3 months

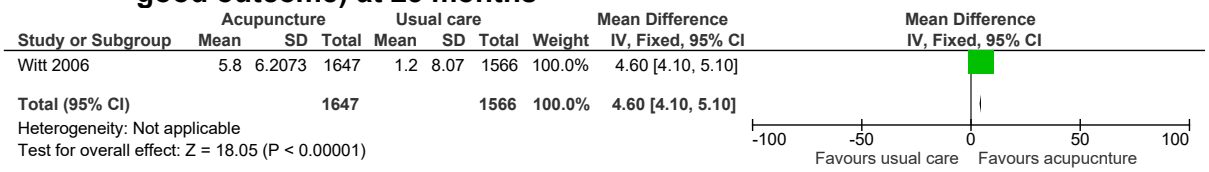


Figure 42: Quality of life (SF36 mental component; 0-100; change scores; high is good outcome) at ≤3 months

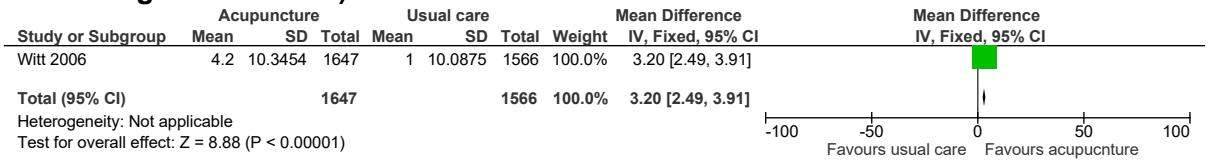


Figure 43: Quality of life (SF36 physical functioning subscale; 0-100; change scores; high is good outcome) at ≤3 months

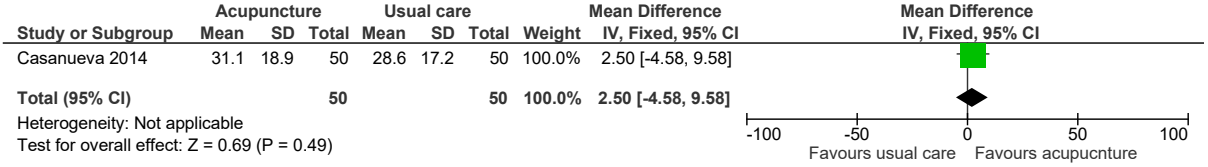


Figure 44: Quality of life (SF36 role limitation subscale; 0-100; change scores; high is good outcome) at ≤3 months

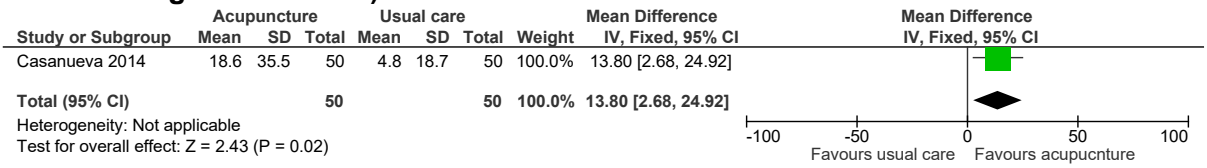


Figure 45: Quality of life (SF36 pain subscale; 0-100; change scores; high is good outcome at ≤3 months

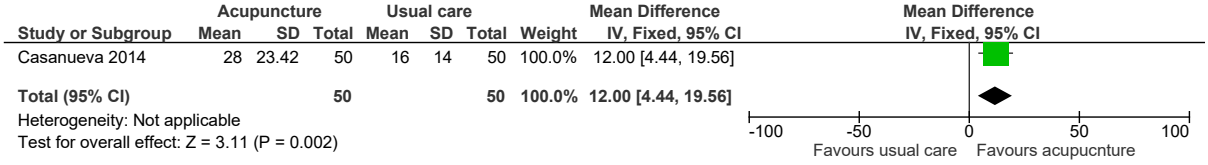


Figure 46: Quality of life (SF36 general health subscale; 0-100; change scores; high is good outcome) at ≤3 months

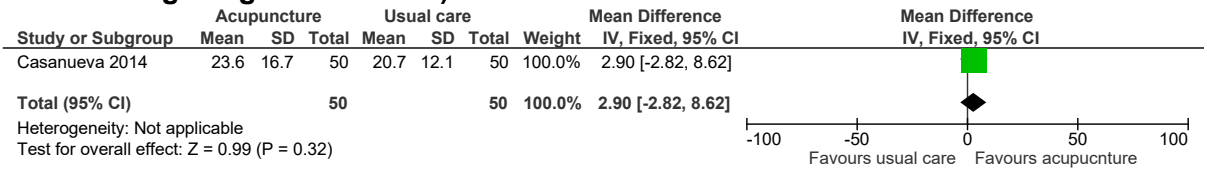


Figure 47: Quality of life (SF36 vitality subscale; 0-100; change scores; high is good outcome) at ≤3 months

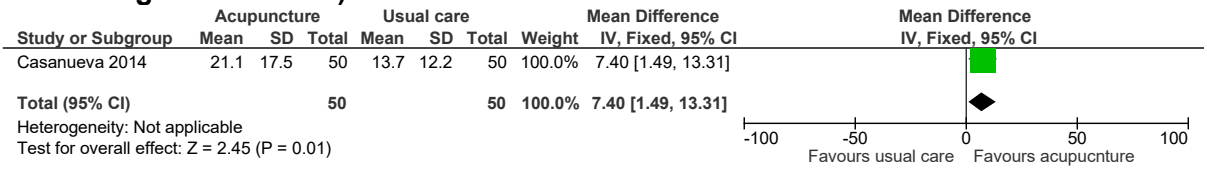


Figure 48: Quality of life (SF36 social functioning subscale; 0-100; change scores; high is good outcome) at ≤3 months

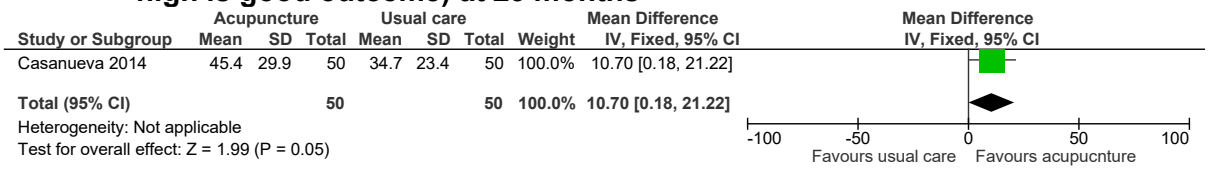


Figure 49: Quality of life (SF36 role limitation subscale; 0-100; change scores; high is good outcome) at ≤3 months

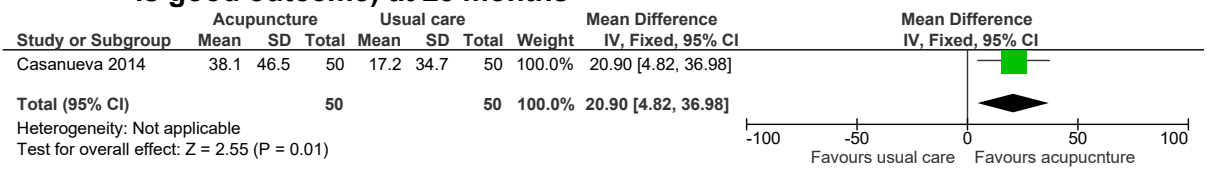


Figure 50: Quality of life (SF36 mental health subscale; 0-100; change scores; high is good outcome) at ≤3 months

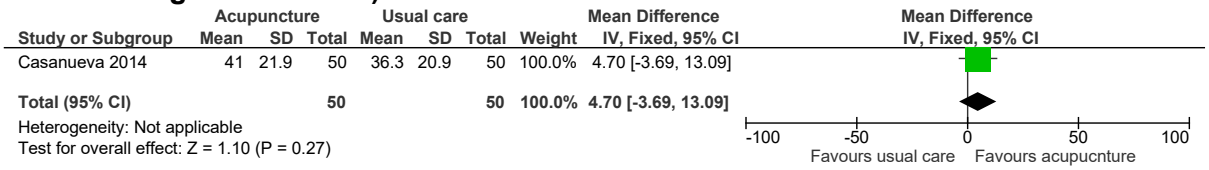


Figure 51: Quality of life (EQ-5D, high is good outcome, -0.594-1, final values) at >3 months

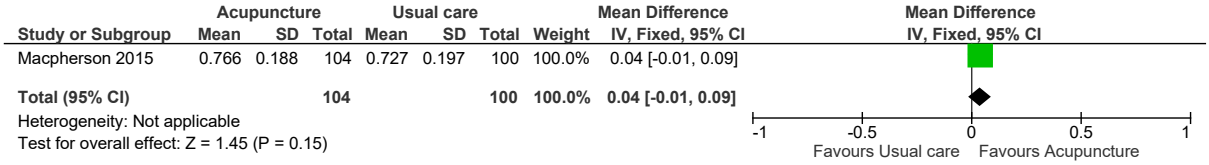


Figure 52: Physical function (Neck Disability Index; 0-100; final scores; high is poor outcome) at ≤3 months

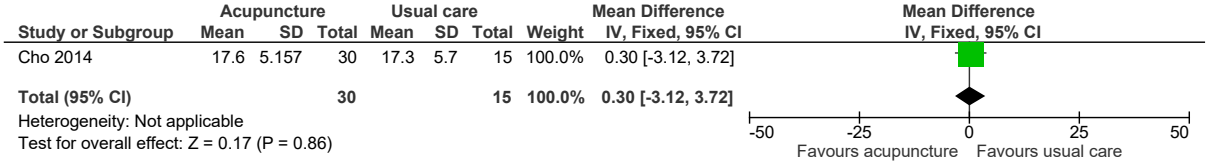


Figure 53: Physical function (6 minute walk test; metres, change scores) at ≤3 months

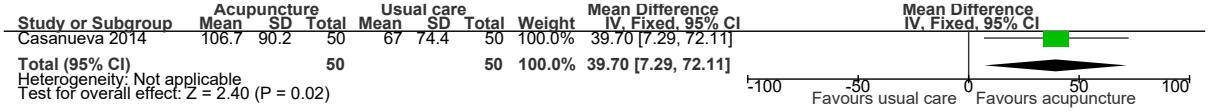


Figure 54: Psychological distress (BDI depression subscale; 0-62, high is poor outcome, final values) at ≤3 months

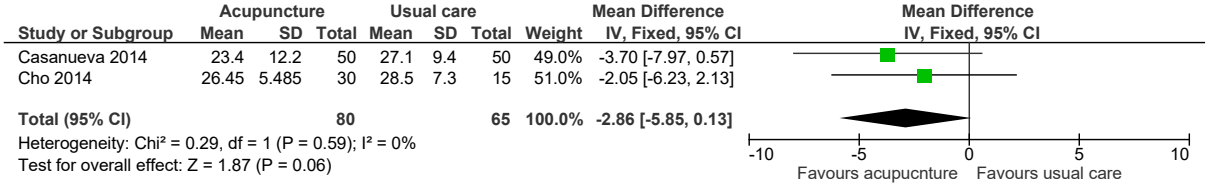


Figure 55: Psychological distress (BDI anxiety subscale;0-62, high is poor outcome, final values) at ≤3 months

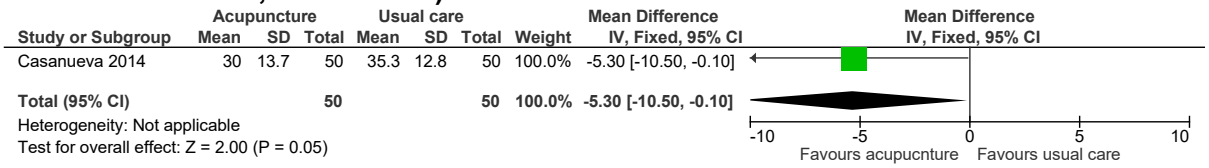


Figure 56: Pain self-efficacy (Chronic pain self-efficacy scale, 0-8, high is good outcome) at >3 months

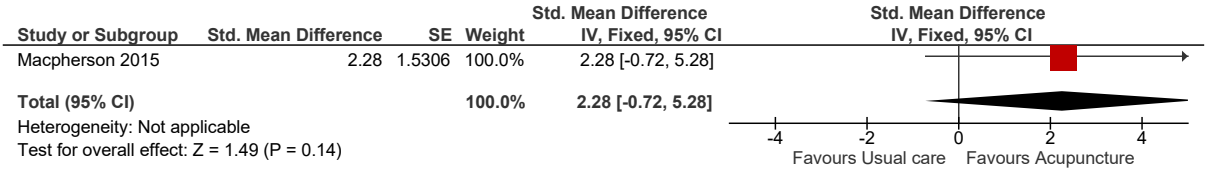


Figure 57: Pain interference (BPI pain interference subscale; 0-10; final scores; high is poor outcome) at ≤3 months

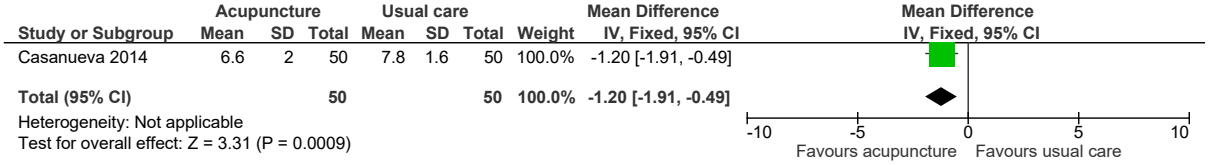


Figure 58: Sleep (Pittsbugh Sleep Quality Index; 0-21; final values, high is poor outcome) at ≤3 months

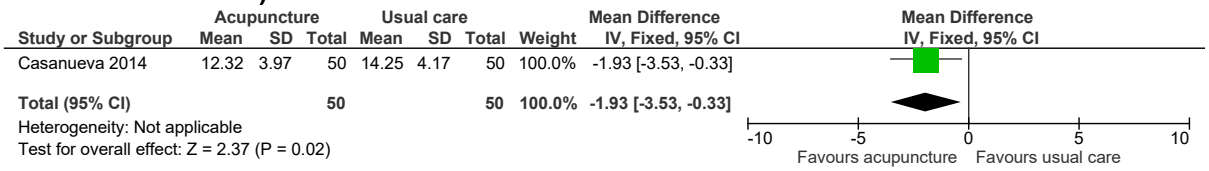
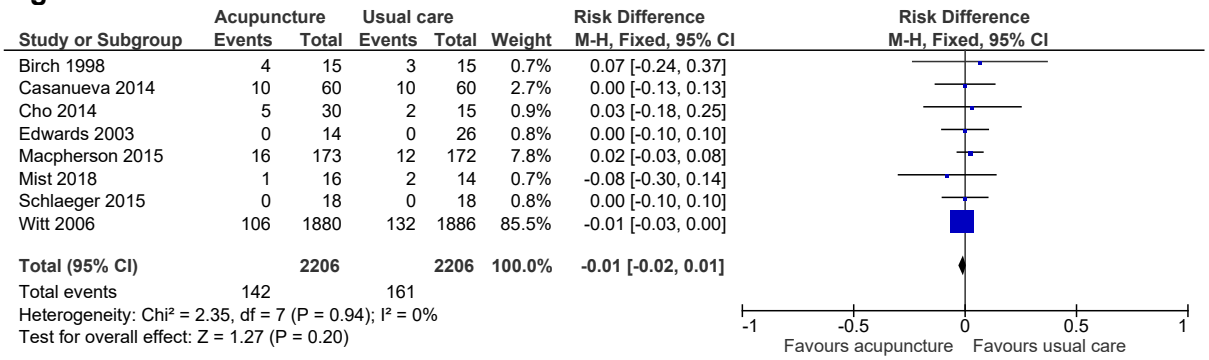


Figure 59: Discontinuation at ≤3 months

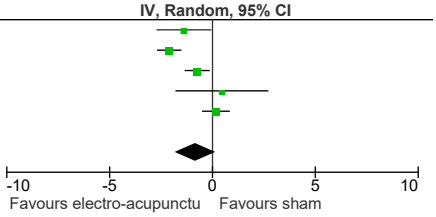


E.3 Electro-acupuncture versus sham electro-acupuncture

Figure 60: Pain (VAS, MPI; 0-10; high is poor outcome; final values) at ≤3 months

Study or Subgroup	Electro-acupuncture Mean	SD	Total	Sham Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
Deluze 1992	3.989	2.63	28	5.378	2.271	27	18.0%	-1.39 [-2.69, -0.09]
He 2004	1.5	0.5	14	3.6	0.8	10	23.8%	-2.10 [-2.66, -1.54]
Martin 2006	3.42	1.14	25	4.16	0.91	24	23.7%	-0.74 [-1.32, -0.16]
Sahin 2010	4	2.97	13	3.54	3.13	16	11.3%	0.46 [-1.77, 2.69]
Zhang 2013	4.68	2.1583	87	4.51	2.013	76	23.2%	0.17 [-0.47, 0.81]
Total (95% CI)			**167**			**153**	**100.0%**	**-0.83 [-1.84, 0.17]**

Heterogeneity: Tau² = 1.02; Chi² = 30.35, df = 4 (P < 0.00001); I² = 87%
Test for overall effect: Z = 1.63 (P = 0.10)



NB: Heterogeneity not explained by subgroup analysis

Figure 61: Pain (VAS, MPI; 0-10; high is poor outcome; final values) at >3 months

Study or Subgroup	Electro-acupuncture Mean	SD	Total	Sham Mean	SD	Total	Weight	Mean Difference IV, Random, 95% CI
He 2004	1.9	0.6	14	4.4	1.1	10	32.9%	-2.50 [-3.25, -1.75]
Martin 2006	3.73	1.31	25	4.14	0.84	24	33.7%	-0.41 [-1.02, 0.20]
Zhang 2013	4.68	2.2118	84	4.36	2.1006	76	33.4%	0.32 [-0.35, 0.99]
Total (95% CI)			**123**			**110**	**100.0%**	**-0.85 [-2.41, 0.70]**

Heterogeneity: Tau² = 1.77; Chi² = 31.88, df = 2 (P < 0.00001); I² = 94%
Test for overall effect: Z = 1.07 (P = 0.28)

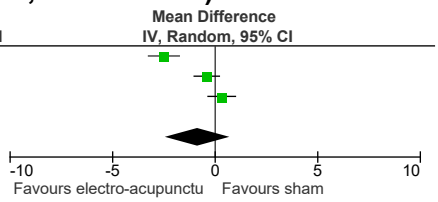


Figure 62: Quality of Life (SF36 physical component; 0-100; high is good outcome; final values) at ≤3 months

Study or Subgroup	Electro-acupuncture Mean	SD	Total	Sham Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Zhang 2013	52.8	4.2228	87	53.3	3.9386	76	100.0%	-0.50 [-1.75, 0.75]
Total (95% CI)			**87**			**76**	**100.0%**	**-0.50 [-1.75, 0.75]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.78 (P = 0.43)

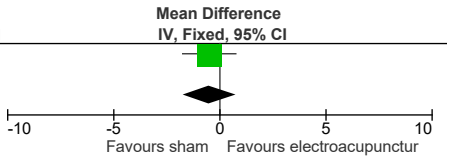


Figure 63: Quality of Life (SF36 mental component; 0-100; high is good outcome; final values) at ≤3 months

Study or Subgroup	Electro-acupuncture Mean	SD	Total	Sham Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Zhang 2013	45.9	4.2228	87	45.3	4.8138	76	100.0%	0.60 [-0.80, 2.00]
Total (95% CI)			**87**			**76**	**100.0%**	**0.60 [-0.80, 2.00]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.84 (P = 0.40)

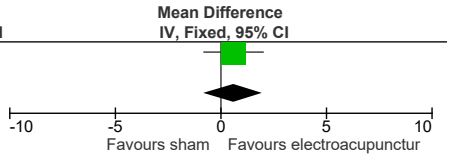


Figure 64: Quality of life (FIQ; 0-100; high is poor outcome, final values) at ≤3 months

Study or Subgroup	Acupuncture Mean	SD	Total	Sham acupuncture Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Martin 2006	34.8	12.1	25	42.2	10.2	24	100.0%	-7.40 [-13.66, -1.14]
Total (95% CI)			**25**			**24**	**100.0%**	**-7.40 [-13.66, -1.14]**

Heterogeneity: Not applicable
Test for overall effect: Z = 2.32 (P = 0.02)

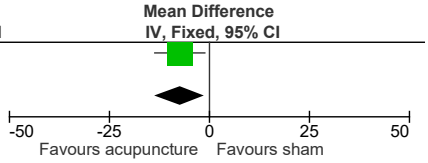


Figure 65: Quality of Life (SF36 physical component; 0-100; high is good outcome; final values) at >3 months

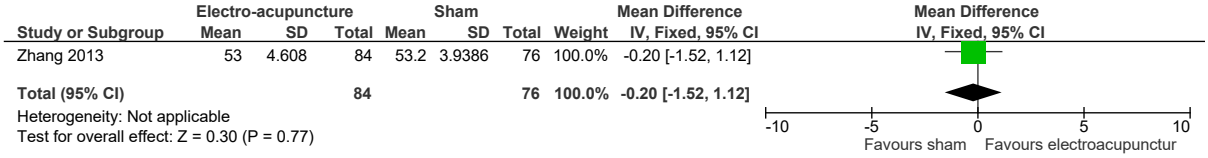


Figure 66: Quality of Life (SF36 mental component; 0-100; high is good outcome; final values) at >3 months

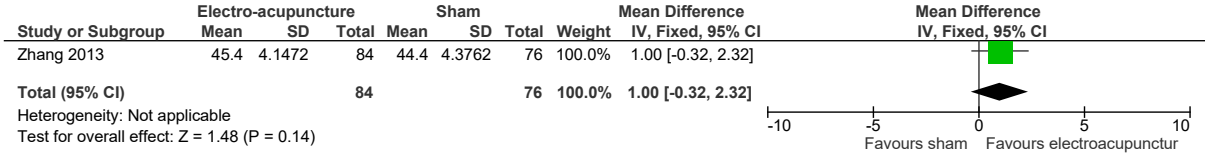


Figure 67: Quality of life (FIQ; 0-100; high is poor outcome, final values) at >3 months

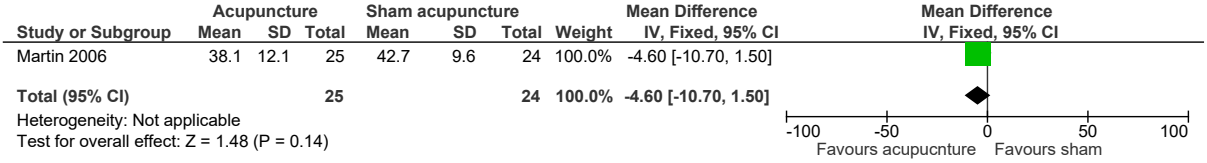


Figure 68: Pain interference (MPI; pain interference; 0-100, high is poor outcome, final values) at ≤3 months

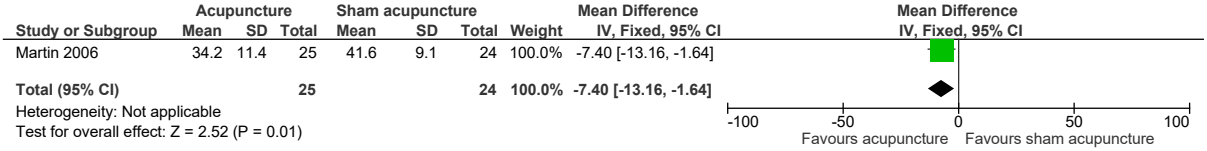


Figure 69: Pain interference (MPI; pain interference; 0-100, high is poor outcome, final values) at >3 months

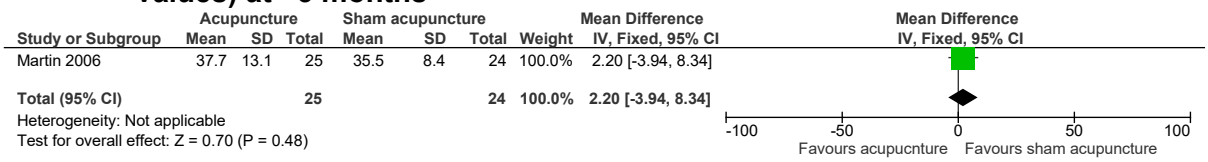


Figure 70: Sleep at ≤3 months (VAS sleep quality scale, 0-10, final values, high is good outcome)

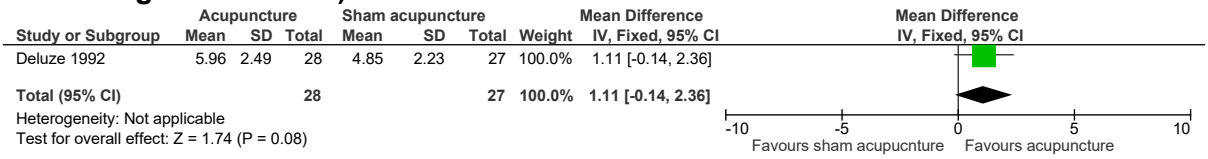
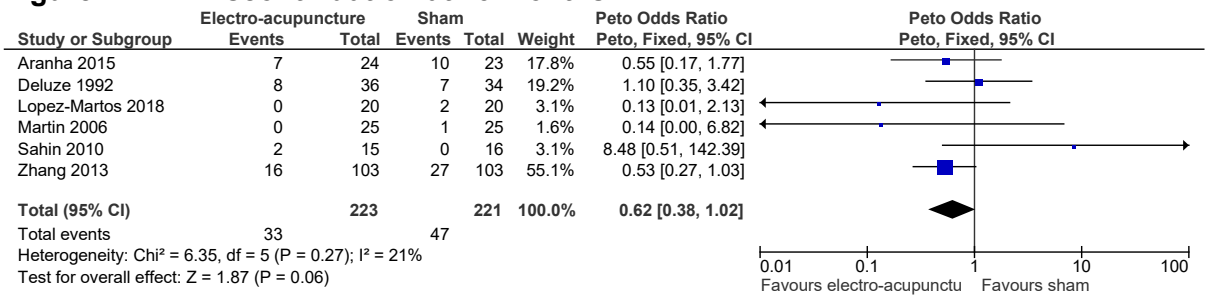


Figure 71: Discontinuation at ≤3 months



Appendix F: GRADE tables

Table 17: Acupuncture compared to sham acupuncture

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acupuncture	Sham acupuncture	Relative (95% CI)	Absolute		
Pain (VAS/NRS; 0-10; final and change scores; high is poor outcome) at ≤3 months												
13	randomised trials	serious[1]	serious[2]	no serious indirectness	serious[3]	none	603	615	-	MD 1.41 lower (2.11 to 0.72 lower)	⊕OOO VERY LOW	CRITICAL
Pain (NIH-CPSI; 0-21, high is poor outcome, final values) at ≤3 months												
2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	79	80	-	MD 2.04 lower (2.83 to 1.26 lower)	⊕⊕OO LOW	CRITICAL
Pain (VAS; 0-10; final values and change scores; high is poor outcome) at >3 months												
4	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	169	207	-	MD 0.81 lower (1.33 to 0.3 lower)	⊕⊕OO LOW	CRITICAL
Pain (NIH-CPSI; 0-21; high is poor outcome, final values) at >3 months												
2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	79	80	-	MD 2.88 lower (3.74 to 2.03 lower)	⊕⊕⊕O MODERATE	CRITICAL
Pain (least square mean difference; VAS; 0-10, final values, high is poor outcome) at >3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	25	71	-	MD 0.5 higher (0.3 lower to 1.3 higher)	⊕⊕OO LOW	CRITICAL
Health related quality of life (SF12 physical composite; 0-100, final values; high is good outcome) at ≤3 months												

2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	104	106	-	MD 11.76 higher (6.49 to 17.02 higher)	⊕⊕⊕O MODERATE	CRITICAL
Health related quality of life (SF12 mental composite; 0-100, final values; high is good outcome) - Fibromyalgia at ≤3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	78	80	-	MD 16.1 higher (0.54 lower to 32.74 higher)	⊕⊕OO LOW	CRITICAL
Health related quality of life (SF12 mental composite; 0-100, final values; high is good outcome) - Myofascial pain syndrome at ≤3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	26	26	-	MD 15.17 lower (21.45 to 8.89 lower)	⊕⊕⊕O MODERATE	CRITICAL
Health related quality of life (SF36 physical component summary; 0-100, high is good outcome, final values) at ≤3 months												
3	randomised trials	very serious[1]	serious[2]	no serious indirectness	serious[3]	none	106	138	-	MD 0.27 lower (4.59 lower to 4.05 higher)	⊕OOO VERY LOW	CRITICAL
Health related quality of life (SF36 mental component summary; 0-100, high is good outcome, final values) at ≤3 months												
3	randomised trials	very serious[1]	serious[2]	no serious indirectness	serious[3]	none	84	84	-	MD 4.76 higher (0.54 lower to 10.06 higher)	⊕OOO VERY LOW	CRITICAL
Health related quality of life (SF36 physical functioning subscale; final values, 0-100, high is good outcome, final values) at ≤3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	88	90	-	MD 1.62 lower (5.92 lower to 2.68 higher)	⊕⊕⊕O MODERATE	CRITICAL
Health related quality of life (SF36 physical role subscale, final values and change scores; 0-100, high is good outcome, final values) at ≤3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	88	90	-	MD 6.09 lower (15.13 lower to 2.95 higher)	⊕⊕OO LOW	CRITICAL
Health related quality of life (SF36 bodily pain subscale, final values; 0-100, high is good outcome, final values) at ≤3 months												

1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	88	90	-	MD 3.16 higher (0.81 lower to 7.13 higher)	⊕⊕OO LOW	CRITICAL
Health related quality of life (SF36 general health subscale, final values; 0-100, high is good outcome, final values) at ≤3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	88	90	-	MD 0.86 higher (4.12 lower to 5.84 higher)	⊕⊕OO LOW	CRITICAL
Health related quality of life (SF36 emotional role subscale, final values; 0-100, high is good outcome, final values) at ≤3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	88	90	-	MD 2.37 higher (7.49 lower to 12.23 higher)	⊕⊕OO LOW	CRITICAL
Health related quality of life (SF36 vitality subscale, final values; 0-100, high is good outcome, final values) at ≤3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	88	90	-	MD 3.93 higher (0.64 to 7.22 higher)	⊕⊕OO LOW	CRITICAL
Health related quality of life (SF36 social functioning subscale, final values; 0-100, high is good outcome, final values) at ≤3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	88	90	-	MD 3.25 higher (0.61 lower to 7.11 higher)	⊕⊕OO LOW	CRITICAL
Health related quality of life (SF36 mental health subscale, final values; 0-100, high is good outcome, final values) at ≤3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	88	90	-	MD 5.49 higher (2.44 to 8.54 higher)	⊕⊕OO LOW	CRITICAL
Health related quality of life (NIH-CPSI; 0-12; high is poor outcome, final values) at ≤3 months												
2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	79	80	-	MD 1.59 lower (2.11 to 1.06 lower)	⊕⊕⊕O MODERATE	CRITICAL
Health related quality of life (FIQ; 0-100; high is poor outcome final values) at ≤3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	24	48	-	MD 13.41 lower (22.88 to 3.98 lower)	⊕⊕OO LOW	CRITICAL

Health related quality of life (SF36 physical component summary; 0-100, high is good outcome, final values) at >3 months												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	22	54	-	MD 5.06 lower (9.55 to 0.57 lower)	⊕OOO VERY LOW	CRITICAL
Health related quality of life (SF36 physical component summary; 0-100, high is good outcome, final values) at >3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	-	-	-	MD 0.4 lower (2.3 lower to 1.5 higher)	⊕OOO VERY LOW	CRITICAL
Health related quality of life (SF36 mental component summary; 0-100, high is good outcome, final values) at >3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	-	-	-	MD 1.5 lower (4 lower to 1 higher)	⊕OOO VERY LOW	CRITICAL
Health related quality of life (SF36 physical component summary; change scores; 0-100, high is good outcome) at >3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	73	80	-	MD 25.8 higher (12.46 to 39.14 higher)	⊕⊕OO LOW	CRITICAL
Health related quality of life (SF12 mental component summary; change scores; 0-100, high is good outcome) at >3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	73	80	-	MD 13.6 higher (1.26 to 25.94 higher)	⊕⊕OO LOW	CRITICAL
Health related quality of life (NIH-CPSI; 0-12; final values, high is poor outcome) at >3 months												
2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	79	80	-	MD 2.22 lower (2.84 to 1.61 lower)	⊕⊕⊕O MODERATE	CRITICAL
Physical function (Neck Pain Questionnaire/Neck Disability Index; 0-100; high is poor outcome, final values) at ≤3 months												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	59	59	-	MD 1.7 lower (4.25 lower to 0.85 higher)	⊕OOO VERY LOW	CRITICAL
Physical function (Neck Disability Index; 0-100;high is poor outcome, final values) at >3 months												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	53	53	-	MD 1.83 lower (4.85 lower to 1.19 higher)	⊕OOO VERY LOW	CRITICAL

Psychological distress (BDI; 0-63; high is poor outcome final values) at ≤3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	25	25	-	MD 9.28 lower (13.72 to 4.84 lower)	⊕⊕⊕O MODERATE	CRITICAL
Psychological distress (HDRS; 0-52; high is poor outcome; change scores and final values) at ≤3 months												
2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	102	104	-	MD 20.17 lower (27.1 to 13.24 lower)	⊕⊕OO LOW	CRITICAL
Psychological distress (HDRS; change score; 0-52; high is poor outcome) at >3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	75	80	-	MD 15 lower (34.13 lower to 4.13 higher)	⊕⊕OO LOW	CRITICAL
Sleep (Visual analogue sleep quality scale; 0-10, final values, high is good outcome) at ≤3 months												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	26	26	-	MD 1.14 higher (0.55 to 1.73 higher)	⊕OOO VERY LOW	IMPORTANT
Sleep (Nottingham Health Profile sleep subscale; 0-100; final values, high is poor outcome) at ≤3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	24	48	-	MD 45.59 lower (59.25 to 31.93 lower)	⊕⊕⊕O MODERATE	IMPORTANT
Sleep (VAS sleep; 0-10, change scores, high is poor outcome) at >3 months												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	25	71	-	MD 0.5 lower (1.2 lower to 0.2 higher)	⊕⊕⊕O MODERATE	IMPORTANT
Discontinuation (≤3 months)												
17	randomised trials	serious[1]	serious[2]	no serious indirectness	serious[3]	none	75/718 (10.4%)	133/759 (17.5%)	See comment	175 fewer per 1000 (from 172 fewer to 186 fewer)	⊕OOO VERY LOW	IMPORTANT
Discontinuation (>3 months)												

3	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	16/157 (10.2%)	8%	RR 1.67 (0.78 to 3.56)	54 more per 1000 (from 18 fewer to 205 more)	⊕OOO VERY LOW	IMPORTANT

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
2 Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis
3 Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs

Table 18: Acupuncture compared to usual care

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Acupuncture versus usual care**		**Relative (95% CI)**	**Absolute**		
Pain (VAS; 0-10; final & change scores; high is poor outcome ≤3 months)												
5	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	124	110	-	MD 1.46 lower (1.98 to 0.94 lower)	⊕⊕OO LOW	CRITICAL
Pain (SF McGill Pain Questionnaire and northwick pain questionnaire; final values, high is poor outcome ≤3 months)												
2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	187	197	-	SMD 0.16 lower (0.37 lower to 0.04 higher)	⊕⊕OO LOW	CRITICAL
Pain (Neck pain and disability scale; 0-100; change scores, high is poor outcome, ≤3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	1618	1544	-	MD 12.3 lower (13.41 to 11.19 lower)	⊕⊕⊕O MODERATE	CRITICAL
Pain (Northwick park questionnaire; 0-100, final values, high is poor outcome; >3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	173	171	-	MD 3.92 lower (14.28 lower to 6.44 higher)	⊕⊕⊕O MODERATE	CRITICAL
Quality of life (SF36 physical component; 0-100; change scores; high is good outcome; ≤3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	1647	1566	-	MD 4.6 higher (4.1 to 5.1 higher)	⊕⊕⊕O MODERATE	CRITICAL

Quality of life (SF36 mental component; 0-100; change scores; high is good outcome; ≤3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	1647	1566	-	MD 3.2 higher (2.49 to 3.91 higher)	⊕⊕⊕O MODERATE	CRITICAL
Quality of life (SF36 physical functioning subscale; 0-100; change scores; high is good outcome; ≤3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	50	50	-	MD 2.5 higher (4.58 lower to 9.58 higher)	⊕OOO VERY LOW	CRITICAL
Quality of life (SF36 role limitation subscale; 0-100; change scores; high is good outcome; ≤3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	50	50	-	MD 13.8 higher (2.68 to 24.92 higher)	⊕OOO VERY LOW	CRITICAL
Quality of life (SF36 pain subscale; 0-100; change scores; high is good outcome; ≤3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	50	50	-	MD 12 higher (4.44 to 19.56 higher)	⊕⊕OO LOW	CRITICAL
Quality of life (SF36 general health subscale; 0-100; change scores; high is good outcome; ≤3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	50	50	-	MD 2.9 higher (2.82 lower to 8.62 higher)	⊕OOO VERY LOW	CRITICAL
Quality of life (SF36 vitality subscale; 0-100; change scores; high is good outcome; ≤3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	50	50	-	MD 7.4 higher (1.49 to 13.31 higher)	⊕OOO VERY LOW	CRITICAL
Quality of life (SF36 social functioning subscale; 0-100; change scores; high is good outcome; ≤3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	50	50	-	MD 10.7 higher (0.18 to 21.22 higher)	⊕OOO VERY LOW	CRITICAL
Quality of life (SF36 role limitation subscale; 0-100; change scores; high is good outcome; ≤3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	50	50	-	MD 20.9 higher (4.82 to 36.98 higher)	⊕⊕OO LOW	CRITICAL
Quality of life (SF36 mental health subscale; 0-100; change scores; high is good outcome; ≤3 months)												

1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	50	50	-	MD 4.7 higher (3.69 lower to 13.09 higher)	⊕OOO VERY LOW	CRITICAL
Quality of life (EQ-5D, -0.594-1, >3 months, high is good outcome)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	104	100	-	MD 0.04 higher (0.01 lower to 0.09 higher)	⊕⊕OO LOW	CRITICAL
Physical function (Neck Disability Index; 0-100; final; high is poor outcome; ≤3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	30	15	-	MD 0.3 higher (3.12 lower to 3.72 higher)	⊕OOO VERY LOW	CRITICAL
Physical function (6 minute walk test; metres, change scores, ≤3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	50	50	-	MD 39.7 higher (7.29 to 72.11 higher)	⊕OOO VERY LOW	CRITICAL
Psychological distress (BDI depression subscale; 0-62, high is poor outcome, final values, ≤3 months)												
2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	80	65	-	MD 2.86 lower (5.85 lower to 0.13 higher)	⊕⊕OO LOW	CRITICAL
Psychological distress (BDI anxiety subscale;0-62, high is poor outcome, final values, ≤3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	50	50	-	MD 5.3 lower (10.5 to 0.1 lower)	⊕OOO VERY LOW	CRITICAL
Pain self-efficacy (Chronic pain self-efficacy scale, 0-8, >3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	150	144	-	SMD 2.28 higher (0.72 higher to 5.28 higher)	⊕⊕⊕O MODERATE	CRITICAL
Pain interference (BPI pain interference subscale; 0-10; final & change scores; high is poor outcome ≤3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	50	50	-	MD 1.2 lower (1.91 to 0.49 lower)	⊕OOO VERY LOW	CRITICAL
Sleep (Pittsbugh Sleep Quality Index; 0-21; final values, high is poor outcome ≤3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	50	50	-	MD 1.93 lower (3.53 to 0.33 lower)	⊕OOO VERY LOW	IMPORTANT

Discontinuation ≤3 months												
8	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	142/2206 (6.4%)	10.2%	See comment	102 fewer per 1000 (from 101 fewer to 104 fewer)	⊕⊕OO LOW	IMPORTANT

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
2 Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs

Table 19: Electro-acupuncture compared to sham electro-acupuncture

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Electro-acupuncture**	**Sham**	**Relative (95% CI)**	**Absolute**		
Pain (VAS; 0-10; high is poor outcome; final values, ≤3 months)												
5	randomised trials	serious[1]	serious[2]	no serious indirectness	serious[3]	none	167	153	-	MD 0.83 lower (0.84 lower to 0.17 higher)	⊕OOO VERY LOW	CRITICAL
Pain (VAS; 0-10; high is poor outcome; final values, >3 months)												
3	randomised trials	serious[1]	serious[2]	no serious indirectness	very serious[3]	none	123	110	-	MD 0.85 lower (2.41 lower to 0.7 higher)	⊕OOO VERY LOW	CRITICAL
Quality of Life (SF36 physical component; 0-100; high is good outcome; final values, ≤3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	87	76	-	MD 0.5 lower (1.75 lower to 0.75 higher)	⊕⊕⊕O MODERATE	CRITICAL
Quality of Life (SF36 mental component; 0-100; high is good outcome; final values, ≤3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	87	76	-	MD 0.6 higher (0.8 lower to 2 higher)	⊕⊕⊕O MODERATE	CRITICAL
Health related quality of life (FIQ; 0-100; high is poor outcome ≤3 months, final values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	25	24	-	MD 7.4 lower (13.66 to 1.14 lower)	⊕OOO VERY LOW	CRITICAL

Quality of Life (SF36 physical component; 0-100; high is good outcome; final values, >3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	84	76	-	MD 0.2 lower (1.52 lower to 1.12 higher)	⊕⊕⊕O MODERATE	CRITICAL
Quality of Life (SF36 mental component; 0-100; high is good outcome; final values, >3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	84	76	-	MD 1 higher (0.32 lower to 2.32 higher)	⊕⊕OO LOW	CRITICAL
Health related quality of life (FIQ; 0-100; high is poor outcome, final values, >3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	25	24	-	MD 4.6 lower (10.7 lower to 1.5 higher)	⊕⊕OO LOW	CRITICAL
Discontinuation ≤3 months												
5	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	33/223 (14.8%)	18.1%	OR 0.63 (0.39 to 1.04)	59 fewer per 1000 (from 102 fewer to 6 more)	⊕⊕OO LOW	IMPORTANT
Sleep (Visual analogue sleep quality scale; 0-10, final values, high is good outcome ≤3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	28	27	-	SMD 0.46 higher (0.07 lower to 1 higher)	⊕OOO VERY LOW	IMPORTANT

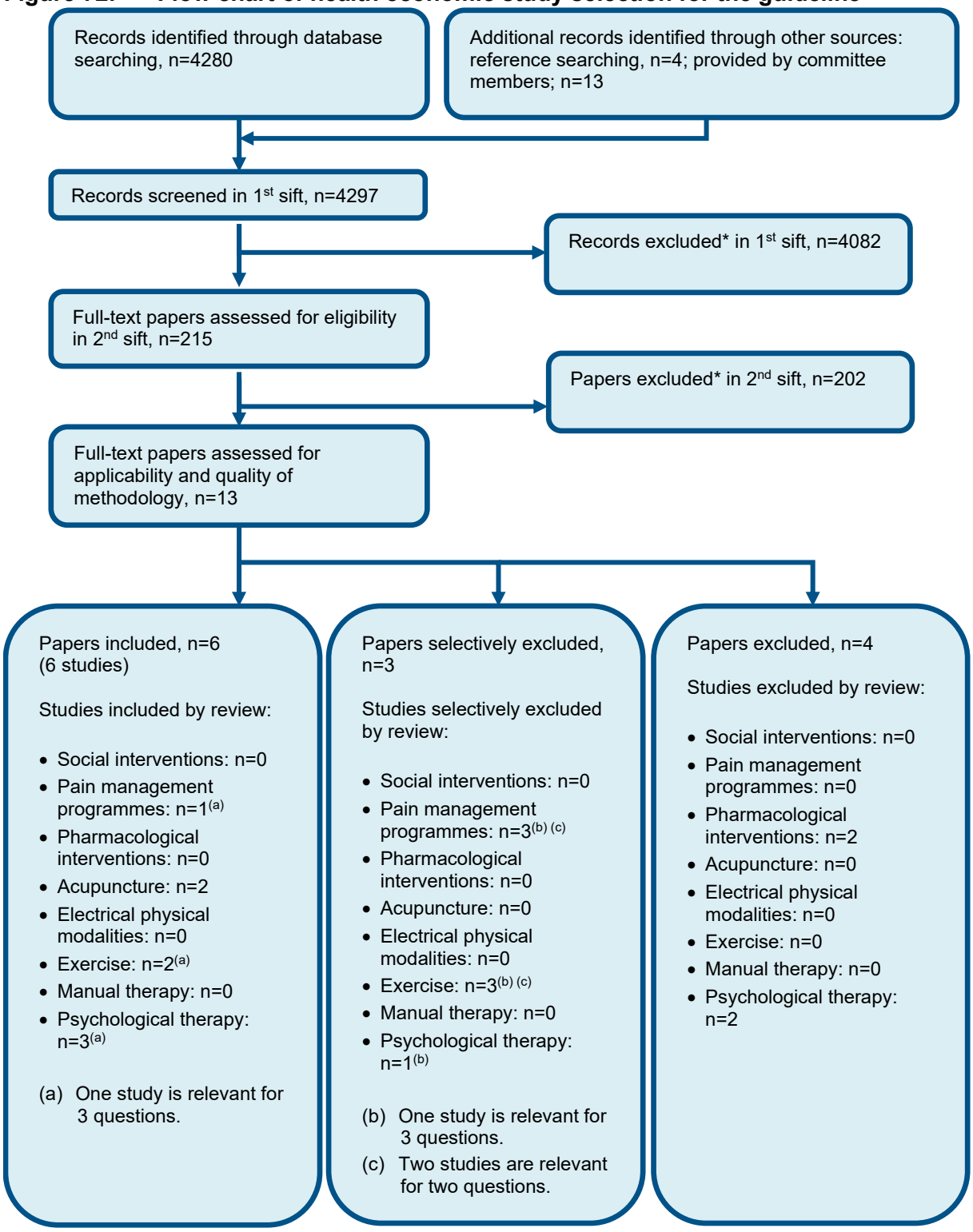
1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias

2 Downgraded by 1 or 2 increments because heterogeneity, unexplained by subgroup analysis

3 Downgraded by 1 increment if the confidence interval crossed 1 MID or by 2 increments if the confidence interval crossed both MIDs

Appendix G: Health economic evidence selection

Figure 72: Flow chart of health economic study selection for the guideline



* Non-relevant population, intervention, comparison, design or setting; non-English language

Appendix H: Health economic evidence tables

Study	Willich SN, Reinhold T, Selim D, Jena S, Brinkhaus B, Witt CM. Cost-effectiveness of acupuncture treatment in patients with chronic neck pain. Pain. 2006; 125(1-2):107-13[218]			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CUA (health outcome: QALYs) **Study design:** RCT (Within-trial analysis) **Approach to analysis:** Analysis of individual level SF-36 data. Resource use obtained within trial and unit costs applied. **Perspective:** German societal perspective, direct and indirect costs reported separately. Only direct costs reported here. **Follow-up:** 3 months **Discounting:** n/a	**Population:** People aged 18 years and over with a clinical diagnosis of chronic neck pain of at least 6 months duration. **Patient characteristics:** N = 3,005 Age: 50.6 Male: 31.1% **Intervention 1:** Waiting list control - received delayed acupuncture treatment after 3 months. **Intervention 2:** Acupuncture - received immediate acupuncture treatment, consisting of 10-15 sessions.	**Total costs (mean per patient):** Intervention 1: £503 Intervention 2: £228 Incremental (2−1): £274 (95% CI: NR; p=NR) **Currency & cost year:** 2005 German Euros (presented here as 2005 UK pounds(a)) **Cost components incorporated:** Direct costs: Acupuncture, physician visits, medication (including patients co-payment), hospital stays. Indirect costs: (caused by work incapacity, determined by the human capital approach) also reported, but not included in total cost calculations above.	**QALYs (mean per patient):** Intervention 1: 0.649 Intervention 2: 0.625 Incremental (2−1): 0.024 (95% CI: 0.020 – 0.028; p= ≤0.001)	**ICER (Intervention 2 versus Intervention 1):** £11,430 per QALY gained (calculated based on deducting indirect costs) 95% CI: NR **Analysis of uncertainty:** Note: analysis of uncertainty was conducted from a societal perspective. Bootstrapping was used (1000 times). <u>Secondary analysis:</u> There was a separate analysis labelled as 'diagnostic specific costs', but it is not clear how these were derived. Led to an ICER of £11,889. <u>Sensitivity analyses:</u> • Observed outcome differences were assumed to gradually decrease over time. The total duration of this decrease was varied from 6 months to 4 years. Treatment effect duration modelled for 4 years gave a 100% probability of cost-effectiveness of acupuncture at the £4,041 threshold. • Treatment duration modelled for 6 month threshold gave a 99.5%

				probability of cost-effectiveness of acupuncture at the £37,417 threshold. • Discount rates for monetary costs and benefits up to 5% and varying discount rates for effects between 0% and 10% did not change the findings. • Lowering acupuncture session payments to £12 (€15) per session gave a probability of 100% cost effectiveness at the £5,837 threshold. • Increasing acupuncture session payments to £45 (€55) gave a probability of 100% cost effectiveness at the £32,104 threshold.
Data sources				
Health outcomes: Based on the Witt 2006 trial.[220] QALYs calculated using patient-level SF-36 data, collected at baseline and 3 months after treatment, converted to SF-6D utility using the algorithm developed by Brazier et al (2002). Participants received a mean number of 10.3 acupuncture sessions over the 3 month study duration. **Quality-of-life weights:** Within trial analysis: SF-36 data transformed to SF-6D, tariff used unclear. **Cost sources:** The payment for each session was €35. Resource use obtained using statutory health insurance databases. In sensitivity analysis of durations longer than 1 year: QALYs were discounted at 1.5% and costs at 3%.				
Comments				
Source of funding: Studies were funded by a number of German Social Health Insurance Funds. **Limitations:** Uses SF-6D not EQ-5D. German resource use data (2006) and unit costs may not reflect current NHS context. Acupuncture costs arbitrarily derived. Discounting for outcomes at 1.5% and costs at 3% rather than NICE reference case of 3.5% in sensitivity analyses. Short follow-up period may not reflect chronic nature of condition and may not be sufficient to capture all benefits and costs. Sensitivity analyses only present results using societal perspective. Within-trial analysis may not reflect full body of evidence. Unclear how they determined if costs were related specifically to the condition. **Other:** A total of 3.451 patients enrolled in the trial, but only 3,005 with complete SF-36 data used for the economic analysis. Mean cost difference was also reported taking the difference between 3 months before and 3 months after the study onset to take account of baseline differences in costs, but only the costs within the 3 months of the study were considered here.				
Overall applicability:[(b)] Partially applicable		**Overall quality:**[(c)] Potentially serious limitations		

Abbreviations: 95% CI: 95% confidence interval; CUA: cost–utility analysis; da: deterministic analysis; EQ-5D: Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER: incremental cost-effectiveness ratio; NR: not reported; QALYs: quality-adjusted life years

(a) Converted using 2005 purchasing power parities[161]. 2005 used as cost year because study was submitted to journal in January 2006 so calculations assumed to be undertaken in previous year rather than year of publication.

(b) Directly applicable / Partially applicable / Not applicable

(c) Minor limitations / Potentially serious limitations / Very serious limitations

Study	Essex et al 2017[60]			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CUA (health outcome: QALYs) **Study design:** RCT (Within-trial analysis) **Approach to analysis:** Analysis of individual level EQ-5D data. Resource use obtained within trial and unit costs applied. **Perspective:** UK NHS. In addition, a broader societal perspective captured costs to patients from a private healthcare and productivity losses due to neck pain. **Time horizon/Follow-up**: 1 Year **Treatment effect duration:**[(a)] 5 months **Discounting:** n/a	**Population:** People with chronic, non-specific neck pain for 3 months or more **Cohort settings:** N: 204 (compete case data for which there was enough data for economic evaluation. Only those in the acupuncture and usual care group). Male: 45.5% **Intervention 1:** Usual care, General neck pain specific treatments such as prescribed medications and visits to physical therapists. **Intervention 2:** Acupuncture, Up to 12 fifty-minute treatments delivered once per week and then once every 2 weeks usually over a 5 month period. In addition to usual care	**Total NHS healthcare costs:** [(b)] Intervention 1: £484.27 Intervention 2: £947.38 Incremental (1−2) (adjusted bootstrapped estimates): £451.32 (95% CI: £285 to £635); p=NR) **Currency & cost year:** 2012/13 UK pounds **Cost components incorporated:** GP appointments, practice nurse appointments, physiotherapist appointments, hospital outpatient visits, accident and emergency admissions, hospital day case admissions, other hospital admissions, prescription medication.	**QALYs:** Intervention 1: 0.715 Intervention 2: 0.74 Incremental (1-2) (adjusted bootstrapped estimates): 0.032 (95% CI: 0.001 to 0.062; p=NR)	**ICER (Intervention 1 versus Intervention 2):** £18,767 per QALY gained (pa) (95% CI: £,4,426 to £74,562) Probability Intervention 1 cost effective (£20K/30K threshold): 71%/85% **Analysis of uncertainty:** Probabilistic sensitivity analyses was conducted and CEACs presented. Sensitivity analyses: • Healthcare resources not relating to neck pain were excluded (ICER of £15,364, 95% CI: £4,156 to £56,763) • Missing data for the EQ-5D and costs were imputed (ICER of £43,838, 95% CI: – £216,427 to £395,047).

Data sources
Health outcomes: Based on the MacPherson 2015 trial[139]. Study had a third arm of Alexander technique that is not relevant to the protocol. **Quality of life:** EQ-5D UK tariff, collected at baseline, six and twelve months. **Cost sources:** The national average unit costs at 2012/13 prices from the department of health. Prescription costs were obtained from the health and social care information centre. Costs per session based on the rate paid to the practitioners (members of the British acupuncture council) reflective of national rates were used for the acupuncture sessions, With the total cost of intervention based on session rates multiplied by number of sessions attended by each participant. Resource use was based on self-reported use. People were also asked to report the resource use they thought was related to neck pain and overall resource use. Base case analysis based on complete case data. Differential mean QALYs were adjusted for baseline costs and practice size using seemingly unrelated regression models. Differential mean costs were adjusted for baseline costs and practice size using seemingly unrelated regression models. Cost data was bootstrapped 1000 times with all analyses adjusted for GP practice size. Imputed data for the sensitivity analysis imputed using Rubins method using iterative chain equations using variables such as duration of pain, age, gender, health resource use, baseline EQ-5D score, treatment allocation and perceived stress.
Comments
Source of funding: Supported by Arthritis research UK. **Limitations:** Based on single-trial. Self-reported resource use, people may not be accurate or also be confused between reporting resource use for neck pain and overall resource use leading to large amount of missing data or double counting, so pre-specified assumptions were made such as if neck pain part was filled in then answers to overall resource use would be replaced with neck pain value. 40% had missing data in the acupuncture arm. **Other:** Complete case data available for 104 people in acupuncture group and 100 in usual care.
Overall applicability:(c) Directly applicable **Overall quality:**(d) Potentially serious limitations

Abbreviations: 95% CI= 95% confidence interval; CUA= cost–utility analysis; da= deterministic analysis; EQ-5D= Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER= incremental cost-effectiveness ratio; NR= not reported; pa= probabilistic analysis; QALYs= quality-adjusted life years

(a) For studies where the time horizon is longer than the treatment duration, an assumption needs to be made about the continuation of the study effect. 1 year time horizon but intervention was around 5 months so could be continuation of effect.

(b) Incremental costs calculated as mean costs of acupuncture group minus mean costs of usual care group.

(c) Directly applicable / Partially applicable / Not applicable

(d) Minor limitations / Potentially serious limitations / Very serious limitations

Appendix I: Excluded studies

I.1 Excluded clinical studies

Table 20: Studies excluded from the clinical review

Study	Exclusion reason
Aigner 2006 [1]	Incorrect population
Airaksinen 1992 [2]	Incorrect intervention
Amin 2015 [3]	Incorrect comparison
An 2010 [4]	No outcomes
Aridici 2016 [6]	Incorrect comparison
Bahrami-Taghanaki 2014 [8]	Incorrect population, incorrect comparison
Batra 1985 [9]	No outcomes
Boureau 1981 [11]	Unclear population, incorrect comparison
Brennan 2017 [12]	Incorrect comparison
Brinkhaus 2006 [13]	Incorrect population
Campa-Moran 2015 [14]	Incorrect comparison
Carlsson 2001 [15]	Incorrect population
Castro Sanchez 2018 [18]	Incorrect comparison
Castro-Sanchez 2017 [17]	Incorrect comparison
Cerezo-Tellez 2016 [19]	Unclear population (acute or chronic pain)
Cerezo-Tellez 2016 [20]	Incorrect population
Cerezo-Tellez 2018 [21]	Incorrect population
Chan 2009 [22]	Incorrect intervention/comparison
Chen 2013 [23]	Incorrect population
Cheng 1986 [24]	Incorrect comparison
Cherkin 2001 [25]	Incorrect population
Cherkin 2009 [26]	Incorrect population
Chiu 2005 [27]	Incorrect intervention
Cho 2013 [29]	Incorrect population
Chong 2015 [30]	Protocol only
Chong 2018 [31]	70% had endometriosis
Coan 1980 [34]	Incorrect population
Collazo Cha, 2012 [35]	Not in English
Collazo Chao, 2012 [36]	Not in English
Collazo Chao, 2013 [37]	Not in English
Collazo, 2014 [38]	Not in English
Collazo, 2015 [39]	Not in English
Corujeira Rivera, 2010 [40]	Not in English
Cotchett 2014 [41]	Incorrect population
David 1998 [44]	Incorrect comparison, no outcomes
Daya 2007 [45]	Literature review
De Meulemeester 2017 [46]	Incorrect comparison

Study	Exclusion reason
Deare 2013 [47]	Cochrane review, references checked. Different outcomes, population and comparisons
Deluze, 1993 [48]	Not in English
Diracoglu 2012 [51]	Not chronic
Dyson-Hudson 2007 [52]	Incorrect population
Ebneshahidi 2005 [53]	Incorrect population
Edelist 1976 [54]	Incorrect population, no outcomes
Eftekharsadat 2016 [56]	Incorrect population
Endres 2007 [57]	Incorrect population
Ernst 1995 [58]	Unclear if chronic or acute
Eroglu 2013 [59]	Incorrect comparison
Fan 2016 [61]	Incorrect study design
Fernandes 1980 [62]	No outcomes
Fox 1976 [63]	Incorrect study design (all participants had same treatments, but in different order)
Ga 2007 [64]	Incorrect comparison
Gallego-Sendarrubias 2020 [65]	Incorrect interventions
Gaw 1975 [66]	Incorrect population
Giles 1999 [67]	Incorrect population
Giles 2003 [68]	Incorrect population, no relevant outcomes
Glazov 2009 [69]	Incorrect population
Glazov 2014 [70]	Incorrect population
Goddard 2002 [71]	Incorrect study design; 1 session, follow up time 30 minutes
Goldman 2008 [72]	Incorrect population
Gonzalez-Perez 2015 [73]	Incorrect comparison
Gunn 1980 [74]	Incorrect population
Haake 2003 [76]	Incorrect population
Haake 2007 [75]	Incorrect population
Hadianfard 2012 [77]	Incorrect comparison
Hakim, 2019 [78]	Incorrect study design
Hall 2014 [79]	No outcomes, abstract only
Hansen 1981 [81]	Not in English
Hansen 1983 [80]	No results
Harris 2008 [82]	Incorrect study design (fMRI)
Harris 2009 [84]	No useable outcomes
Hinman 2014 [87]	Incorrect population
Hirota 2007 [88]	Not in English
Hollisaz 2007 [89]	Incorrect population
Hsieh 2007 [90]	Study design - before and after study
Hunter 2012 [91]	Incorrect population
Ichida 2017 [92]	Incorrect population
Irnich 2000 [98]	Not in English
Irnich 2001 [95]	Incorrect population (includes whiplash)

Study	Exclusion reason
Irnich 2001 [96]	Not in English
Irnich 2001 [97]	Not in English
Irnich 2002 [94]	Cross over study
Itoh 2006 [99]	Incorrect population, incorrect study design
Itoh 2010 [100]	Incorrect comparison
Itoh, 2009 [102]	Not in English
Jang, 2010 [103]	Not in English
Jiang, 2013 [104]	Not in English
Johansson 1991 [105]	No outcomes
Junnila 1982 [106]	Incorrect population
Jurisic Kvesic 2015 [107]	Incorrect comparison
Kalauokalani, 2001 [108]	Incorrect population
Kamali 2019 [109]	Incorrect population
Kamanli 2005 [110]	Incorrect comparison
Karst 2000 [112]	Incorrect population
Kerr 2003 [113]	Incorrect population
Kho 1995 [114]	Incorrect population (acute)
Kim 2007 [115]	Incorrect study design (observational/audit/survey)
Kim, 2009 [116]	Not in English
König, 2003 [117]	Not in English
Korpan 2002 [118]	No outcomes (only graphically)
Kucuk 2015 [119]	Incorrect comparison
Kumnerddee 2009 [120]	Incorrect population
Kwon, 2007 [121]	Not in English
Langley 1984 [122]	Incorrect population
Lathia 2009 [123]	Incorrect population
Lee 2008 [125]	No useable outcomes, medians with no useable variability data
Lee 2009 [124]	Incorrect interventions (combined acupuncture and exercise)
Lehmann 1983 [127]	Incorrect population
Lehmann 1986 [128]	Incorrect population
Leibing 2002 [129]	Incorrect population
Li, 2016 [130]	Not in English
Lin 2010 [132]	Incorrect comparison, no usable outcomes
Lin 2017 [133]	Incorrect population
Liu 2016 [134]	Incorrect comparison
Llamas-Ramos 2014 [135]	Incorrect comparison
Ma 2010 [137]	Incorrect interventions (acupuncture plus exercise)
Macdonald 1983 [138]	Incorrect population, no outcomes
Madani 2020 [140]	No useable outcome data (no useable variability data)
Maeda 2013 [141]	Incorrect population
Maeda 2017 [142]	Incorrect population
Mavrommatis 2012 [144]	Incorrect population

Study	Exclusion reason
McMillan 1997	No useable outcomes (measured before treatment)
Melzack 1980 [145]	Incorrect population
Mendelson 1978 [146]	Incorrect population
Mendelson 1983 [147]	Incorrect population
Meng 2003 [148]	Incorrect population
Mira 2015 [149]	Incorrect population, incorrect comparison
Molsberger 2002 [151]	Incorrect population
Moore 1976 [153]	No validated outcomes (just 'average post treatment rating improved over pre-treatment %)'
Muller 2005 [154]	Incorrect comparison
Nabeta 2002 [155]	No useable outcomes
Najafi, 2013 [156]	Incorrect study design (before and after study)/letter to editor
Najm 2008 [157]	No useable outcomes, medians with no useable variability data (duplicate of Lee 2008)
Olivan 2007 [160]	Not in English
Pecos-Martin 2015 [162]	Intervention duration unclear
Peng 1987 [163]	Incorrect study design (not randomised)
Perez-Palomares 2017 [164]	Incorrect population
Petrie 1983 [166]	No outcomes
Petrie 1986 [165]	Incorrect comparison (TENS)
Prady 2007 [167]	Incorrect population
Ratcliffe 2006 [169]	Incorrect population
Raustia 1985 [170]	Incorrect population (dysfunction not pain), incorrect comparison
Rayegani 2014 [171]	Incorrect comparison
Reinhold 2008 [172]	Incorrect population
Riikonen 1985 [173]	No outcomes, abstract only
Ruth 2010 [174]	Not in English
Salter 2006 [177]	Incorrect population (acute neck pain)
Sator-Katzenschlager 2003 [179]	Incorrect comparison
Sator-Katzenschlager 2004 [178]	Incorrect population
Schaeffer 2015 [180]	Editorial comment
Scharf, 2006 [181]	Incorrect population
Scharf, 2007 [182]	Not in English
Schmid-Schwap 2006 [184]	Incorrect population
Seo, 2017 [185]	Incorrect population, incorrect comparison
Shankar, 2011 [186]	Incorrect population
Shen 2007 [187]	Incorrect study design; 1 15 minute session and no follow up
Shen, 2009 [188]	Incorrect study design; 1 20 minute session and no follow up
Shi 2018 [189]	Incorrect population
Shin 2012 [190]	Incorrect population
Simma, 2009 [191]	Only medians and quartile ranges reported

Study	Exclusion reason
Smith 2007 [192]	No useable outcomes
Sobhani, 2017 [193]	Incorrect comparison
Song, 2015 [194]	Not in English
Sprott 1998 [195]	No outcomes
Stieven 2020 [196]	Incorrect interventions
Stival, 2014 [197]	Not in English
Streitberger, 2007 [198]	Not in English
Sun 2010 [199]	Not chronic (only 1 month)
Targino, 2008 [200]	No useable outcomes (no variability data)
Tobbackx, 2013 [202]	Incorrect study design (crossover
Tonev 2010 [203]	Not in English
Toroski, 2018 [204]	Incorrect study design (observational/non-randomised)
Tough 2010 [205]	Incorrect population
Tsui 2004 [206]	Incorrect population
Tuzun, 2017 [207]	Incorrect population
Uhlemann, 2001 [209]	Not in English
Ushinohama, 2016 [210]	Incorrect population
Venâncio 2008 [212]	Incorrect interventions
Wang, 2016 [213]	Not in English
Weiner 2007 [214]	Incorrect population
Weiss 2013 [215]	Incorrect population
Wiles 1982 [217]	Letter to editor
Willich 2006 [218]	Unclear intervention
Witt, 2005 [219]	Incorrect population
Witt, 2006 [221]	Incorrect population
Witt, 2006 [222]	Incorrect population
Wu 2016 [223]	Incorrect comparison
Yeung 2003 [224]	Incorrect population
Yoshimizu 2012 [225]	Incorrect study design
Yue 1978 [226]	No results
Yun 2012 [227]	Incorrect population
Yun 2012 [228]	Incorrect population
Zavareo, 2017 [229]	Incorrect comparison
Zhang, 2009 [231]	Not available
Zhang, 2016 [230]	Incorrect comparison
Zheng 2008 [234]	Unclear population
Zheng 2019 [233]	Incorrect intervention (opioids)
Zhou 2018 [235]	Protocol
Ziaeifar 2014 [236]	Incorrect comparison
Zotelli, 2017 [237]	Incorrect population
Zucker 2017 [238]	No usable outcomes

I.2 Excluded health economic studies

None.

Appendix J: Research recommendations

Research question:

What is the clinical and cost-effectiveness of repeat courses of acupuncture or dry needling for the management of chronic primary pain in adults?

Why this is important:

Evidence from this guideline has demonstrated that acupuncture is a clinically and cost effective treatment option for the management of chronic primary pain. This has therefore been recommended as an intervention that should be considered for this population. The recommendation for acupuncture is restricted to a course of acupuncture that lasts no more than 5 hours in total. As a chronic condition, treatments with sustained benefits or those that remain effective when reintroduced are of utmost relevance to people with chronic primary pain. However, there was no evidence included in the review to inform whether or not the benefits of acupuncture would be sustained once treatment finished, or what the effectiveness would be if repeat courses were offered should the benefits wear off. Repeat courses would have cost implications for the NHS, therefore without evidence of effectiveness they cannot be recommended. This research would seek to answer that question in order to inform future updates of this guideline.

PICO question	Population: People with Primary Chronic Pain aged 16 years or over who have received one course of acupuncture according to the guideline recommendations. Intervention(s): • Chinese or Western Acupuncture, maximum 5 hours of healthcare professional's time. Delivered by a band 7 or lower healthcare professional in a community setting. Comparison: • Usual care • Sham or placebo. Outcome(s): • Pain reduction • Health related quality of life (measured by the EQ5D) • Physical function (e.g. Oswestry disability inventory, Roland Morris disability questionnaire) • Psychological distress (depression/anxiety) (preferably Hospital Anxiety and Depression Scale) • Pain interference (brief pain inventory interference subscale) • Pain self-efficacy (pain self-efficacy questionnaire) Secondary outcomes: healthcare utilisation, sleep, discontinuation.
Importance to patients or the population	If there is additional benefit from repeat courses of interventions which have already proven to be effective, patients could be offered further treatment if their symptoms worsened, following initial good response to intervention. Conversely, if repeat courses are demonstrated not to be effective, it would enable treatment to be targeted to alternative options that would be more likely to be of benefit to the patient.
Relevance to NICE guidance	The evidence reviewed within the current guideline only enabled recommendations to be made for one course of treatment. High quality research in this area would generate new evidence and may enable future updates of this guidance to make recommendations for ongoing treatment.

Relevance to the NHS	Evidence informing whether repeat courses of the intervention are effective for those who have benefitted previously would help make best use of NHS resources. Although an intervention should not be offered without evidence of effectiveness, if evidence does support its use it can help reduce unnecessary resource use and better target the treatment for this population, potentially reducing downstream resource use.
National priorities	None
Current evidence base	The evidence included in chapter G all relates to single courses of treatment. It cannot be assumed that repeat courses in people who have already received this intervention will have equal effectiveness, and the number of repeat courses offered would also impact on the cost-effectiveness. Without the clinical evidence to inform this, recommendations cannot be made on repeat courses.
Equality	No specific equality issues
Study design	Randomised controlled trial with a long-term follow up, minimum 12 months, in people with chronic primary pain who have previously had a course of acupuncture that was deemed to be beneficial.
Feasibility	There are no feasibility issues with this proposed research. There are a large number of people with chronic primary pain, and if some of these people acupuncture as part of their care as this guideline recommends, there will be people suitable to be recruited into such a trial.
Other comments	None.
Importance	High: the research is essential to inform future updates of key recommendations in the guideline.

Appendix K: MIDs for continuous outcomes

Table 21: MIDs for continuous outcomes: Acupuncture compared to sham acupuncture

Outcomes	MID
Pain (VAS/NRS; 0-10; final and change scores; high is poor outcome) at ≤3 months	1.02
Pain (NIH-CPSI; 0-21, high is poor outcome, final values) at ≤3 months	1.45
Pain (VAS; 0-10; final values and change scores; high is poor outcome) at >3 months	1.29
Pain (NIH-CPSI; 0-21; high is poor outcome, final values) at >3 months	1.57
Pain (least square mean difference; VAS; 0-10, final values, high is poor outcome) at >3 months	0.79
Health related quality of life (SF12 physical composite; 0-100, final values; high is good outcome) at ≤3 months	11.65
Health related quality of life (SF12 mental composite; 0-100, final values; high is good outcome) - Fibromyalgia at ≤3 months	26.29
Health related quality of life (SF12 mental composite; 0-100, final values; high is good outcome) - Myofascial pain syndrome at ≤3 months	5.47
Health related quality of life (NIH-CPSI; 0-12; high is poor outcome, final values) at ≤3 months	1.04
Health related quality of life (FIQ; 0-100; high is poor outcome final values) at ≤3 months	10.6
Health related quality of life (SF12 physical component summary; change scores; 0-100, high is good outcome) at >3 months	19.55
Health related quality of life (SF12 mental component summary; change scores; 0-100, high is good outcome) at >3 months	17.30
Health related quality of life (NIH-CPSI; 0-12; final values, high is poor outcome) at >3 months	1.22
Physical function (Neck Pain Questionnaire/Neck Disability Index; 0-100; high is poor outcome, final values) at ≤3 months	3.9
Physical function (Neck Disability Index; 0-100;high is poor outcome, final values) at >3 months	4.56
Psychological distress (BDI; 0-63; high is poor outcome final values) at ≤3 months	4.16
Psychological distress (HDRS; 0-52; high is poor outcome; change scores and final values) at ≤3 months	16.15
Psychological distress (HDRS; change score; 0-52; high is poor outcome) at >3 months	24.49
Sleep (Visual analogue sleep quality scale; 0-10, final values, high is good outcome) at ≤3 months	0.74
Sleep (Nottingham Health Profile sleep subscale; 0-100; final values, high is poor outcome) at ≤3 months	19.6

Outcomes	MID
Sleep (VAS sleep; 0-10, change scores, high is poor outcome) at >3 months	0.79

Table 22: MIDs for continuous outcomes: Acupuncture compared to usual care

Outcomes	MID
Pain (VAS; 0-10; final values and change scores; high is poor outcome) at ≤3 months	1.1
Pain (SF McGill Pain Questionnaire and Northwick pain questionnaire; final values, high is poor outcome) at ≤3 months	0.5 (SMD)
Pain (Neck pain and disability scale; change scores, high is poor outcome) at ≤3 months	7.86
Pain (Northwick park questionnaire; 0-100, final values, high is poor outcome) at >3 months	26.43
Physical function (Neck Disability Index; 0-100; final values and change scores; high is poor outcome) at ≤3 months	2.85
Physical function (6 minute walk test; metres, change scores) at ≤3 months	37.2
Psychological distress (BDI depression subscale; 0-62, high is poor outcome, final values) at ≤3 months	4.18
Psychological distress (BDI anxiety subscale; 0-62, high is poor outcome, final values) at ≤3 months	6.4
Pain self-efficacy (Chronic pain self-efficacy scale, 0-8, high is good outcome) at >3 months	0.5 (SMD)
Pain interference (BPI pain interference subscale; 0-10; final and change scores; high is poor outcome) at ≤3 months	0.80
Sleep (Pittsbugh Sleep Quality Index; 0-21; final values, high is poor outcome) at ≤3 months	2.09

Table 23: MIDs for continuous outcomes: Electro-acupuncture compared to sham electro-acupuncture

Outcomes	MID
Pain (VAS, MPI; 0-10; high is poor outcome; final values) at ≤3 months	1.01
Pain (VAS, MPI; 0-10; high is poor outcome; final values) at >3 months	0.55
Health related quality of life (FIQ; 0-100; high is poor outcome, final values) at ≤3 months	5.1
Health related quality of life (FIQ; 0-100; high is poor outcome, final values) at >3 months	4.80
Pain interference (MPI; pain interference; 0-100, high is poor outcome, final values) at ≤3 months	4.55
Pain interference (MPI; pain interference; 0-100, high is poor outcome, final values) at >3 months	4.20
Sleep (VAS sleep quality scale; 0-10, final values, high is good outcome) at ≤3 months	1.12